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Original Article

Anaesthesia Section

Evaluation of Postoperative Analgesia on Addition of Dexmedetomidine to Ropivacaine 0.2% in Femoral Nerve Block in Patients undergoing Open Knee Surgery- A Randomised Single Blinded Study

NEHA M SHAH[1], JAYESH KATAKIYA[2], AFROZA N SYED[3], PINAL BUMIYA[4], NEHA CHERAYA[5]

ABSTRACT

Introduction: Femoral Nerve Block (FNB) renders marked postoperative analgesia in patients undergoing knee surgery and use of adjuvant to Local Anaesthetic (LA) agent is more advantageous in lengthening duration of sensory effect of block.

Aim: To evaluate the effect of addition of dexmedetomidine to 0.2% Ropivacaine in FNB.

Materials and Methods: The randomised clinical trial was conducted in the Department of Anaesthesiology, Medical College and SSG Hospital, Vadodara, Gujarat, India. The trial included 60 patients of either sex, American Society of Anaesthesiologists (ASA) Grade-I,II,III posted for open knee surgery. Patients were randomly allocated to two groups-group RD patients received 0.2% ropivacaine 20 milliliter (mL) with dexmedetomidine 2 mL (50 µg) and Group R received 0.2% ropivacaine 20 mL with normal saline 2 mL for FNB. Duration of postoperative analgesia, total requirement of systemic rescue analgesic in 24 hours, vital parameters and complications were observed. Statistical analysis was done with Medcalc 14.8.1 statistical software. A $p<0.05$ considered as significant.

Results: Duration of analgesia was significantly longer in group RD (484±26.98 min) than in group R (338±29.40 min), $p<0.0001$. Mean postoperative cumulative requirement of analgesic (Tramadol) was lesser in group RD (207±25 milligram (mg)) than in group R (290±30 mg), $p<0.0001$.

Conclusion: Dexmedetomidine to ropivacaine 0.2% for FNB significantly augments duration of analgesia and reduces requirement of systemic analgesic declining its unfavourable effect.

Keywords: Adjuvant, Advantage, Nerve blocks

INTRODUCTION

Open surgeries of knee are often associated with noticeable postoperative pain and provision of freedom from pain is an important measure for the patients who passed through major surgeries [1-4]. Postsurgical pain extends hospitalisation, impairs early mobilisation and rehabilitation and thereby decline end result. Multimodal analgesia incorporate different systemic analgesics and nerve block techniques to control pain following surgery [5,6].

Innervation of knee joint is from femoral nerve (L2-4) mainly in anterior part and the sciatic nerve (L4,5 and S1-3) supplies posteriorly. Both anterior and posterior segments blockage through Local Anaesthetic (LA) injection solution into the femoral or the sciatic nerves should completely reduce the pain fiber transmission [7,8]. However, combined blocks are limited due to unwanted effect on muscle strengthening [2,4,8,9]. Recently, researchers analysed that FNB may be the preferred method for postoperative analgesia after open knee surgeries, reducing the requirement for rescue analgesics and possibly lowering the risk of medication-induced adverse effects, emotional stress, and sleep disruptions [2,3,5,7].

Improvement was observed in duration and quality of peripheral nerve blocks by adding adjuvants to LA. One such agent is dexmedetomidine, a α2-agonist having an eight times more affinity for α2-adrenergic receptors (hypnotic, analgesic effects) than clonidine and less α1-effects [1,10-12]. The unintended use of dexmedetomidine has been approved for intravenous use by Food and Drug Administration (FDA), but there is growing evidence that it can also be used for peripheral and neuraxial nerve blocks, with promising outcomes [1,4,10,11]. Dexmedetomidine and ropivacaine are approved by Director General of India (DCGI) in 2009 [1]. Dexmedetomidine has a short elimination half-life (2-3 hours), yet the analgesia that is typically experienced following a perineural injection lasts for 12-24 hours. Moreover, its usage as a sedative and anxiolytic has been also suggested [4,10-12].

The study aimed at evaluating the efficacy of single injection in FNB with or without addition of dexmedetomidine to 0.2% Ropivacaine. Primary aim was to access duration of analgesia postoperatively by observing pain scores and additional analgesic requirements in 24 hours. Vital parameters, sedation and complications were observed secondarily. Authors also hypothesised that addition of dexmedetomidine to 0.2% ropivacaine would intensify the block and prolong analgesia in patients of open knee surgery.

MATERIALS AND METHODS

The present prospective single blind randomised clinical trial was carried out during October 2018 to November 2021 after taking permission from the Scientific Research Committee and Institutional Ethics Committee for Human Research, in the Department of Anaesthesiology, Medical College and SSG Hospital, Vadodara, Gujarat, India. The trial was registered in the Clinical Trials Registry of India (CTRI) (CTRI/2018/09/015782).

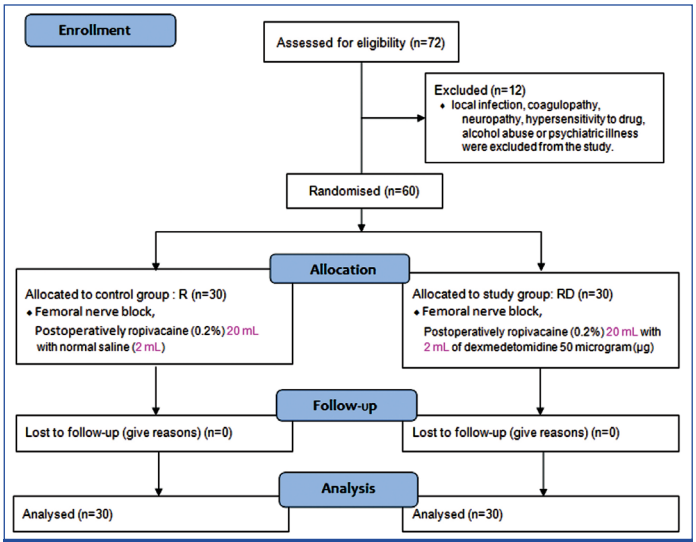
Inclusion criteria: A total of 60 patients of either sex, age of 30-60 years, weighing 40-70 kg, ASA grade I, II, III, posted for open knee surgery {Total Knee Replacement (TKR), patella surgery}, able to give consent and understand VAS score were included in the study.

Exclusion criteria: Patient with local infection, coagulopathy, neuropathy, hypersensitivity to drug, alcohol abuse or psychiatric illness were excluded from the study.

Sample size calculation: Sample size was calculated using N-master 2.0 software by taking parameter time for first demand bolus of rescue analgesia from the study done by Sharma B et al., which was 150±115.2 and 346.8±240 in control and study group respectively [1]. Minimum 56 patients were required to get 196 mean difference with standard deviation of 178 with 90% power at 1% risk, (99% confidence interval). Predicting the dropouts, 30 patients in each group were included.

Study Procedure

All patients were randomly allocated to either of the two groups, group R and RD (n=30) by computer generated random numbers. Group R received Injection (Inj.) ropivacaine (0.2%) 20 mL with normal saline (2 mL) and group RD received Inj. ropivacaine (0.2%) 20 mL with 2 mL of dexmedetomidine 50 µg in FNB [Table/Fig-1].



[Table/Fig-1]: Change in mean pulse rate and mean blood pressure.

All patients induced with subarachnoid block using 2.5 mL of 0.5% hyperbaric bupivacaine. After the completion of surgery, FNB was given, approximately 1 cm lateral to the pulsation and 1-2 cm below the inguinal ligament, 22G insulated needle was inserted and with help of peripheral nerve stimulator quadriceps contraction (dancing patella) was elicited using 1.5 mA current. Once contractions were achieved current was gradually reduced till 0.4 mA and presence of minimal contractions were confirmed. Here, after needle aspiration, LA agent was injected perineurally as per groups. Inj. paracetamol (1 g) i.v. was given as a part of multimodal analgesia to all the patients after procedure to relieve pain posterior aspect of knee.

Pain assessment was done using Visual Analogue Scale (VAS) score. All patients were observed from the time of injection, at regular interval of 2,4,6,8,10,12,16,20 and 24 hours for VAS score, modified Ramsay sedation score and vital parameters like pulse, blood pressure, respiratory rate, oxygen saturation [13,14]. Time for first demand and total dose of systemic rescue analgesic in 24 hours was noted. When patient's VAS score was observed ≥4 at rest, Inj. Tramadol (100 mg) i.v. was given as a rescue analgesic in both the groups.

Visual Analogue Scale (VAS) Score: •0: No pain •1-3: Mild pain •4-6: Moderate pain •7-9: Severe pain •10: Worst pain.

STATISTICAL ANALYSIS

Parametric variables were described as mean±SD form, analysed by Student's t-test and Fisher's-exact test. Statistical analysis was done with Medcalc 14.8.1 statistical software. Significance of statistical data was obtained in a form of p-value, (p<0.05) was considered as significant.

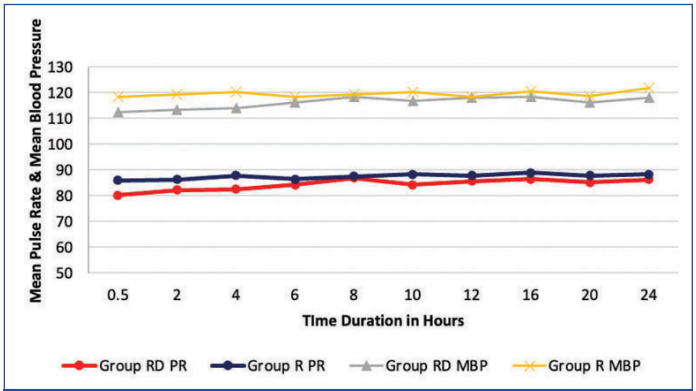
RESULTS

Duration of analgesia was significantly longer in group RD (484±26.98 min) than in group R (338±29.40 min), p<0.0001. [Table/Fig-2] shows, demographic data in terms of age, weight, gender, ASA grading were comparable between both the groups. There was no significant difference between the groups based on demographics.

Parameters	Group RD	Group R	p-value
Age (Mean±SD) (years)	54.56±7.02	51.03±14.14	0.2142
Weight (Mean±SD) (kg)	58.33±5.1	57.9±5.24	0.3342
Gender (Male: Female)	12:18	13:17	1.0
ASA physical status (ASA I: ASA II)	9:21	12:18	0.5889

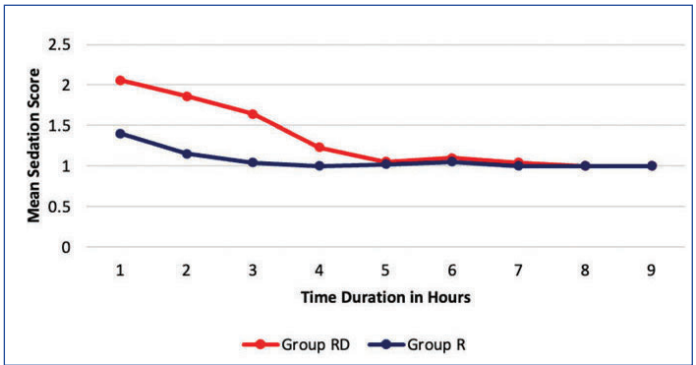
[Table/Fig-2]: Demographic data.

[Table/Fig-3] shows, at all intervals haemodynamics were preserved in physiological range, although somewhat difference in pulse rate was observed between two groups till four hours. They were 80.2±6.4 beats per minute (bpm), 82.1±7.6, 82.5±6.4 in RD group and 85.9±7.57, 86.2±7.6, 87.8±6.84 in R group till four hours. The p-value at 0.5, 2,4 hours was 0.0026, 0.0411, 0.003, respectively. No significant difference was observed in mean blood pressure at all intervals, p-value at 0.5, 2, 4 hours: 0.0618, 0.0654, 0.0672.



[Table/Fig-3]: Change in mean pulse rate and mean blood pressure.

As shown in [Table/Fig-4] sedation score remained significantly higher in group RD (mean±SD) at interval of two hours (2.06±0.63), four hours (1.86±0.41), six hours (1.64±0.18) as compared to group R at two, four, six hours, respectively (p-value: 0.0001).



[Table/Fig-4]: Modified Ramsay Sedation score.

In present study, as shown in [Table/Fig-5,6] none of the patient had respiratory depression in both the groups. At all intervals in respiratory rate and oxygen saturation remained stable and comparable between both the groups. Any other side-effects like haematoma and infection at site of injection, systemic LA toxicity, allergic reaction/anaphylaxis, femoral nerve neuritis were not observed.

As shown in [Table/Fig-7] postblock VAS score at 2,4,6,10,12, 16 hours' time intervals in group RD Mean±SD were 0.67±0.47, 2.26±0.49, 3.83±0.89, 2.88±0.97, 3.96±1.6, 2.41±1.28 as compared to 0.94±0.52, 3.96±0.82, 2.4±1.42, 5.1±1.82, 2.97±2.02 4.76±1.71 in group R, respectively. Differences were statistically significant

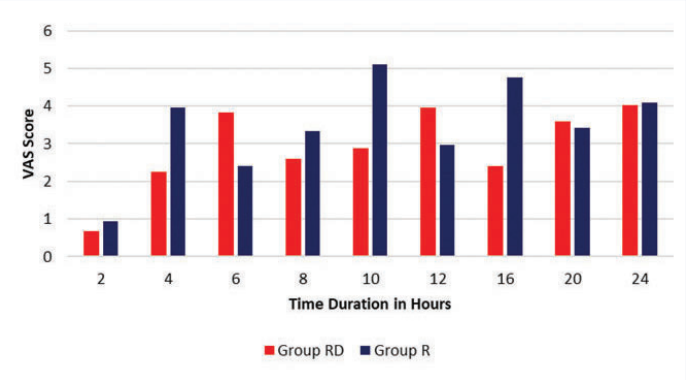
between both the groups. The p-value: 0.0392 at 2 hours, 0.0001 at 4, 6, 10, 16 hours, and 0.0397 at 12 hours.

Time (in hours)	Group RD (Mean±SD)	Group R (Mean±SD)	p-value
Before block	16.1±1.1	16.5±1.09	0.1625
Postblock			
0.5	15.93±1.7	16.1±1.35	0.6696
2	15.8±1.76	16±1.65	0.6515
4	15.86±1.65	16.2±1.54	0.4127
8	15.8±1.91	16.23±1.81	0.3745
16	15.86±1.47	15.9±1.67	0.9219
20	16±2.03	16.3±1.97	0.5636
24	16.06±1.43	16.1±1.63	0.9199

[Table/Fig-5]: Changes respiratory rate.

Time (in hours)	Group RD (Mean±SD)	Group R (Mean±SD)	p-value
Before block	98.47±0.51	98.57±0.5	0.4463
Postblock			
0.5	98.63±0.25	98.64±0.18	0.8595
2	98.6±0.44	98.65±0.37	0.6356
4	98.56±0.56	98.7±0.46	0.2944
8	98.53±0.57	98.7±0.59	0.261
16	98.03±2.1	98.43±0.5	0.3144
24	98.5±0.64	98.45±0.62	0.7597

[Table/Fig-6]: Changes in mean oxygen saturation at different time interval.



[Table/Fig-7]: VAS score.

As shown in [Table/Fig-8] duration of analgesia was longer and total requirement of analgesic was lesser in group RD. Difference were significant.

Parameters	Group RD (Mean±SD)	Group R (Mean±SD)	p-value
Duration of analgesia (minutes)	484±26.98	338±29.4	0.0001
Total systemic analgesic requirement (mg)	207±25	290±30	0.0001

[Table/Fig-8]: Duration of analgesia and mean cumulative dose of rescue analgesia.

DISCUSSION

Nerve blocks provide more benefits if postoperative analgesia is extended. Present study reflects that dexmedetomidine as a LA adjuvant with 0.2% ropivacaine for FNB can prolong the duration of analgesia. Furthermore, sparing of motor involvement is preferred by surgeons specially for total Total Knee Replacement (TKR) surgeries while selecting analgesia technique. Pain as well as motor blockade delay the early mobilisation and may augment thromboembolism incidences. Untreated pain may disturb sleep and lead to psychological problems [3]. The present study found that, duration of postoperative analgesia was significantly extended in RD group than group R. Requirement of tramadol as rescue analgesic was also significantly lower in group RD as compared to group R.

Various strategies of multimodal analgesia strategies include analgesic agent combinations, epidural infusion, patient-controlled analgesia and regional blocks. Sharma B et al., and Cheng J et al., mentioned that continuous FNB analgesia produces fewer side-effect than epidural analgesia [1,15]. Innervations of knee joint are from the femoral nerve (L2-4) mainly in anterior part and sciatic nerve (L4-5 and S1-3) supplies posteriorly [7,8]. Although combined block of both the nerves completely reduce pain fiber transmission. However, their uses are limited due to unwanted effect on muscle strengthening [2,4,8,9]. Ropivacaine 0.2% was selected (20 mL+2 mL saline, total 22 mL) for both groups because of its weak motor effect property helps in early ambulation [3,16]. Present study added dexmedetomidine 50 µg (2 mL) as adjuvant with 0.2% ropivacaine (20 mL, total volume 22 mL) in study group.

Dexmedetomidine is widely used perioperatively to attenuate stress response of anaesthesia and surgery as well as for postoperative pain management. Previously clonidine was used as an adjuvant successfully for nerve blocks which gave thought of dexmedetomidine instead. However, clonidine inhibits hyperpolarisation-activated cation current rather than through alpha-2 mediated mechanism. Its affinity for binding receptor is 220:1 compare with 1600:1 for dexmedetomidine which is newer alpha-2 agonist [10]. Use of dexmedetomidine as an adjuvant is known to increase LA effect without damaging the nerve [1,4,10]. A number of studies have reported the pharmacological effect of dexmedetomidine, its efficacy and safety as an adjuvant to LA [3,10,11,17]. Very few referential evidence was found with combination of dexmedetomidine, ropivacaine and FNB. Hence, to add a further knowledge, authors decided to carry out the present study to evaluate the effects of addition of dexmedetomidine (50 µg) to ropivacaine 0.2% for FNB in patients undergoing open knee surgery and observed the duration of analgesia, rescue analgesics requirement, haemodynamics and postoperative complications.

Many supportive studies of administration of dexmedetomidine using different doses and roots were reviewed. In TKR patients, Sharma B et al., used dexmedetomidine 1.5 µg/kg with 0.2% ropivacaine for FNB and also used Inj. diclofenac and paracetamol intravenously as a part of multimodal analgesia [1]. Gupta R et al., and Shukla D et al., had used 0.75% ropivacaine, 0.75% bupivacaine with dexmedetomidine in spinal anaesthesia [18,19]. Gandhi R et al., and Ammar AS and Mahmoud KM had studied effect of dexmedetomidine with bupivacaine for brachial plexus block [20,21]. Abdulatif M et al., performed a FNB with bupivacaine and three different doses of dexmedetomidine prior to general anaesthesia as part of a multimodal analgesic regime [22]. Babu S et al., used FNB to compare 0.125% bupivacaine and 0.2% ropivacaine for knee arthroplasty whereas Packiasabapathy SK et al., evaluated 1 and 2 µg/kg dexmedetomidine with bupivacaine for TKR [3,10]. Few other studies also evaluated that dexmedetomidine is a potential LA adjuvant which produce extended effect when administered perineurally [2,7,23,24]. FNB was specifically recommended for pain management in femur fractures [25]. It has been reported that systemic absorption of ropivacaine is biphasic following FNB in providing analgesia [26,27].

Significantly longer duration of postoperative analgesia was found in RD group as compared to R group in current study. Similarly, Sharma B et al., reported significant extension in duration of analgesia but failed to achieve significant reduction of tramadol consumption in Dexmedetomidine group because they used additional analgesics as a part of multimodal regime [1].

Packiasabapathy SK et al., and Abdulatif M et al., stated a prolonged duration of FNB with higher doses [10,22]. Abdulatif M et al., also claimed that postoperative morphine consumption was significantly higher in control group. Significantly increased requirement of

tramadol in group R than group RD was found in present study which was consonant with Abdulatif M et al., [22]. While addition of dexmedetomidine for other perineural blocks and with epidural anaesthesia, also found significant prolongation in duration of analgesia [4,17,18]. Esmaoglu A et al., added dexmedetomidine to levobupivacaine in axillary brachial plexus block. They reported prolongation of analgesia but it was not statistically significant [28]. Thus, dexmedetomidine has been the subject of numerous experimental research and it has been found to improve LA solutions' ability to block sensory and motor pathways. They came to the conclusion that alpha-2 receptor agonists enhance hyperpolarisation by inhibiting the hyperpolarisation-activated cation-current. Proposed mechanism by which dexmedetomidine affects duration of analgesia are alpha-2b adrenoceptor mediated vasoconstrictive effects, centrally mediated analgesia, direct action on peripheral nerve and attenuation of inflammatory response [4,10].

When postoperative pain score was indicated VAS ≥4, intravenous tramadol was supplemented by us as rescue analgesia. In present study, VAS score at rest was observed significantly less in group RD as compared to group R at time intervals of 2,4,6,10,12,16 hours. Consonance to present study, many studies reported reduced VAS score using dexmedetomidine as an adjuvant [1,5,17].

Intravenous administration of dexmedetomidine is associated with significant reduction in arterial blood pressure and pulse rate. However, haemodynamic side-effects in awake patients reported less and mostly related with transient bradycardia. Infact hypotension was associated with higher dose and this may be due to systemic absorption [4,20,26]. In present study, haemodynamics were preserved with in clinical range but statistically significant difference was observed in group RD (80.2±6.4, 82.1±7.6, 82.5±6.4) as compared to R (85.9±7.57, 86.2±7.6, 87.8±6.84) till four hours in pulse rate (p-value at 0.5,2,4 hours: 0.0026, 0.0411, 0.003). Similarly, Packiasabapathy SK et al., noticed low incidence of bradycardia and hypotension in their dose-response study considering the law incidence of systemic adverse effects associated with perineural dexmedetomidine [10].

Group RD continued to have a somewhat greater sedation score which also contributes to the patients' ability to get a decent sleep at night after surgery. Dexmedetomidine sedation was shown in numerous trials to be dose-dependent remained little higher in group RD. Postoperative pain relief also provides good sleep to the patients which can be explain for sedation in addition [1,22]. Meta-analysis by Kathuria S et al., reported that dexmedetomidine with brachial plexus block had significantly greater sedation but meta-analysis by Abdallah FW et al., reported that patients receiving intrathecal dexmedetomidine for spinal anaesthesia didn't find any difference between two groups related to sedation [29,30]. In present study, respiratory depression wasn't noticed. No statistically significant difference was observed at all intervals in respiratory rate and oxygen saturation between both the groups. Any other side-effect wasn't observed in the present study.

Limitation(s)

Double-blind clinical trial couldn't be conducted by authors. More recommended Ultrasound (USG) guided method wasn't employed and postblock muscle strength was not included as secondary parameter.

CONCLUSION(S)

Addition of dexmedetomidine to ropivacaine 0.2% in FNB was superior as compared to ropivacaine 0.2% alone. It provided extended duration of analgesia and reduced requirement of systemic analgesic declining its adverse effect. However, there was no difference in the vital parameters after block administration between the two groups.

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PARTICULARS OF CONTRIBUTORS:
1. Associate Professor (H.G.), Department of Anaesthesiology, Medical College Baroda, Vadodara, Gujarat, India.
2. Anaesthesiologist (Class-1), Department of Anaesthesiology, Government General Hospital (Maansa), Gandhinagar, Gujarat, India.
3. Associate Professor (H.G.), Department of Anaesthesiology, Medical College Baroda, Vadodara, Gujarat, India.
4. Assistant Professor, Department of Anaesthesiology, Medical College Baroda, Vadodara, Gujarat, India.
5. Ex-Assistant Professor, Department of Anaesthesiology, Medical College Baroda, Vadodara, Gujarat, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Neha M Shah,
63, Pitamber Society, Old Padra Road, Near Akshar Chowk,
Vadodara-390020, Gujarat, India.
E-mail: nehakinitshah@gmail.com

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