

A Comparative Study of Efficacy of Epidural Ropivacaine (0.2%) and Bupivacaine (0.125%) with Fentanyl (2 µg/mL) for Postoperative Analgesia in Patients Undergoing Joint Replacement Surgeries

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ABSTRACT

BACKGROUND

Epidural analgesia is an important component of the multimodal approach to pain management. It is used effectively for postoperative pain management following joint replacement surgeries. In this study, we aimed to evaluate the post-operative analgesic efficacy of epidural Ropivacaine (0.2%) – Fentanyl (2 µg/mL) and epidural Bupivacaine (0.125%) - Fentanyl (2 µg/mL) on patients undergoing joint replacement surgeries.

METHODS

60 adult patients of ASAPS grade I or II between ages 25 - 65 years of either sex undergoing elective joint replacement surgeries were randomly allocated to two groups: Group A (ropivacaine group) receiving ropivacaine 0.2% (40 mL) + fentanyl (2 µg/mL) and Group B (bupivacaine group) receiving bupivacaine 0.125% (40 mL) + fentanyl (2 µg/mL).

RESULTS

The immediate post-operative VAS scores for pain at rest and on touch of patients in the two groups were close to no-pain status. Mean VAS scores at rest showed an incremental trend with passage of time. At 24 hour postoperative interval, mean VAS score at rest was 3.13 ± 0.43 in group A and 3.10 ± 0.40 in group B while mean VAS score on touch was 3.20 ± 0.55 in group A and 3.40 ± 0.68 in group B. Statistically, there was no significant difference between the two groups at any of the follow-up intervals. Thus, as far as analgesic effect of the two drugs was concerned, both the drugs have comparable efficacy in terms of mean VAS scores. In the present study, median VAS scores peaked at 6-hour postoperative interval and remained at same level till the end of study.

CONCLUSIONS

In our study, both ropivacaine (0.2%) and bupivacaine (0.125%) with fentanyl (2 µg/mL) combinations showed similar efficacy in postoperative pain management with almost stable hemodynamic profile. Moreover, the ropivacaine group gives better motor blockade and lower overall rescue analgesic needs.

KEY WORDS

Ropivacaine, Bupivacaine, Epidural Analgesia, Fentanyl, Joint Replacement

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BACKGROUND

Postoperative pain is one of the most common issue following joint replacement surgeries. Although, number of advancements in techniques and pain control modalities have taken place, yet majority of patients experiences extreme pain immediately after the surgery.^[1] Poorly controlled pain after surgeries is strongly associated with development of chronic pain.^[2] Effective control of postoperative pain blunts autonomic, somatic and endocrine responses and results in early recovery, mobilization and discharge from hospital.

The most important concept of current pain management is the pre-emptive use of multimodal approach. "Pre-emptive" refers to initiate pain management before the surgical stimulus and "multimodal approach" refers more than 2 drugs or modalities with different mechanisms or sites for synergistic effects.^[3]

Epidural analgesia is one of the important component of the multimodal approach to pain management. Facility of continuous infusion and top-ups of analgesic drugs provide good analgesia, early ambulation and smooth recovery. Compared with general anaesthesia, epidural anaesthesia has reportedly been associated with reduced post-operative mortality, length of stay, and in-hospital complication rates in a large population-based study of lower limb joint replacement surgeries.^[4,5]

Epidural bupivacaine has been used extensively in the past for providing adequate postoperative pain relief in patients undergoing joint replacement surgeries.^[6] However, in recent years a new long acting local anaesthetic drug ropivacaine has increasingly replaced bupivacaine for the said purpose because of its similar analgesic properties, lesser motor blockade, greater selectivity for sensory blockade and cardiac stability.^[7,8] Though a slightly larger dose of ropivacaine is required as compared to bupivacaine to achieve adequate effects, the addition of an adjuvant can decrease the dose of ropivacaine required, thereby eliminating side effects associated with larger doses of ropivacaine.^[9]

Local anaesthetic and opioid combination has shown to be more effective as their effects start rapidly and last longer when compared with local anaesthetics given alone.^[10] Epidural fentanyl has been widely used as a better alternative to morphine as far as opioid-induced complications and side effects are concerned. It is associated with lower incidence of nausea, vomiting and pruritus and may not cause clinically significant respiratory depression.^[10]

The study is designed to evaluate and compare efficacy of epidural Ropivacaine (0.2%) - Fentanyl (2 µg/mL) and Bupivacaine (0.125%) - Fentanyl (2 µg/mL) on postoperative analgesia in respect of duration and quality of analgesia and any complications in patients undergoing joint replacement surgeries. Ropivacaine has been demonstrated to be nearly 1-1.5 times less potent than Bupivacaine. Hence, we have taken equipotent doses of Bupivacaine and Ropivacaine.^[11] Studies comparing equipotent doses of bupivacaine and ropivacaine as continuous epidural infusion are limited and hence the present study was planned.

METHODS

A randomized, double-blinded prospective study was conducted in the operation theatre complex, post anaesthesia care unit and orthopaedic ward at Vivekananda Polyclinic and Institute of Medical Sciences, Lucknow, after getting approval from the ethical committee.

Sample Size Calculation

In a previous randomized study by Berti et al^[12], the total patient controlled epidural analgesia volume (mL) was 208 ± 36.5 mL in Ropivacaine and 236 ± 33.3 mL in Bupivacaine group. In present study, we target a similar efficacy of two drugs by keeping volume of drugs constant and evaluating the difference in analgesic efficacy. Assuming 80% power and 5% significance level, the sample size can be calculated by the following formula (Hayes and Bennet, 1999)^[13]

$$n = (Z_{\alpha} + Z_{\beta/2})^2 \times \frac{(\sigma_0^2 + \sigma_1^2)}{(\mu_0 - \mu_1)^2}$$

Where, n=sample size per group, σ=standard deviation, Z_α=Significance level, Z_{β/2}=Power of the study. The calculated sample size came out to be 24.41. Assuming 20% loss to follow-up and rounding off to nearest ten, the extended sample size was calculated as 30 in each group.

Therefore, total 60 patients between ages of 25-65 years of either gender with ASAPS grade I or II (American Society of Anesthesiologists Physical Status) undergoing elective joint replacement surgeries were included in this study. Patients who were not willing to participate in the study, ASAPS grade III & IV, any contraindication to epidural block, allergic to local anaesthetics, severe psychiatric disorders, depression and dementia were excluded from study.

The patients were randomly divided into two groups. Randomisation was done by computer generated random number tables. Group A received epidural ropivacaine 0.2% (40 mL) + fentanyl (2 µg/mL) and Group B received epidural Bupivacaine 0.125% (40 mL) + fentanyl (2 µg/mL).

A written informed consent were obtained from patients. After thorough preanaesthetic check-up including relevant history and examination one day prior to surgery, patients were instructed to be six hours nil per oral before surgery. On entering the operation theatre, standard monitoring including non-invasive blood pressure, pulse oximetry and electrocardiogram leads were attached to the patients and baseline blood pressure and heart rate were recorded. Intravenous access established and preloading with appropriate fluid was done.

Under all aseptic precautions, an 18-gauge Tuohy needle was introduced into epidural space at L2 - L3 or L3 - L4 interspace using the loss of resistance technique. Epidural catheter threaded 3-5 cm into the epidural space. Tuohy needle was withdrawn. Epidural catheter was secured and epidural test dose with 60 mg of lignocaine and 15 µg of epinephrine was then inserted and observed for any motor block or rise in heart rate. Spinal anaesthesia was then performed using 27-gauge Quincke needle in lower space.

Patient was positioned appropriately for surgery and surgery was performed under combined spinal epidural (CSE) block.

Epidural infusion was administered postoperatively at "two segment sensory regression" time. The study solutions for infusion was prepared by another anaesthesiologist who was not involved in the clinical care of the patient. Both patient and anaesthesiologist caring for postoperative analgesia and recording parameters, were blinded to the group of study solution. The study period commenced at the time of start of epidural infusion (time 0 minute) and terminated at 24 hours postoperatively.

The age, sex of patient, ASAPS grade, anaesthesia duration and surgery duration were recorded. The visual analogue scale (VAS)^[14] score for operative site pain at rest and on touch, as assessed by blinded investigators at following time intervals- Immediate post-surgery, after 15 minutes, half an hour, 1, 6, 12, 24 hours post-surgery. The number of doses of rescue analgesia (tramadol 100 mg intravenously) were also recorded. Bromage Scale^[15] used to assess level of motor blockade at above mentioned time intervals.

Incidence of nausea, vomiting, hypotension, bradycardia, pruritus, urinary retention and any other adverse effects were also noted. The Haemodynamic parameters such as Heart rate (HR), Systolic blood pressure (SBP), Diastolic blood pressure (DBP) and Mean arterial blood pressure (MAP) were recorded at the above mentioned time intervals.

Statistical Analysis

Data was presented as categorical and continuous variables. Categorical variables were presented in number and percentage (%). Continuous variables were presented as mean \pm SD. For comparing the statistical significance of qualitative variables, Chi square/ Fishers exact test was used. For quantitative variables, statistical significance was determined by unpaired student t-test or the non-parametric Mann-Whitney test. $P < 0.05$ was taken as a level of statistical significance. The data was analysed by the most recent version of SPSS Statistical Software.

RESULTS

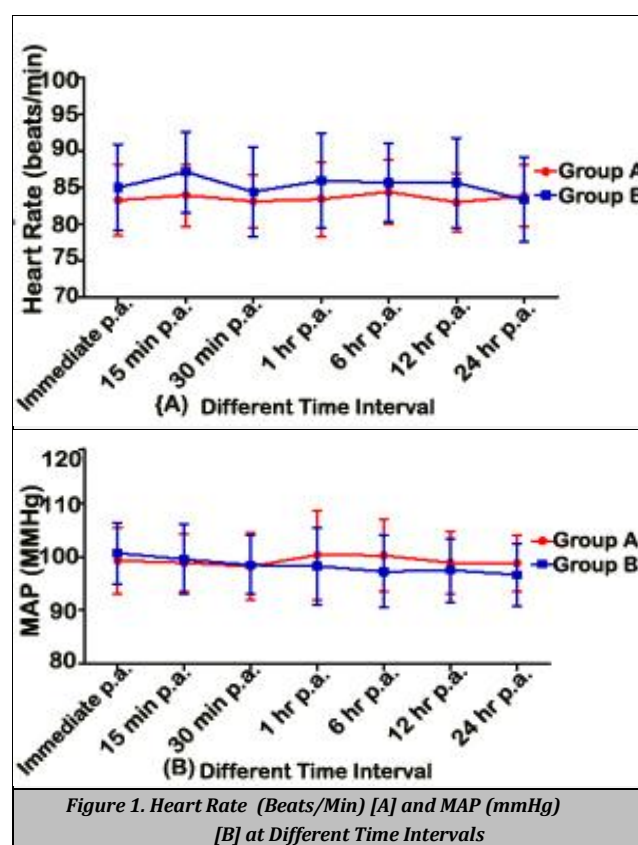
Baseline characteristics of the patients such as age, gender, heart rate and mean arterial blood pressure (MAP) were recorded. The Age of patients ranged from 46 to 79 years. Overall, as well as in both the groups, majority of patients were aged between 51 and 70 years. Mean age of patients was not significant different in between group A (62.63 ± 8.48) and group B (62.03 ± 7.03).

The females was higher in group B (86.67%) as compared to that in group A (66.67%) yet this difference was not significant statistically ($p=0.067$). At baseline, mean heart rate and mean arterial pressure were 83.27 ± 4.88 beats per minute and 99.27 ± 6.16 mmHg respectively in group A and 85.00 ± 5.94 bpm and 100.63 ± 5.72 mmHg respectively in group B. The mean heart rate and mean MAP were comparable in between group A and group B ($p>0.05$).

The heart rate (beats/min) is shown in Fig. 1[A]. At immediate post-operative (p.o.), the mean heart rate was comparable in between group A (83.27 ± 4.88) group B

(85.00 ± 5.94), however, the difference was not significant statistically ($p=0.222$). However, during different follow-up intervals, the heart rate was significantly higher in group B as compared to that of group A at 15 min and 12 hr post-operative intervals. At other time intervals, the difference between two groups was not significant statistically ($p>0.05$). At 24 hr post-operative interval, mean heart rate was not statistically significant difference between group A (83.83 ± 4.19) and group B (83.33 ± 5.74).

The mean arterial blood pressure (MAP) is shown in Fig. 1[B]. The mean MAP were 99.27 ± 6.16 mmHg in group A and 100.63 ± 5.72 mmHg in group B at immediate p.o. At different follow up intervals, mean values ranged from 98.17 ± 6.26 mmHg (30 min p.o.) to 100.30 ± 8.30 mmHg (1 hr p.o.) in group A and ranged from 96.63 ± 5.73 (24 hr p.o.) to 99.50 ± 6.51 (15 min p.o.) in group B. On evaluating the data statistically, the MAP were not significantly different in between group A and group B at time different intervals.



At baseline, mean VAS scores were 0.97 ± 0.61 (median 1) in group A and 1.03 ± 0.67 (median 1) in group B at rest. Statistically, the two groups were matched and did not show a significant different ($p=0.686$). Mean VAS scores were 1.50 ± 0.51 (median 1.50) in group A and 1.47 ± 0.51 (median 1) in group B on touch. However, the difference between two groups was not significant statistically ($p=0.798$) as shown in Table 1.

The mean VAS score at immediate post-operative period was 0.97 ± 0.61 (median 1) group A at rest which reached to 1.50 ± 0.51 (median 1.5) and 1.47 ± 0.51 (median 1) at 15 and 30 min p.o. interval. At 1 hr post-operative interval the mean VAS score at rest was 1.93 ± 0.64 (median 2) and continued to show a regular increase to reach at 3.13 ± 0.43 at 24 hr post-operative interval. Between 6 and 24 hours post-

operative intervals, the median value remained 3. Whereas the mean VAS score at immediate p.o. was 1.03 ± 0.67 (median 1) in group B at rest which reached to 1.53 ± 0.51 (median 2) and 1.47 ± 0.51 (median 1) at 15 and 30 min post-operative interval. At 1 hr. post-operative interval the mean VAS score at rest was 1.93 ± 0.64 (median 2) and continued to show a regular increase to reach at 3.10 ± 0.40 at 24 hr. post-operative interval. Between 6 and 24 hours post-operative intervals, the median value remained 3. On comparing between the groups at various time intervals, the VAS scores were not significantly different at different time intervals in between two groups ($p > 0.05$) as shown in Table 1.

The mean VAS scores (on touch) were 1.50 ± 0.51 (median 1.50) and 1.47 ± 0.51 (median 1.00) in group A and group B, respectively at immediate p.o. In Group A, mean VAS scores reached to 1.80 ± 0.55 at 15 min p.o. interval, to 1.93 ± 0.58 at 30 min p.o. interval and to 2.30 ± 0.60 at 1 hr. p.o. interval. At these three time intervals (15 min, 30 min and 1 hr.), the median value was 2. At 6 hr., 12 hr and 24 hr. post-operative intervals, mean values were 3.00 ± 0.37 , 3.10 ± 0.31 and 3.20 ± 0.55 respectively. At these time intervals, median value was 3. In group B, mean VAS scores reached to 1.80 ± 0.55 at 15 min p.o. interval, to 1.77 ± 0.63 at 30 min p.o. interval and to 2.27 ± 0.58 at 1 hr. p.o. interval. At these three time intervals (15 min, 30 min and 1 hr.), the median value was 2. At 6 hr., 12 hr. and 24 hr. post-operative intervals, mean values were 3.00 ± 0.46 , 3.20 ± 0.48 and 3.40 ± 0.68 respectively. At these time intervals, median value was 3. On comparing the differences between two groups there were no significant difference was observed at any of the time intervals ($p > 0.05$) as shown in Table 1.

Parameter	Group A (n=30)			Group B (n=30)			Statistical Significance	
	Median	Mean	SD	Median	Mean	SD	z	P
At Rest								
Immediate p.o.	1.00	0.97	0.61	1.00	1.03	0.67	0.405	0.686
15 min p.o.	1.50	1.50	0.51	2.00	1.53	0.51	0.256	0.798
30 min p.o.	1.00	1.47	0.51	1.00	1.47	0.51	0.000	1.000
1 hr p.o.	2.00	1.93	0.64	2.00	1.93	0.64	0.000	1.000
6 hr p.o.	3.00	2.50	0.57	3.00	2.63	0.61	0.627	0.530
12 hr p.o.	3.00	2.83	0.59	3.00	2.77	0.63	0.496	0.620
24 hr p.o.	3.00	3.13	0.43	3.00	3.10	0.40	0.319	0.750
On Touch								
Immediate p.o.	1.50	1.50	0.51	1.00	1.47	0.51	0.256	0.798
15 min p.o.	2.00	1.80	0.55	2.00	1.80	0.55	0.000	1.000
30 min p.o.	2.00	1.93	0.58	2.00	1.77	0.63	1.096	0.273
1 hr p.o.	2.00	2.30	0.60	2.00	2.27	0.58	0.238	0.812
6 hr p.o.	3.00	3.00	0.37	3.00	3.00	0.46	0.000	1.000
12 hr p.o.	3.00	3.10	0.31	3.00	3.20	0.48	1.024	0.306
24 hr p.o.	3.00	3.20	0.55	3.00	3.40	0.68	1.146	0.252

Table 1. Comparison of VAS Scores at Rest at Different Time Periods between Groups

¹= Mann-Whitney U test

The increasing trend of VAS scores (at rest) were seen with the passage of time in both groups. In group A, the % increase was close to 50% at 15 and 30 minutes, almost 100% at 1 hour and 223.37% at 24 hour. At all the follow up intervals, the change in VAS scores as compare to baseline was statistically significant ($p < 0.05$). In group B, the % change was close to 50% at 15 minute, however at 30 min post-operative interval it was close to 40% at 30 minutes, 87.38% at 1 hour and 200.65% at 24 hour. On evaluating the data statistically, mean VAS scores (at rest) at different follow-up intervals were found to be significantly higher as compared to baseline ($p < 0.05$) as shown in Fig. 2.

The % change in VAS score as compared to baseline were 20%, 28.89%, 53.33%, 100%, 106.67% and 113.33% at 15 min, 30 min, 1 hr., 6 hr., 12 hr. and 24 hr. post-operative intervals, respectively in group A. At all these time intervals, the change from baseline was significant statistically ($p < 0.05$). Whereas in group B, % change in VAS score as compared to baseline were 22.68%, 20.41%, 54.42%, 104.31%, 117.91% and 131.52% at 15 min, 30 min, 1 hr., 6 hr., 12 hr. and 24 hr. post-operative intervals respectively. At all the time intervals except at 30 min interval, the change from baseline was significant statistically ($p < 0.05$) as shown in Fig. 2.

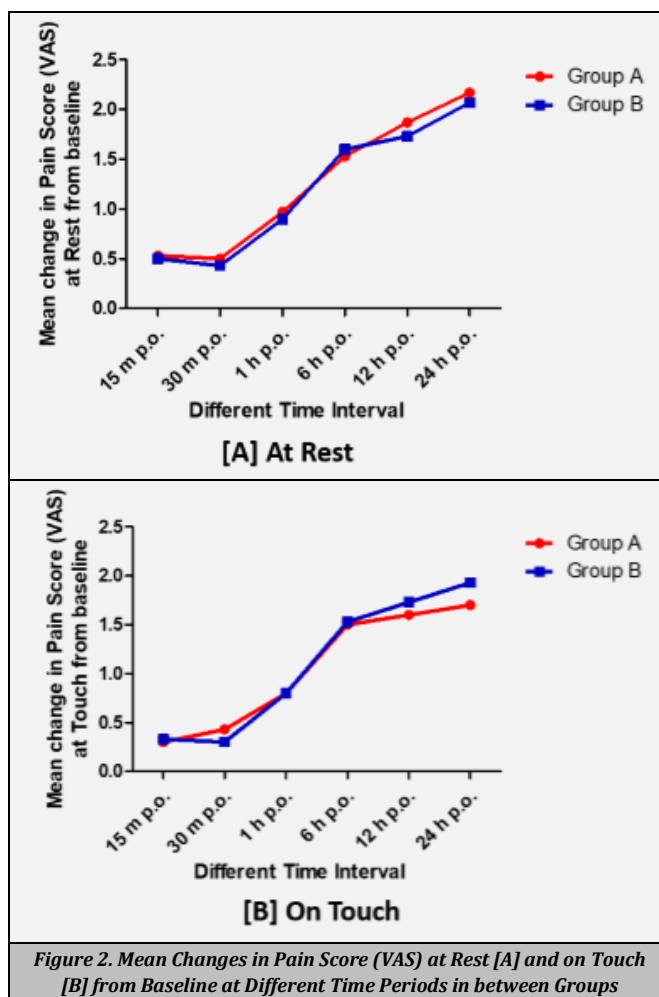


Figure 2. Mean Changes in Pain Score (VAS) at Rest [A] and on Touch [B] from Baseline at Different Time Periods in between Groups

No. of Rescue Analgesics Needed	Group A (n=30)		Group B (n=30)		z-Value	¹ P-Value
	No.	%	No.	%		
0	19	63.3	18	60.0	0.731	0.465
1	11	36.7	7	23.3		
2	0	0	5	16.7		

Table 2. Comparison of Number of Rescue Analgesic Dosages in between Groups

¹= Mann-Whitney U test

During the study period, a total of 11 (36.7%) patients required rescue analgesia in group A. All these patients required only one dose of analgesia. However, although only 12 (40%) patients required analgesia yet of these 7 (23.3%) required only one dose and 5 (16.7%) required 2 doses in group B. Moreover, the overall analgesic need was higher in group B as compared to that in group A yet the difference

between two groups was not significant statistically ($p=0.465$) as shown in Table 2.

In both the groups, median block score was 2 at immediate post-operative and 15 min post-operative intervals. At 30 min p.o. interval median score was 1 in group A and 2 in group B, however, this difference was not significant statistically ($p=0.186$). However, at 1 hr p.o. interval, median score was 1 in group A and 2 in score B and difference was significant statistically ($p=0.001$) with significantly higher proportion of cases in group B having scores 2 or above (66.7%) as compared to those in group A (16.7%). At 6 hours, though median score was 0 in both the groups however, proportion of those with score 1 was significantly higher in group B (26.7%) as compared to that in group A (6.7%) ($p=0.038$). From 12 hr p.o. onwards both the groups had score 0 in all the patients as shown in Table 3.

Parameter	Group A (n=30)					Group B (n=30)					Statistical Significance (Chi-Square Test)	
	0	1	2	3	Md	0	1	2	3	Md	χ^2	'P'
1 mm. p.o.	0	4	14	12	2	0	5	14	11	2	0.155	0.926
15 min p.o.	0	11	12	7	2	0	7	12	11	2	1.780	0.411
30 min p.o.	0	16	8	6	1	0	9	12	9	2	3.360	0.186
1 hr p.o.	3	22	5	0	1	0	10	15	5	2	17.500	0.001*
6 hr p.o.	28	2	0	0	0	22	8	0	0	0	4.32	0.038*
12 hr p.o.	30	0	0	0	0	30	0	0	0	0	-	-
24 hr p.o.	30	0	0	0	0	30	0	0	0	0	-	-

Table 3. Comparison of Motor Block at Different Time Periods (Bromage Score) in between Groups

Md=Median, *=Significant

Vomiting, urinary retention (n=19 each) and nausea (n=14) were the common side effects while headache (n=4), restlessness (n=5) and tachycardia (n=1) were some less common side effects. However, the difference between two groups was significant statistically for vomiting and restlessness only, both these side effects were more common in group B as compared to group A.

DISCUSSION

Combined spinal epidural anaesthesia facilitates the rapid onset of spinal block which allows the operative procedure to begin earlier, combined with epidural catheter placement that allows anaesthesia to be extended as the spinal resolves and provides effective postoperative analgesia.^[16] Ropivacaine is an amide local anaesthetic, pure S (-) enantiomer with low lipid solubility, produces analgesia (sensory block) with a limited and non-progressive motor block which is often slower in onset, shorter in duration and less intense. It is more cardio stable than Bupivacaine.^[17] It has been shown that opioids and local anaesthetics administered together intrathecally have a potent synergistic analgesic effect.^[18,19] Coupled with low dose-opioids, ropivacaine has shown to be effective in postoperative pain management in patients undergoing joint replacement surgery^[20,21,22,23,24] either as a single dose or in form of a continuous infusion.

In present study we have used a 2 µg/mL dose of fentanyl as a low dose opioid coupled with 0.2% Ropivacaine or 0.125% Bupivacaine administered epidurally. This

combination was selected in particular after proper trade-off between potency of the drugs as well as minimization of side effects. Ropivacaine has a unique pharmacokinetics. It has equivalent potency as compared to bupivacaine at higher dosages but at lower dosages, such as those used for epidural or intrathecal analgesia, it has lower potency as compared to bupivacaine.^[25] Ropivacaine has been demonstrated to be nearly 1-1.5 times less potent than bupivacaine.^[11] Hence, we have taken equipotent doses of bupivacaine and ropivacaine viz. 0.125% bupivacaine to be comparable to 0.2% ropivacaine and decided to use as a trial combination in our study.

In this study, the age of patients ranged from 47 to 79 years with a median age of 62 years. Also majority of patients were females (76.67%) with a low male-to-female ratio 0.3. It is an established fact that relatively a greater number of women as compared to men undergo joint replacement surgeries throughout the world probably owing to an increased age and gender related susceptibility to degenerative conditions like arthritis.^[26,27]

The immediate post-operative VAS scores for pain at rest and on touch of patients in two groups were close to no-pain status. Mean VAS scores at rest showed an incremental trend with passage of time. At 24 hour postoperative interval mean VAS score at rest was 3.13 ± 0.43 in group A and 3.10 ± 0.40 in group B while mean VAS score on touch was 3.20 ± 0.55 in group A and 3.40 ± 0.68 in Group B. Statistically, there was no significant difference between two groups at any of the follow-up intervals. Thus as far as analgesic effect of two drugs were concerned, both the drugs have comparable efficacy in terms of mean VAS scores. In present study, median VAS scores peaked at 6 hour postoperative interval and remained at same level till the end of study.

There was no significant difference in rescue analgesic needed between two groups, though proportion of patients requiring rescue analgesia (n=12 vs n=11) as well as those requiring more than one rescue doses within 24 hr (n=5 vs n=0) were higher in bupivacaine group as compared to ropivacaine group. Haemodynamics remained stable throughout the study period. In heart rate, maximum change at any follow up period was 1.36% in Group A and 2.51% in Group B. Maximum change in blood pressure was -1.11% in Group A and -3.97% in Group B. The changes were not significant. As far as motor block was concerned, no significant motor blockade was observed in either of two groups after 6 hours, however, the residual motor blockade was more intense in bupivacaine group as compared to ropivacaine group until 6 hours postoperative period. Incidence of side effects such as vomiting and restlessness was significantly higher in bupivacaine group as compared to that in ropivacaine group. Vomiting, nausea and urinary retention were the common side effects seen in 16.67% to 23.33% of ropivacaine and 23.33% to 46.67% of patients in bupivacaine group. However, the difference between two groups was not statistically significant for any of the side effects.

Thus, in this study, equipotent combinations of 0.125% bupivacaine and 0.2% ropivacaine with 2 µg/mL fentanyl were almost similar in postoperative pain management in patients undergoing joint replacement surgeries with almost stable hemodynamic profile and no major side effects. A relatively better motor blockade profile and lower overall

rescue analgesic needs suggested the superiority of ropivacaine (0.2%) - fentanyl (2 µg/mL) combination over bupivacaine (0.125%) - fentanyl (2 µg/mL) combination. These findings are encouraging, however, they need further substantiation given a wide variability in clinical reports on these two drug combinations. Hence, further studies on larger sample size and/or systematic reviews to evaluate the efficacy of one combination over the other are recommended.

CONCLUSIONS

Both combinations, i.e. ropivacaine - fentanyl and bupivacaine - fentanyl showed an equivalent efficacy against postoperative pain, with ropivacaine-fentanyl combination needing lower overall rescue analgesics as compared to that of bupivacaine - fentanyl combination. Residual motor blockade in postoperative period seems to be higher in bupivacaine - fentanyl than ropivacaine - fentanyl group leading to early ambulation, smooth recovery and lesser hospital stay in ropivacaine - fentanyl group. Given the fewer associated side effects and early recession of motor blockade ropivacaine - fentanyl has an edge over bupivacaine - fentanyl combination. Hence the findings of present study support the use of Ropivacaine (0.2%) - Fentanyl (2 µg/mL) over Bupivacaine (0.125%) - Fentanyl (2 µg/mL).

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