Original Research Paper

Volume-9 | Issue-12 | December - 2019 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Anesthesiology

COMPARATIVE EVALUATION OF EPIDURAL ADMINISTRATION OF 0.1% ROPIVACAINE + 2MCG/ML FENTANYL AND 0.1% BUPIVACAINE + 2MCG/ML FENTANYL FOR POSTOPERATIVE ANALGESIA DURING FIRST 24 HOURS IN PATIENTS UNDERGOING TOTAL KNEE REPLACEMENT.

Dr Ashwini Sonsale Assistant Professor, Department Of Anaesthesiology, SKN Medical College, Narhe, Pune

Dr Rajesh Sonsale* Associate Professor, Department Of General Surgery, SKN, Medical College, Narhe, Pune *Corresponding Author

ABSTRACT

Background: Epidural analgesia is most preferred technique for postoperative analgesia in total knee replacement patients. The study is aimed at comparing adequacy& efficacy of pain relief and safety in patients undergoing total knee replacement managed with epidural administration of 0.1% ropivacaine + 2mcg/ml fentanyl and 0.1% bupivacaine + 2mcg/ml fentanyl postoperatively for 24hrs.

Study design: It is 'Prospective, randomized,double blind comparative clinical study'.

Methodology: Total 65 patients underwent unilateral total knee replacement under combined spinal epidural anesthesia and continuous epidural infusion was started according to group after two segment regression for postoperative analgesia. We divided the patient in two treatment groups by using simple random sampling method (by using MS-Excel). Group B was containing 33 patients who were given 0.1% Bupivacaine + 2mcg/ml Fentanyl and Group R was containing 32 patients who were given 0.1% ropivacaine + 2mcg/ml Fentanyl for postoperative analgesia. 3 patients in Group B and 2 patients in Group R excluded because of missing data. Finally 30 patients in each group compared for various parameters like hemodynamic changes, the adequacy of analgesia, number of rescue analgesics required, the incidence of side effects like motor blockade, nausea, pruritus and hypotension.

Results: Both groups were comparable with respect to age and gender.

There was no significant difference in changes in hemodynamic parameters in both groups.

Apparently more rescue analgesics were required for ropivacaine group (p value 0.504).

There was no significant difference in the total amount of drug required in bupivacaine or ropivacaine group for postoperative analgesia (p value 0.504).

On comparing the VAS scores over 24 hours there was no significant difference between the two groups as p-value was >0.05.

Motor blockade was observed more in bupivacaine group but p value was 0.353 which was not stastically significant.

There were no significant incidences of side effects in both groups.

Conclusion: Continuous epidural analgesia with either 0.1% Bupivacaine or 0.1% ropivacaine provides satisfactory pain relief in postoperative period in Total knee replacement surgery patients, without significant alteration in hemodynamics and without any side effects. Both the drugs have comparable potency with apparently slightly more motor blockade with 0.1% bupivacaine. Further large study is required to prove or rule out the significance. Thus ropivacaine can be seen as preferred alternative to bupivacaine with comparable potency and better safety profile in total knee replacement surgery patients.

KEYWORDS :

INTRODUCTION

Anaesthesia is not just concerned with relieving pain during surgery but also during post operative period. Good postoperative analgesia improves quality of life and results in fast recovery and reduces medical cost[1].

Presently, epidural analgesia is an established and accepted technique of post operative pain management. Epidural infusion of local anaesthetic and opioid combination are the most commonly used epidural technique based on the clinical observation that combination of local anaesthetic and opioid drug limits the regression of sensory block seen with local anaesthetic alone and improves the quality of dynamic pain relief[2,3,4,5,6]. Combination of bupivacaine and fentanyl is routinely used combination for epidural analgesia postoperatively.

Recently in 1996, a newer local anaesthetic ropivacaine with improved safety margin for cardiotoxicity and central nervous system toxicity and potential advantage of less motor blockade has been introduced[7,8,9].

Hence comparative study of epidural administration of 0.1% ropivacaine + 2mcg/ml fentanyl and 0.1% bupivacaine + 2mcg/ml fentanyl is undertaken to evaluate their efficacy and safety in providing postoperative analgesia during first 24 hrs in patients undergoing Total Knee Replacement surgery.

MATERIALS AND METHODS:

It is 'Prospective, randomized, comparative clinical study'. Data collected over the duration of 2 years. In this duration total 65 patients underwent unilateral total knee replacement excluding those according to exclusion criteria.

Exclusion Criteria-

1) Patients with preoperative coagulation abnormality,
2) Patients on anticoagulant medication,
3) Patients with severe systemic infection,
4) Patient with infection near site of insertion of epidural,
5) Patients with history of allergy to bupivacaine, ropivacaine or fentanyl,
6) Patients with ASA Grade III and more,
7) Patients with severely compromised cardiovascular and respiratory systems,
8) Patient not giving consent for Epidural analgesia.

Those 65 patients were included in the study. We divided the patient in two treatment groups by using simple random sampling method (by using MS-Excel). Group B was containing 33 patients who were given 0.1% Bupivacaine + 2mcg/ml Fentanyl and Group R was containing 32 patients who were given 0.1% ropivacaine + 2mcg/ml Fentanyl for postoperative analgesia. 3 patients in Group B and 2 patients in Group R excluded because of missing data. Finally 30 patients in each group compared for various parameters.

All patients were given combined spinal epidural anesthesia for surgery and started on continuous epidural infusion with either 0.1% Bupivacaine + 2mcg/ml Fentanyl or 0.1% ropivacaine + 2mcg/ml Fentanyl according to group after two segment regression for postoperative analgesia. Baseline pulse rate, systolic blood pressure, diastolic blood pressure, VAS scores were recorded. Infusion started at 6ml/hr and we increased the rate of infusion as per exacerbation of pain.

The patients were observed for 24 hours postoperatively. Parameters were observed hourly and data entered at 3 hour interval. During the complaints of pain rescue analgesics, such as Inj. Paracetamol 15mg/Kg intravenously as first rescue analgesic and Inj. Tramadol 1mg/kg as second rescue analgesic, were given and rate of infusion increased by 1ml/hr. Total amount of drug required was recorded during 24 hours. Side effects like motor blockade, nausea, pruritus and hypotension were also recorded during 24 hours.

The data was obtained from patients according to proforma and from patient files.

We compared the hemodynamic changes occurring in both the groups over 24 hours postoperatively. We also evaluated and compared the adequacy of analgesia using VAS (Visual Analog Scale) score and number of rescue analgesics required. We also tried to compare the incidence of side effects like motor blockade, nausea, pruritus and hypotension in both groups.

Figure 1: Visual Analog Scale

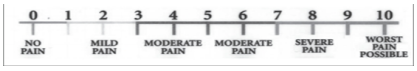

Table1: Bromage score:-

Grade	Criteria	Degree of block
I	Free movement of legs and feet	Nil (0%)
II	Just able t o flex knees with free movement of feet	Partial (33%)
III	Unable to flex knees, but with free movement of feet	Almost complete (66%)
IV	Unable to move legs or feet	Complete (100%)

Statistics – Data analysis done by using SPSS (Statistical package for social sciences) version 17.0. We have used 2 independent sample proportion test, 2 independent sample t-test, Chi-square test to find the significance in 2 groups with respect to various parameters. All statistical tests used at 5% level of significance. p-value < 0.05 considered as significant.

Results:
Both groups were comparable with respect to age and gender.

Table 2:Comparison of pulse rate in group B and group R.

Pulse rate	Number of patients	Pulse Rate				P-value
		Group B		Group R		
		Mean	SD	Mean	SD	
0 min	30	65.20	5.62	65.27	5.29	0.962
3rd hr	30	77.67	4.67	79.00	6.47	0.364
6th hr	30	80.20	5.39	79.67	5.31	0.701
9th hr	30	81.07	5.67	81.33	5.81	0.858
12th hr	30	81.67	5.31	80.40	6.00	0.390
15th hr	30	79.93	3.66	81.53	4.32	0.127
18th hr	30	81.13	4.78	81.00	5.17	0.918
21st hr	30	81.07	4.16	82.47	4.29	0.204
24th hr	30	82.07	3.91	81.60	5.02	0.690

By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between mean pulse rate in group B and group R at 0 min to 24th hr.

Table 3: Comparison of systolic blood pressure in group B and group R.

SBP	Number of patients	SBP				P-value
		Group B		Group R		
		Mean	SD	Mean	SD	
0 min	30	113.07	9.98	114.40	11.88	0.640
3rd hr	30	124.93	8.03	126.13	6.87	0.540
6th hr	30	129.93	5.57	128.53	6.41	0.370
9th hr	30	132.00	5.90	131.13	6.64	0.595
12th hr	30	133.40	5.20	132.27	5.25	0.404
15th hr	30	132.13	5.82	131.53	4.447	0.656
18th hr	30	131.73	5.22	132.20	5.02	0.725
21st hr	30	132.07	6.05	132.33	4.581	0.848
24th hr	30	132.87	3.99	132.73	4.62	0.905

By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between mean systolic blood pressure (SBP) in group B and group R at 0 min to 24th hr.

Table 4: Comparison of diastolic blood pressure in group B and group R.

DBP	Number of patients	DBP				P-value
		Group B		Group R		
		Mean	SD	Mean	SD	
0 min	30	68.80	4.51	69.80	7.01	0.514
3rd hr	30	74.93	5.25	77.20	5.74	0.116
6th hr	30	78.67	3.80	77.53	3.78	0.251
9th hr	30	79.33	4.40	78.07	4.53	0.277
12th hr	30	79.07	3.81	79.27	4.59	0.855
15th hr	30	79.00	4.06	78.73	4.12	0.801
18th hr	30	77.60	4.47	79.40	4.27	0.116
21st hr	30	78.93	4.57	78.53	3.10	0.693
24th hr	30	79.40	3.49	79.20	4.09	0.839

By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between mean diastolic blood pressure (SBP) in group B and group R at 0 min to 24th hr.

There was no significant difference in changes in hemodynamic parameters like pulse rate, systolic and diastolic blood pressure in both groups.

5 out of 30 patients in group B required rescue analgesic and 1 out of those 5 required two rescue analgesics and other 4 required single rescue analgesic .7 patients out of 30 patients in group R required rescue analgesic out of which 2 patients required two rescue analgesics and rest 5 patients required single rescue analgesic. Apparently more rescue analgesics were required for ropivacaine group but p value 0.504, therefore difference between requirements of rescue analgesic in both groups was not significant.

The total amount of drug required in bupivacaine group was 146.47±6.44 and that in ropivacaine group was 147.90±8.33. The p-value was 0.459 which was statistically not significant. This shows that there was no significant difference in the total amount of drug required in bupivacaine or ropivacaine group for postoperative analgesia.

Baseline VAS scores in bupivacaine and ropivacaine group were comparable as p-value is 0.999 which was not statistically significant. On comparing the VAS scores over 24 hours there was no significant difference between the two groups as p-value was >0.05.

In bupivacaine group 4 patients had motor blockade out of 30 patients. On the contrary 1 patient out of 30 patients in Ropivacaine group had motor blockade. So motor blockade was observed more in bupivacaine group but p value was 0.353 which was not stastically significant. Hence observed difference in motor blockade was not significant and larger study is needed to establish the clinical significance.

In bupivacaine group 3 patients had nausea out of 30 patients. In ropivacaine group 2 patients had nausea out of 30 patients. p-value for nausea was 0.999 which was statistically not significant. Hence both the groups are comparable with respect to nausea.

In bupivacaine group 1 out of 30 patients had pruritus. In ropivacaine group 2 patients had pruritus out of 30 patients. the p-value was 0.999 which was not statistically significant. Hence both groups are comparable with respect to pruritus Significant hypotension was not observed in any patient of bupivacaine or ropivacaine group. This shows that the low concentration of 0.1% of bupivacaine and ropivacaine help to decrease the incidence of side effect like hypotension.

DISCUSSION

The p values of age and gender distribution are 0.935& 0.812 respectively which are statistically not significant. Hence both groups are comparable with respect to age and gender distribution.

The baseline PR of both the groups are comparable. (p-value 0.962) .When comparing mean PR at different intervals postoperatively, the difference between two groups is not statistically significant.

The baseline SBP and DBP in both groups were comparable (P values 0.640 and 0.514 respectively). When comparing the mean SBP and DBP at different intervals postoperatively, the difference between the two groups is not statistically significant.

Hence in our study there was no significant difference in hemodynamics of the patients in both groups – Group B and Group R.

There are not many studies comparing the hemodynamics of the patient in Bupivacaine/Fentanyl Vs Ropivacaine/Fentanyl.

According to some studies [10, 11] patients with epidural analgesia with Ropivacaine/Fentanyl required more rescue analgesics as compared to those with epidural infusion with Bupivacaine/Fentanyl, as ropivacaine is 40% less potent than bupivacaine. While there are other studies [12,13] which concluded that there is no significant difference in potency of both drugs and requirement of rescue analgesics.

In our study also, apparently more rescue analgesics are required for ropivacaine group but p value 0.504, therefore it is not statistically significant. This may be due to small sample size. Further studies on larger sample size need to be done to prove the statistical significance.

According to the studies[10,11]ropivacaine is less potent than bupivacaine. In our study, there is no significant difference in the total amount of drug required in bupivacaine or ropivacaine group for postoperative analgesia which indicates comparable potency of the 0.125% Bupivacaine with fentanyl and 0.125% Ropivacaine with fentanyl for post op analgesia as opposed to other studies [10, 11]. Further studies on larger sample size needs to be done.

According to studies [12, 14] quality of epidural analgesia produced with 0.125% ropivacaine and 0.125% bupivacaine is similar as assessed by pain scales. But there are other studies[15] which have mentioned slightly higher VAS scores in Ropivacaine group.

In our study, on comparing the VAS scores over 24 hours there was no significant difference between the two groups as p-value was >0.05.

Thus, in our study, perception of pain documented by VAS scores was not significantly different in both groups as was the need for rescue analgesics.

This suggests that there is no difference in quality of analgesia with 0.125% ropivacaine and 0.125% bupivacaine.

According to the studies[2, 12, 15, 16] the patients administered ropivacaine/fentanyl developed significantly less motor blockade than patients administered bupivacaine/fentanyl.

In our study, motor blockade was observed more in bupivacaine group but p value is 0.353 which is not statistically significant. Hence observed difference in motor blockade is not significant and larger study is needed to establish the clinical significance.

According to the literature[12, 14, 17] there is no difference in side effects other than motor blockade between ropivacaine/fentanyl and bupivacaine/fentanyl group.

In our study there is no difference in occurrence of side effect like nausea in both groups.

According to the literature[12, 14, 17] there is no difference in side effects other than motor blockade between ropivacaine/fentanyl and bupivacaine/fentanyl group.

In our study there is no difference in occurance of side effect like pruritus in both groups.

Significant hypotension was not observed in any patient of bupivacaine or ropivacaine group. This shows that the low concentration of 0.1% of bupivacaine and ropivacaine help to decrease the incidence of side effect like hypotension.

CONCLUSIONS:

Continuous epidural analgesia with either 0.1% Bupivacaine or 0.1% ropivacaine provides satisfactory pain relief in postoperative period in Total knee replacement surgery patients, without significant alteration in hemodynamics and without any side effects. Both the drugs have comparable potency with apparently slightly more motor blockade with 0.1% bupivacaine. Further large study is required to prove or rule out the significance. Thus ropivacaine can be seen as preferred alternative to bupivacaine with comparable potency and better safety profile in total knee replacement surgery patients.

REFERENCES

1. Kehlet, H., Wilmore, D.W. Multimodal strategies to improve surgical outcome. Am J Surg, 2002; 183(6):630-641.
2. Liu, S., Carpenter, R.L., Neal, J.M. Epidural anesthesia and analgesia: Their role in postoperative outcome. Anesthesiology, 1995; 82(6):1474-1506.
3. Axelsson, K., Johanzon, E., Essving, P., Weckstrom, J., Ekback, G. Postoperative extradural analgesia with morphine and ropivacaine. A double-blind comparison between placebo and ropivacaine 10 mg/h or 16 mg/h. Acta Anaesthesiol Scand, 2005; 49(8):1191-1199.
4. Kehlet, H., Werner, M., Perkins, F., Balanced analgesia: what is it and what are its advantages in postoperative pain? Drugs, 1999; 58(5):793-797.
5. Block, B.M., Liu, S.S., Rowlingson, A.J., Cowan, A.R., Cowan, J.A., Jr., Wu, C.L. Efficacy of postoperative epidural analgesia: a meta-analysis. JAMA, 2003; 290(18):2455-2463.
6. Choi, P.T., Bhandari, M., Scott, J., Douketis, J. Epidural analgesia for pain relief following hip or knee replacement. Cochrane Database Syst Rev, 2003;(3):CD003071.
7. Ankit Agarwal, R.K. Verma, Shivika Srinivasta. Ropivacaine- The latest Local Anaesthetic in the Indian market. J Anaesth Clin Pharmacology. 2010; 26(2): 223-228.
8. Stefania Leonee, Di Cianni, Andrea Casati, Guido Fanelli. Pharmacology, toxicology and clinical use of new long acting local anesthetics, Ropivacaine and Levobupivacaine. ACTA BIOMED. 2008; 70: 92-105.
9. Akerman, B., Hellberg, I. B., Trossvik, C. Primary evaluation of the local anesthetic properties of the amidoamide agent ropivacaine (LEA 103). Acta anaesthesiaiol Scand, 1988; 32: 571-578.
10. H. Jorgensen, J. S. Fomsgaard, J. Dirks, J. Wetterslev and J. B. Dahl. Effect of continuous epidural 0.2% ropivacaine vs 0.2% bupivacaine on postoperative pain, motor block and gastrointestinal function after abdominal hysterectomy. Br. J. Anaesth, 2000; 84 (2): 144-150.
11. D'Angelo, Robert, M.D., James, Robert, L. M.S, M. Stat. Is Ropivacaine Less Potent than Bupivacaine? Anesthesiology, Volume 90, April 1999; 941-943.
12. Greg C. Meister, Robert D'Angelo, Medge Owen, Kenneth E. Nelson and Renee Gaver. A Comparison of Epidural Analgesia with 0.125% Ropivacaine with Fentanyl Versus 0.125% Bupivacaine with Fentanyl during Labor. A & A, March 2000; vol. 90 no. 3: 632-637.
13. Bertini, L., Mancini, S., Di Benedetto, P., Ciaschi, A., Martini, O., Nava, S., Tagariello, V. Postoperative analgesia by combined continuous infusion and patient-controlled epidural analgesia (PCEA) following hip replacement, Ropivacaine versus Bupivacaine, ACTA Anaesthesiol. Scand., 2001; 45 (6): 782-785.
14. Hodgson, P.S., Liu, S.S. A comparison of ropivacaine with fentanyl to bupivacaine with fentanyl for postoperative patient-controlled epidural analgesia, Anesth Analg. 2001 Apr; 92(4):1024-8
15. Muldoon, T., Milligan, K., Quinn, P., Connolly, D. C., Nilsson, K. Comparison between extradural infusion of Ropivacaine or Bupivacaine for the prevention of postoperative pain after total knee arthroplasty, BR. J. ANAESTH, 1998; 80 (5): 680-681.
16. Zink, W., Graf, B.M. Benefit-risk assessment of ropivacaine in the management of postoperative pain, Drug Saf. 2004; 27(14):1093-114.
17. Berti, M., Fanelli, G., Casati, A., Albertin, A., Palmisano, S., Deni, F., Perotti, V., Torri, G. Patient supplemented epidural analgesia after major abdominal surgery with bupivacaine/fentanyl or ropivacaine/fentanyl, Can J Anaesth, Jan 2000; 47(1):27-32.