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COMPARISION OF EPIDURAL ROPIVACAINE PLUS DEXMEDETOMIDINE WITH EPIDURAL ROPIVACAINE PLUS FENTANYL IN TOTAL HIP REPLACEMENT SURGERIES.

Anaesthesiology

S A Mannan Asst.prof. Anesthsiology SKIMS Medical College, Bemina. - Corresponding Author

Rabiaarifa Medical officer JK Health Services

Sajad Hamid Asst.prof. Anatomy, SKIMS Medical College, Bemina

ABSTRACT

OBJECTIVE: Our study compared the effect of epidural ropivacaine plus dexmedetomidine with epidural ropivacaine plus fentanyl for comparing the sedative, and analgesia potentiating effects of epidurally administered fentanyl and dexmedetomidine when combined with ropivacaine in total hip replacement surgeries during intra and post operative period.

Materials and Methods: Sixty patients undergoing total hip replacement were randomized into two groups. In first group Inj. Ropivacaine, 20 ml of 0.5%, with addition of 1 µg/kg of dexmedetomidine(RD group) was administered epidurally while second group received Inj. Ropivacaine, 20 ml of 0.5%, with addition of 1 µg/kg of fentanyl (RF group). The intraoperative pain and postoperative pain relief was evaluated by a visual analog scale (VAS) using a 10cm visual analog scale. sedation scores and various block characteristics were also observed which included time to onset of analgesia at T10, maximum sensory analgesic level, time to complete motor blockade, time to two segmental dermatomal regressions, and time to first rescue analgesic.

Results: Onset of sensory analgesia at T10 (6.87±1.86 vs 9.89±5.67) and establishment of complete motor blockade (15.89±9.52 vs 19.12±8.79) was significantly earlier in the RD group than in RF group. Postoperative analgesia was prolonged significantly in the RD group (387.62±14.38 vs 278.37±14.67) and consequently less consumption of ropivacaine(54.34±17.23 vs 87.38±12.63) during epidural top-ups postoperatively. Sedation scores were better in the RD group and highly significant on statistical comparison (P<0.05). Incidence of nausea and vomiting was significantly high in the RF group (26% and 6%), and incidence of pruritis was also significantly higher in the RF group (23%) (P<0.05).

Conclusions: Our results showed dexmedetomidine to be a better alternative than fentanyl as an epidural adjuvant as it provides 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.

KEYWORDS:

Dexmedetomidine, ,total hip replacement, epidural anesthesia , fentanyl , ropivacaine

INTRODUCTION

Epidural anesthesia is performed to provide anesthesia for surgical procedures carried on lower abdomen, pelvis, and lower limbs. Early postoperative mobilization and rehabilitation with minimally associated pain and discomfort is the most desirable feature in modern orthopaedic surgery[1,2]. Epidural anesthesia reduces the surgical stress by blocking the nociceptive impulses from the operative site and also reduces the blood loss, improve respiratory and bowel function and decreased incidence of deep vein thrombosis, but it is associated with hemodynamic fluctuations due to use of large volumes of local anesthetic drug.[3]

Ropivacaine has minimal cardio-vascular and central nervous system toxicity as well as a lesser propensity of motor block during post-operative epidural analgesia[4,5]. fentanyl have been used as an adjunct for epidural administration in combination with a lower dose of local anaesthetic to achieve the desired anaesthetic effect[6] with dose sparing effect of local anaesthetic and superior analgesia.

Dexmedetomidine is α-2 adrenergic agonists with analgesic properties which potentiate local anesthetic effects when epidurally administered[7]. 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 hemodynamic effects[8,9,10].

Aim and objectives

The aim of this randomized study was to compare anesthetic effects and postoperative pain relief of epidurally administered dexmedetomidine with epidurally administered fentanyl as adjuvants with ropivacaine in patients undergoing total hip replacement surgeries.

METHODS

After informed consent a total 0f 60 patients of either sex weighing between 60-80 kg and age between 50-60 years belonging to ASA-I and ASA-II presenting for total hip replacement surgery were included in the study. 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. Patients were divided randomly into two groups:

Group (RD) : 30 patients in whom Ropivacaine+Dexmedetomidine (RD) was used

Group (RF): 30 patients in whom Ropivacaine+Fentanyl (RF) was used

After securing venous access all the patients were prehydrated with 500ml of lactated Ringer's solution. All the baseline parameters were observed and recorded using electrocardiography (ECG), heart rate (HR), non-invasive blood pressure (NIBP), and pulse oximetry (SpO_2).

Lumbar epidural anesthesia was performed using 18G Touhy needle through 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 3–4 cm into the epidural space and patients were placed supine. The following solutions were randomly administered: 20 ml of 0.5% ropivacaine with 1 µg/kg of dexmedetomidine in group RD (*n*=30) and 20 ml of 0.5% ropivacaine with 1 µg/kg of fentanyl in group RF (*n*=30) at the rate of 1 ml/second. The following parameters were observed immediately after the administration of epidural block.

1. Time to onset of analgesia at T10
2. Maximum sensory level achieved
3. Time to achieve the maximum sensory level
4. Time to complete motor blockade
5. Time to two segmental dermatomal regression
6. Regression to S1
7. First feeling of pain/rescue analgesia
8. Total dose consumption of ropivacaine used over 24 hours.

Motor blockade was assessed using modified Bromage scale (0=no block, 1=inability to raise extended leg, 2=inability to flex knee and 3=inability to flex ankle and foot) before surgery and at regular intervals of 1 hour post-operatively. Sedation was also assessed at

intervals of 30 minutes intra-operatively and at intervals of 1 hour during post-op period. The degree of sedation was determined according to Ramsay sedation scale ranging from 1 to 5 (1 pt. Is anxious and agitated or restless or both, 2 pt. is cooperative, oriented and tranquil, 3 pt. responds to command only ,4 pt. exhibits brisk response to light glabellar tap or loud auditory stimulus, 5 exhibits sluggish response to light glabellar tap or loud auditory stimulus , 6 pt. exhibits no response) .

Finally all study observations were documented and tabulated, they were analyzed statistically and results were recorded.

The statistical analysis of the data was done by using statistic student's t-test for difference of means for quantitative data analysis.

For nominal data chi-square test (χ^2-test) and fisher's exact test were used.

All these tests were two sided and were referred for p-values for their significance. Any p-value less than 0.05 i.e. ($p< 0.05$) were taken to be statistically significant.

The analysis of the data was performed on statistical package for social sciences, Chicago, USA for windows.

RESULTS

A total of 60 patients who underwent total hip replacement surgery were enrolled for the study and were randomly divided into two groups. The demographic characteristics in both the groups resemble and did not show any statistical significant difference ($P>0.05$) [Table 1].

Table 1
The demographic profile of the patients of both the groups

Variable	Group (RD) n=30	Group (RF) n=30
Age (yrs)	58±6.7	59± 7.7
Weight(kg)	71±18.5	72±17.8
ASA physicalstatus(I/II)	20/10	21/9
Sex(m/f)	23/7	22/8
Mean duration of surgery(min)	138±12.7	135±15.2

Table 2.
The comparison of initial block characteristics in both the groups

Initial block characteristic	Group (RD) n=30	Group (RF) n=30	p-value
onset time of sensory block at t10min	6.87±1.86	9.89±5.67	<0.05
time to maximum sensory block level(min)	12.67±8.23	16.13±6.54	<0.05
onset time of motor block at t10min	15.89±9.52	19.12±8.79	<0.05
mean total dose of ephedrine(mg)	10.34±12	7.12	<0.05

The onset of analgesia at T10 dermatomal level was significantly earlier in the RD group (6.87±1.86) as compared to the RF group (8.89±5.67). (P <0.05). Motor block was assessed using modified Bromage scale and complete motor block was achieved significantly earlier in the (15.89±9.52) patients who were administered dexmedetomidine as compared to RF group (19.12±8.79). (P <0.05))

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

Sedation score during surgery	Group (RD)	Group (RF)	p-value
1	2	20	<0.05
2	12	8	<0.05
3	14	2	<0.05
4	2	0	<0.05
5	0	0	
6	0	0	

The sedation scores were highly significant on statistical comparison (P<0.05). Majority of patients had a score of 2 and 3 in group RD, whereas in group RF 66% patients had a score of 1.

Table 4.
The comparison of post-op block characteristics in both the groups

Post op.block In min.	Group (RD) n=30	Group (RF) n=30	p-value <0.05
Mean time to two segment regression	150.43±18.46	117.89±15.29	<0.05
Mean time to sensory regression at S1	360.23±21.76	247.43±21.33	<0.05
time to ist rescue top-up	387±14.38	278.37±14.67	<0.05
Total dose of ropivacaine mg	54.34±17.23	87.38±12.63	<0.05

Post-op block characteristics

Dexmedetomidine provided a smooth and prolonged post-operative analgesia than fentanyl that was statistically significant on comparison. The evidence was vividly visible in the prolonged time to two segmental dermatomal regression (150.43±18.46 in RD vs 117.89±15.29 in RF) (P <0.05). As a result, the time for rescue analgesia was comparatively shorter (278.37±14.67) in the patients who were administered fentanyl as compared to RD group who experienced prolonged pain free period (387±14.38) (P<0.05). The superior block characteristics by the addition of dexmedetomidine were clearly evident from the lower dose consumption (54.34±17.23 vs 87.38±12.63) of ropivacaine for postoperative analgesia for the next 24 hours (P<0.05) in Group (RD) and Group (RF)

Table 5
The comparison of side effects observed in both the groups during and after the operative period

Side effects	Group (RD) n=30	Group (RF) n=30	p-value
Nausea/vomiting	**2**	**6**	**<0.05**
Shivering	**2**	**3**	
Respiratory depression	**0**	**0**	
urinary retention	**5**	**5**	
pruritis	**0**	**7**	**<0.05**
Side effects			

Nausea/vomiting were observed to a significant extent in the RF group than in the RD group (P<0.05). The incidence of pruritis was significantly higher in the RF group as compared to the RD group. (P<0.05)The incidence of pruritis in orthopedic surgeries after intrathecal opiod range from 30-60%. We successfully treated the patients by i/v ondansetron 0.1mg/kg body wt. The incidence of other side effects like shivering and urinary retention were comparable in both the groups and statistically non-significant (P>0.05). there was no respiratory depression in any of the patient from either group.

DISCUSSION

We compared two pharmacological approaches of epidural anesthesia (ropivacaine-dexmedetomidine and ropivacaine - fentanyl) on two groups of patients. 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-operative analgesia and much better sedation levels[11]. Epidural anesthesia offers several benefits to the patients but at the same time it is linked with drawbacks like pain at the puncture site, fear of needles, and recall of the procedure[12, 13, 14.]. These factors stress the importance of sedation that offers analgesia, anxiolysis, and amnesia. Sedation is known to increase patient's acceptance of regional anesthesia and to greatly improve patient wellbeing during the surgical procedure[15].

The demographic profile in the present study did not show any significant difference on statistical comparison. Onset of sensory analgesia at T10 dermatomal level was earlier in RD group than in RF group (6.87±1.86 vs 9.89±5.67) that was statistically significant. The time to reach peak sensory level was significantly (P<.05) shorter in group RD (12.67±8.23) as compared to group RF (16.13±6.54). Throughout the surgery, patients were calm and compose in both the groups but sedation scores were better in a highly significant manner in the RD group as 40% and 46% of patients had grade 2 and 3 Ramsay sedation scores during the peri operative period as compared to 66% and 26% of patients in the RF group. The sedative properties of dexmedetomidine are far superior to fentanyl as no patient required any other sedative during the peri-operative period. None of the patients in either of the group required any additional epidural top-up dose during the surgical period. The analgesia was assessed using visual analogue scale (VAS) and patients in both the groups showed 1-1.5 scores during the entire surgical period. The duration of post-operative analgesia was significantly prolonged in patients in whom

dexmedetomidine was administered as adjuvant with ropivacaine. Thus the total top-up dose of ropivacaine decreased in RD group postoperatively. None of the patients in either of the groups experienced any respiratory difficulty requiring active intervention.

Decrease in heart rate is a known clinical effect of opioids but in the present study similar negative chronotropic effect was exhibited by dexmedetomidine. The heart rate remained stable in both the groups. Similarly, mean arterial pressure (MAP) decreased from the baseline in both the groups after the epidural injection but it never went below 90 mmHg. Postoperatively, HR and MAP remained stable in both the groups. The decrease in HR caused by α-2 agonist can again be explained on the basis of their central action whereby they decrease sympathetic outflow and nor-epinephrine release[16,17,18].The requirement of vasopressors for maintenance of stable hemodynamic parameters did not reveal any significant difference between both the groups on statistical comparison.

Nausea / vomiting occurred in 20% of the patients in group RF as compared to 6.6% in group RD. This higher incidence of nausea/vomiting was observed in RF group despite a low dose of fentanyl used epidurally. We observed same incidence of urinary retention in both groups (16%).

The absence of respiratory depression can be explained on the basis that *we* used fentanyl in a lower dosage. As far as α-2 agonists are concerned, the respiratory depression is not a known feature of this group of drugs.

CONCLUSIONS

Dexmedetomidine seems to be a better alternative to fentanyl as an epidural adjuvant as it provides early onset and establishment of sensory anesthesia, prolonged post-op analgesia, lower consumption of post-op LA for epidural analgesia, much better sedation levels and fewer side effects such as nausea and pruritis, thus better patient satisfactions.

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