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Comparison of clonidine and dexmedetomidine as an adjuvant to bupivacaine for PNS guided femoral-sciatic nerve block for post-operative analgesia in below knee surgeries under spinal anaesthesia.

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Abstract

Title: Comparison of Clonidine and Dexmedetomidine as an adjuvant to Bupivacaine for PNS guided femoral-sciatic nerve block for post-operative analgesia in below knee surgeries under spinal anaesthesia.

Background: In patients undergoing lower limb orthopaedic surgeries, regional anaesthesia like subarachnoid blocks are safe, having excellent analgesia for shorter duration of time. To provide prolonged analgesia femoral-sciatic nerve block (FSNB) is reliable, safe and effective method in immediate post-operative period.

Aim: To assess the duration of analgesia after FSNB and Compare efficacy of equal doses of clonidine and dexmedetomidine as an adjuvant to bupivacaine for post-operative analgesia in below knee orthopedic surgeries.

Material and Methods: 60 ASA I and II patients admitted under orthopaedic wards for below knee surgeries were randomly divided into 2 groups of 30 each: Group C 0.125% Bupivacaine 25cc + 0.5mcg/kg Clonidine and Group D 0.125% Bupivacaine 25cc + 0.5mcg/kg Dexmedetomidine

Statistical analysis:- The inter-group statistical comparison of categorical variables is tested using Chi-Square test or Fisher's exact probability test and of continuous variables is done using independent sample t test.

Results: The duration of analgesia was significantly prolonged in group D (10.17 ± 1.80 h) as compared to group C (7.0 ± 1.36 h) and the difference was statistically significant.

Conclusion: Our study demonstrated that addition of dexmedetomidine to bupivacaine in femoro sciatic nerve block prolonged the duration and improved the quality of analgesia as compared to clonidine with hemodynamic stability and lack of side effects.

Keywords: Femora sciatic nerve block, dexmedetomidine, clonidine, bupivacaine, subarachnoid block.

Introduction

In patients undergoing orthopaedic surgery, unrelieved post-operative pain not only causes patients anxiety but also predisposes them to develop chronic pain syndromes^[1].

These lower limb procedures are amenable to regional anesthesia techniques which reduce neuroendocrine stress responses, central sensitization of nervous system and muscle spasms which occur in response to pain stimuli^[2]. Postoperative pain is still inadequately relieved, despite substantial improvements in the knowledge of the mechanisms and treatment of pain. Inadequate relief of postoperative pain may result in harmful physiologic and psychological consequences that lead to significant morbidity; this may delay recovery and return to daily activities. The presence of postoperative pain significantly contributes to patient's dissatisfaction with their anesthetic and surgical experience. It has been recognized that inadequately treated postoperative pain may lead to chronic pain^[2].

Regional anesthetic techniques have an advantage over general anesthesia such as excellent pain control with less adverse effects and shortened stay in the post-anesthesia care unit^[3].

Moderate to severe postoperative pain is associated with immobility and a decrease in effective early mobilization^[4].

Multimodal analgesia is a multidisciplinary approach to pain management, with the aim of maximizing the positive aspects of the treatment while limiting the associated side effects.

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The addition of non-opioid analgesics reduces opioid use, improves analgesia, and decreases opioid-related side effects. The use of peripheral or neuraxial regional anesthetic techniques and a combination of non-opioid analgesic agents for breakthrough pain results in superior pain control and attenuation of the stress response, and decreases opioid requirements and hence reduced complications [5].

Several perineural adjuvant medications like dexmedetomidine and clonidine which are highly specific and selective alpha-2 adrenoceptor agonist were used to increase duration of post-operative analgesia. Some recent investigations have studied the effect of mixing dexmedetomidine and clonidine during peripheral nerve blocks and showed they prolonged the duration of blocked and post-operative analgesia but to the authors knowledge no previous study was done for comparison of dexmedetomidine and clonidine for peripheral nerve blocks. Advantages of giving Femoro-sciatic nerve block (FSNB) is, it is a reliable, safe and effective method of providing analgesia in the immediate postoperative period in orthopaedic surgery below the knee [3].

We hypothesized that adding dexmedetomidine and clonidine would lengthen the time to the first request for post-operative analgesia and increase the duration of sensory blockade.

2. Material and Methods

After obtaining the approval of Ethical Committee (SKNMC/Ethics/App/2017/362) and written informed patient's consent, 60 patients of age group 20 to 60 years of both gender and ASA I and II who were scheduled for below knee surgery under subarachnoid block were included in this prospective, randomized, double blind study. Sample size was calculated by Epi-Info software. Randomization was achieved by computer generated random number table. Random group assigned was enclosed in a sealed envelope to ensure concealment of allocation numbers. Study solution was prepared by anesthesiologist not involved in the study according to the randomization. Duration of the study was 18 months.

Patients were excluded if they have significant cardiac, pulmonary, renal, hepatic, neurological, neuromuscular, or psychotic disorders and coagulopathies. Pregnant patients, patients with BMI >35 kg/m², those receiving adrenoceptor agonist or antagonist anticoagulants, antiplatelet, patients with history of hypersensitivity to study medications and those who refuse to participate in the study were excluded.

60 Patients were divided in equal groups of 30 each of, Group C: received 0.125% Bupivacaine 25cc + 0.5mcg/kg Clonidine.

Group D: received 0.125% Bupivacaine 25cc + 0.5mcg/kg Dexmedetomidine.

Patients were nil orally for 8hrs and given Tab. Alprazolam 0.5mg and Tab. Omeprazole a day before surgery. Intravenous access was secured and all patients were pre-loaded with 500ml of RL. In the operation theatre all Standard monitors like NIBP, ECG, and PULSE OXIMETER were attached, baseline BP, SPO2 were recorded.

Patients were given subarachnoid block in the sitting position using 26G Quinke's spinal needle at L₃-L₄ interspace with 3cc of 0.5% hyperbaric bupivacaine after ensuring free flow of CSF and patient was made supine.

After confirming adequate level i.e. T₁₀ surgery was allowed to proceed.

Intraoperative hemodynamic parameters were assessed and any complications like bradycardia, hypotension, and respiratory depression were observed and treated accordingly.

At the end of procedure patients were shifted to post-operative room and sensory and motor block was assessed. When sensory level was regressed by 2 segments and patients were able to move their leg, Sciatic and femoral nerve block was given.

PNS guided Sciatic block was given with the patient in lateral decubitus position (with the hip flexed at 40 degree and knee at 90 degree), with Labet approach (greater trochanter and PSIS are located; from the midpoint of the connecting line, a line is drawn perpendicular and injection point is marked at 5cm {Labet line}).

To check this, another line connecting the greater trochanter and sacral hiatus is bisected {Winnie line}. (The two points coincide)

Stimulator connected to a 21G 100mm stimuplex block needle.

Stimulation frequency was initially set at 2Hz and the intensity of the stimulating current was gradually reduced between 0.3 to 0.5mA to see plantar flexion in the foot and then study solution was injected for sciatic nerve block according to randomization using mixture of 15ml of 0.125% bupivacaine with 0.5mcg/kg clonidine in group C and 0.5mcg/kg dexmedetomidine in group D.

Femoral nerve block was given in supine position (the stimulating needle inserted 1.5 - 2cm lateral to the femoral artery and 1 -2 cm distal to inguinal ligament at the insertion of line connecting the ASIS to the pubic tubercle).

On elicitation of dancing patella response with current 0.3 to 0.5mA 10 ml of the study solution was given to the respective groups.

Post-operative monitoring

- Post operatively patient was monitored every 15 min for 1st 1hour and then hourly for next 24hrs pulse, NIBP, SP02, ECG, VAS score, Ramsay Sedation Score, Patient Satisfaction Score.
- Breakthrough Pain was supplemented with analgesics like Inj Paracetamol 15mg/kg over 10 minutes through intravenous route if V.A.S >4, Visual Analog Scale (VAS) is a validated, subjective measure acute and chronic pain. Scores are recorded by making a hand written mark on a 10cm line, 0 represents no pain and 10 represents the worst pain.) and monitored for the time to first analgesic usage and also the total no. of analgesic doses required in first 48hrs.

Objective of the study was to assess, duration of effective analgesia (time from the femoro-sciatic nerve block to the first analgesic requirement, visual analogue scale [VAS] score ≥ 4) and any side effects.

Statistical data analysis

The inter-group statistical comparison of distribution of categorical variables is tested using Chi-Square test or Fisher's exact probability test. The inter-group statistical comparison of means of continuous variables is done using independent sample t test. The underlying normality assumption was tested before subjecting the study variables

to t test.

In the entire study, the p-values less than 0.05 are considered to be statistically significant. All the hypotheses were formulated using two tailed alternatives against each null hypothesis (hypothesis of no difference).

3. Results

There is no statistical difference in both the groups as p value is non-significant, so both groups are demographically comparable. (Table 1)

Table 1: Demographic Characteristics:

	Group D	Group C
Age	39.10(15.24)	36.37(11.61)
Sex M/F	18/12	14/16
ASA 1/2	22/8	21/9
BMI	23.14(1.54)	23.29(2.51)
Duration of Surgery	120 ± 16 min	120 ± 19 min

3.1 Inter-Group Comparison of mean pain score

Table 2: Inter-Group Comparison of Mean Pain Scores (VAS Score):

Pain Score (VAS)	Group D (n=30)		Group C (n=30)		P-value (Inter group)
	Mean	SD	Mean	SD	
15min - 1hr	0.00	0.00	0.00	0.00	0.999NS
1 - 4hr	0.00	0.00	0.00	0.00	0.999NS
4 - 8hr	0.11	0.31	1.13	0.35	0.001***
8 - 12hr	1.13	0.35	2.10	0.48	0.001***
12 - 16hr	1.20	0.41	6.43	0.86	0.001***
16 - 20hr	6.43	0.86	7.63	0.49	0.001***
20 - 24hr	7.63	0.49	8.70	0.47	0.001***

Values are mean and SD P-value (Inter-Group) by independent sample t test. P-value<0.05 is Considered to be statistically significant. ***P-value<0.001, NS-Statistically significant.

Distribution of mean pain score at 15min – 1hr and 1 – 4hr among the cases studied did not differ significantly between two study groups (P-value>0.05 for all).

Distribution of mean pain score at 4 – 8hr, 8 – 12hr, 12 – 16hr, 16 – 20hr and 20 – 24hr among the cases studied is significantly higher in Group C compared to Group D (P-value<0.001 for all).

3.2 Inter-Group Comparisons

Table 3: Inter-Group Comparisons

	Group C	Group D	P value
Duration of sensory block (min)	364.00 ± 63.06	560.61 ± 80.68	0.001*
Duration of analgesia (min)	418.64 ± 81.06	642.61 ± 90.68	0.001*
VAS Score at 12-16hrs	1.20 ± 0.41	6.43 ± 0.86	0.001*

- Total duration of sensory blockade was considered as time interval between femoro-sciatic nerve block (FSNB) and complete recovery of sensation which was assessed with pin-prick method. Which was 364.00 ± 63.06 for group C and 560.61 ± 80.68 for group D which was highly significant (p value 0.001*)
- The total duration of analgesia defined as time interval between administration of FSNB and demand for first rescue analgesic was maximum in dexmedetomidine group (10.17 ± 1.80 h) as compared to clonidine (7.0 ± 1.36 h). (p<0.00001).
- VAS score at 12 and 16 hours in group C was 1.20 ±

0.41 and in group D was 6.43 ± 0.86 which was highly significant(p value of 0.001*)

4. Discussion

Dexmedetomidine is a dextro-enantiomer and active component of medetomidine [6] approved as intravenous sedative and co analgesic drug. Its alpha2/alpha1 selectivity ratio is 8 times than that of clonidine that is why it is considered more potent than that of clonidine [7].

In our prospective double-blinded randomized comparative study, we have compared the analgesic efficacy of clonidine and dexmedetomidine as an adjuvant to bupivacaine in FSNB. There is no study which has compared the dose equivalence of these drugs in peripheral nerve block. The dose of studied drugs was selected on the basis of study by Abosedira [8] in which they used dexmedetomidine 0.5 µg/kg and clonidine 0.5µg/kg in lidocaine during Bier's block. Therefore, to avoid sedative and hemodynamic adverse effects we chose the dose of 0.5mcg/kg for both clonidine and dexmedetomidine.

In our study, mean duration of analgesia was significantly prolonged in dexmedetomidine group (10.17 ± 1.80 h) as compared to clonidine group (7.0 ± 1.36 h). (P< 0.001).

Our data supports specific action of α₂-adrenoreceptors on peripheral nerves leading to better pain scores and decrease in post-operative analgesic requirement and hospital stay.

Casati A *et al.* demonstrated that, when providing combined sciatic-femoral nerve block for hallux valgus repair, the addition of 1 mcg/kg clonidine to 0.75% Ropivacaine prolongs the duration of postoperative analgesia by 3 hours, with only a slight and short-lived increase in the degree of sedation and no hemodynamic adverse effects so we preferred to use Bupivacaine over Ropivacaine [9].

Das *et al.* concluded that addition of 100 mcg dexmedetomidine Ropivacaine 0.50% solution in supraclavicular brachial plexus block prolongs the duration of sensory and motor blockade reduces the requirement of rescue analgesic in the post-operative period [10].

Tripathi A. *et al.* [11] compared clonidine (1mcg/kg) and dexmedetomidine (1mcg/kg) as an adjunct to bupivacaine in supraclavicular brachial plexus block with respect to the onset and duration of sensory and motor block and duration of analgesia. They concluded that, the addition of dexmedetomidine prolongs the durations of sensory and motor block and duration of analgesia and improves the quality of anesthesia as compared with clonidine when injected with bupivacaine in supraclavicular brachial plexus block.

No side effect was reported in both the groups in our study and also in the study by Esmaglu *et al.*, [12, 13], Swami *et al.*, [14] and by Kaygusuz *et al.*, [15] whereas Ammar and Mahmoud [16] observed nausea-vomiting, pruritis, and dizziness in 7, 2, and 4 patients, respectively, in control group compared to 4, 0, and 1 patients in dexmedetomidine group, but the difference did not reach statistical significance.

We have not assessed the onset of sensory and motor blockade of FSNB due to residual effect of subarachnoid block. We have also not assessed the duration of motor blockade as patients were operated for below knee surgeries and applied cast post-operatively and limb was immobilized for 24hours. We have not monitored the long term effects of FSNB and α₂ agonist as patients were discharged early from hospitals. No control group was taken as it has been proven

earlier in many articles that FSNB as an addition to subarachnoid block prolongs the duration of analgesia this were some of the limitations of our study.

5. Conclusion

Thus we can infer that Dexmedetomidine in lower concentrations is a safer adjuvant without side effect with lower concentrations of local anesthetic for prolongation of post-operative analgesia in lower limb orthopedic surgery in Femoro Sciatic Nerve Block without any side effect.

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