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Research Article

Efficacy of Magnesium vs Dexamethasone as an Adjuvant to Ropivacaine in Ultrasound Guided Femoral and Sciatic Nerve Block for Postoperative Analgesia: A Prospective, Double Blinded Randomized Controlled Study

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ABSTRACT

Background: In patients undergoing lower limb orthopaedic surgery, unrelieved post-operative pain not only results in discomfort to the patients but also predispose to the development of chronic pain syndromes. The dawn of ultrasonographic-guided techniques has led to increased interest in femoro-sciatic nerve block (FSNB) for lower limb orthopaedic surgeries. Efficacy of various adjuvants have been studied to prolong the block and analgesia. In recent years, there is growing interest in magnesium sulphate (MgSO4) and dexamethasone as adjuvants to local anaesthetics in nerve blocks. Duration of post-operative analgesia was the primary outcome of our study, whereas the rescue analgesics requirement, VAS scores and haemodynamic parameters and time required for toe movement were the secondary outcomes.

Methods: Sixty-patients scheduled to undergo below knee orthopaedic surgeries under subarachnoid block were divided into 2 groups: Group RM(n=30) patients received 38 mL of 0.375% Ropivacaine with MgSO4 150 mg in 2 mL NS and Group RD(n=30) patients received 38 mL of 0.375% Ropivacaine with Dexamethasone 8 mg(2mL) to make total drug volume of 40 mL. In all patients, 20 mL of LA solution was injected around femoral nerve and 20 mL around sciatic nerve. The primary outcome was duration of post-op analgesia and secondary being requirement of rescue analgesia and time for toe movement. Mean variables were analysed and compared with unpaired t-test. Proportions were compared with Chi-square test and Fischer-exact test.

Results: Duration of analgesia was prolonged with Dexamethasone (18.8 ± 7.8) as compared to MgSO4 (8.8 ± 4.2). In regards to early ambulation, MgSO4(6.78 ± 2.25) was a cut above Dexamethasone (16.43 ± 4.56).

Conclusion: Both MgSO4 or Dexamethasone added to Ropivacaine prolonged the duration of analgesia, decreased requirement of rescue analgesia. Dexamethasone delays requirement of rescue analgesics with better pain scores as compared to MgSO4.

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Introduction

In patients undergoing orthopaedic surgeries, unrelieved post-operative pain not only results in discomfort to patients but predisposes to the development of chronic pain syndromes [1]. Regional anaesthetic techniques surpass general anaesthesia by providing excellent pain control, less adverse effects and shortened stay in the post-anaesthesia care unit [2].

Femoro-sciatic nerve block (FSNB) is a well founded, safe and effective method of providing analgesia in the immediate post-operative period [3]. The use of ultrasonographic (USG)-guided FSNB has various advantages including precise needle insertion, lesser time consumption, rapid block onset and lesser requirement of analgesics post-operatively [1-3]. As in proportion large volume of LAs is administered in FSNB, ropivacaine and levobupivacaine [4] are favoured as they have greater margin of safety, with ropivacaine furnishing better sensory and motor differentiation. Efficacy of various adjuvants have been studied to prolong the block and analgesia. In recent years, there is growing scrutiny in magnesium sulphate and dexamethasone due to their beneficial effects.

Ropivacaine is an aminoamide local anaesthetic that blocks the peripheral afferents acting on voltage dependent sodium channels. It has less toxicity pertaining to cardiac and central nervous system (CNS) as compared to other long acting local anaesthetics like bupivacaine [4]. Anti-nociceptive effects of magnesium are due to regulation of calcium influx into the cell and antagonism of the N-methyl D-aspartate (NMDA) receptors [4-5]. Magnesium has popularly been used as antihypertensive agent. Thus, it has long been used for its analgesic, antihypertensive, and anaesthetic sparing effects. Magnesium has been used safely and effectively as an adjuvant for neuraxial and peripheral nerve blocks like brachial plexus block, transversus abdominis block and femoral-sciatic nerve block [6-12].

Corticosteroids induce analgesia through their anti-inflammatory or immunosuppressive effects [13]. Moreover, steroids may potentiate the action of local anaesthetic through modulation of the function of the K+ channels in excitable cells [14]. Some authors also believe that analgesic effect of corticosteroids are due to their systemic effects. A recent study shows potential neuroprotection and anti-hyperalgesic effects with clinically relevant dosing of perineural dexamethasone with bupivacaine.

This study aims to directly assess the comparative efficacies of dexamethasone and magnesium when used separately as an adjuvant in femoral and sciatic nerve blocks. The primary objective of our study was to evaluate the role of magnesium versus dexamethasone as an adjuvant to ropivacaine in combined femoral sciatic block with respect to postoperative analgesia and the secondary objectives being evaluating total analgesic requirement and time required for toe movement in both the groups.

during the surgery. Blood pressure was maintained between 100-120/60-80 mm of Hg. Adequate fluid resuscitation was done to maintain Central Venous Pressure between 8-10 cm of water, replaced the blood loss (300ml) with 1 pint Packed cell volume of blood. There were no intra-operative untoward events noted. Hence, it was decided to extubate this patient.

After completion of surgery, Inj. Esmolol 2mg IV was administered to attenuate extubation reponse. Patient was reversed with Inj. Neostigmine 2.5mg and Inj. Glycopyrrolate 0.4mg IV. Patient was later shifted to SICU for post-op monitoring. She was comfortable and pain free in post-operative period for 28 hours, later discharged towards the next day.

Methods

After obtaining clearance from institutional ethical committee (SKNMC/Ethics/App/2017/291) and written informed consent from each patient, 60 patients between age group 18 to 60 years and ASA physical status I and II, undergoing lower extremity surgeries were recruited for the study. The study was conducted at Smt. Kashibai Navale Medical College & General Hospital.

A minimum of 28 patients were required in each group to achieve a significance level of 95% and power of 80% with type 1α error of 0.05. Hence, we included 30 patients in each group to consider any dropouts. Patients were randomly allocated by computer generated randomization number into two groups. Group RD (Ropivacaine + Dexamethasone) and Group RM (Ropivacaine + MgSO4).

The data was entered in Ms Excel and was analysed by SPSS version 24. Proportions are compared with Chi-square test and Mean compared with unpaired T- test. For comparing rescue analgesia required in first 24 hours (table no.2), Fischer -exact test has been used. P value of <0.05 is considered for significance.

Inclusion criteria

- Age group 18 to 60
- ASA physical status I & II patients.
- Gender- both male and female.

Exclusion criteria

- Age < 18 or > 60
- Contraindication to spinal and nerve block
- History of allergy to local anaesthetics
- ASA physical status III & IV.
- Injection site infection.
- Central or peripheral neuropathies.
- Patient refusal.
- Pregnant or lactating women.

On arrival to the OT, patient's baseline pulse rate, electrocardiogram and non-invasive blood pressure were recorded and a wide bore intravenous line established. An infusion started with lactated Ringer's solution. Hemodynamic variables were measured on arrival to the OT and every 5 min thereafter till the end of surgery. All patients included in the study were given SAB in sitting position using 26-gauge Quincke's spinal needle at L3-L4 interspace with 15 mg (3 mL) 0.5% hyperbaric bupivacaine after ensuring free flow of cerebrospinal fluid. After confirmation of adequate level (T6), surgery was allowed to proceed. After the surgery was over and the sensory level regressed to T10, following proper positioning of patients, USG-guided FSNB was given in allocated patients with respective drug solutions. The femoral block was performed under ultrasound Sonosite Nanomaxx® (Sonosite®, Bothell, WA, USA) guidance with patient being supine and leg in neutral position. After skin disinfection with povidone iodine, sterile drapes were applied. Femoral nerve and vessels were identified (femoral nerve lies lateral to femoral artery in a groove formed by iliacus and psoas muscle) in short axis view using linear probe (8-12 Hz) covered with sterile plastic sheath and with sufficient application of sterilised gel. A 22-gauge echogenic needle (Stimuplex®, B. Braun, Melsungen, Germany) was used by an ultrasound-guided in-plane (lateral to medial) technique and positioned between the fascia iliaca and iliopsoas muscle near lateral corner of femoral nerve. After checking the exact location of the needle tip, 1 mL of NS was injected to open the plane and after confirmation of hypoechoic area on USG image, the injection of the 20 mL of drug solution was given.

Sciatic nerve block was given by popliteal approach with patient in supine position by same ultrasound probe mentioned above. Leg of the patient was elevated by putting sterile pillow between lower aspect of leg and table to allow the access of probe.

After draping popliteal fossa and applying sufficient gel, a short axis view of popliteal neurovascular bundle was obtained. A 22-gauge echogenic needle was used by ultrasound-guided in-plane (lateral to medial) technique and under continuous ultrasound guidance, tip is placed between the tibial and common peroneal component of sciatic nerve near the division and 1 mL of NS was injected to open the plane and after confirmation of hypoechoic area on USG image, the injection of the 20mL of drug solution was given. The patients in Group RM (n = 30) received 38mL of 0.375% Ropivacaine with Magnesium sulphate 150mg in 2mL NS. Patients in Group RD (n = 30) received 38mL of 0.375% ropivacaine with dexamethasone 8mg(2mL) to make total drug volume of 40mL. In all patients, 20mL of LA solution was injected around femoral nerve and 20 mL around sciatic nerve. Block assessment was done at hourly interval up to 24 h by a blinded anaesthesiologist. Post-operatively, the patients were evaluated for pain, nausea or vomiting, sedation, haemodynamic parameters (HR, systolic blood pressure, diastolic blood pressure) and VAS in the post-anaesthesia care unit at 0, 2, 4,8, 12 and 24 h by an investigator blinded to group assignment. For the first 24 h, the protocol for post-operative analgesia consisted of standard orders for intramuscular diclofenac 75 mg on demand for VAS >4. Patients were asked to rate average pain they experience over a period of 24 h post-operatively by 11point VAS, where 0 was no pain and 10 was worst pain. Patient's satisfaction score was recorded with the help of five-point scale: very satisfied (1), satisfied (2), average (3), dissatisfied (4) quite dissatisfied (5). Duration of post-operative analgesia was the primary outcome of our study, whereas the rescue analgesics requirement, VAS scores and haemodynamic parameters and time required for toe movement were the secondary outcomes.

Both the groups were compared with respect to:

1. Postoperative analgesia.
2. Total analgesic consumption.
3. Time required for toe movement.

The time from the end of anesthetic injection in the operated hand till the first request for postoperative rescue analgesic was recorded in each patient.

The results were analysed statistically using appropriate tests.

Results

Table 1- Comparison of mean postoperative time at which first analgesia required

Parameter	Ropivacaine + MgSO4 Mean + SD	Ropivacaine + Dexamethasone Mean + SD	P value
Time at which first analgesia required	8.8 ± 4.2	18.8 ± 7.8	<0.001

Above table shows that mean postoperative time at which first analgesia required was significantly (p <0.001) less in Ropivacaine + Dexamethasone group as compared with another group.

Table 2- Distribution of study subjects according to number of patients required rescue analgesia in first 24 hours

Number of patients required rescue analgesia in first 24 hours	Ropivacaine + MgSO4	Ropivacaine + Dexamethasone	Total
Yes	20	3	23
No	10	27	37
Total	30	30	60

Above table shows that proportion of patients required rescue analgesia in first 24 hours was significantly less in Ropivacaine + Dexamethasone group as compared with another group.

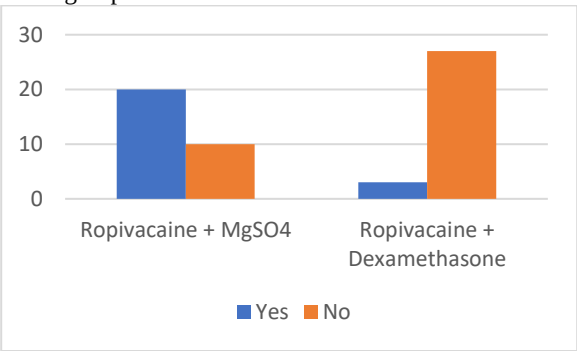

Figure 1- Distribution of study subjects according to number of patients required rescue analgesia in first 24 hours

Table 3- Distribution of study subjects according to consumption of diclofenac in mg first 24 hours

Parameter	Ropivacaine + MgSO4 Mean + SD	Ropivacaine + Dexamethasone Mean + SD	P value
Consumption of diclofenac in mg first 24 hours	168.68 ± 27.9	56.53 ± 22.6	<0.001

Above table shows that mean consumption of diclofenac in mg first 24 hours was significantly ($p<0.001$) less in Ropivacaine + Dexamethasone group as compared with another group.

Table 4- Distribution of study subjects according to adverse effects

Adverse effects	Ropivacaine + MgSO4 (n=30)	Ropivacaine + Dexamethasone (n=30)	P value
Nausea	0	0	
Shivering	6	0	0.023

Above table shows that there was no nausea seen in any patient in both the groups. There were no patients with shivering seen in Ropivacaine + Dexamethasone group, while in another group there were 6 patients with shivering observed.

Table 5- Comparison of mean postoperative time required for toe movement

Parameter	Ropivacaine + MgSO4 Mean + SD	Ropivacaine + Dexamethasone Mean + SD	P value
Time required for toe movement	6.78 ± 2.25	16.43 ± 4.56	<0.001

Above table shows that mean time required for toe movement was significantly ($p<0.001$) less in Ropivacaine + Dexamethasone group as compared with another group.

Discussion

This study aims to directly assess the comparative efficacies of dexamethasone and magnesium when used separately as adjuvants in femoral and sciatic nerve blocks. We found prolongation in analgesia duration in both groups but more with dexamethasone compared to magnesium.

Ropivacaine is a newer long acting amide local anaesthetic having improved safety profile as compared to bupivacaine. Ropivacaine has several other advantages namely to produce differential blockade with less motor blockade along with reduced cardiovascular and neurological toxicity. Due to the lower lipid solubility, it produces less motor blockade and more sensory blockade.

To date, the precise mechanism with which dexamethasone prolong the duration of nerve blocks is not fully understood, but it is thought to be multifactorial. Dexamethasone on its part impairs inflammation and transmission of sensory signals in unmyelinated C-fiber cells. As far as these mechanisms are currently mastered, it has not been discovered that they can cause serious adverse consequences, especially whether this “off-label” method of perineural administration will cause potential neurological complications. Studies have found that dexamethasone significantly prolonged the duration of ropivacaine and bupivacaine when used for the interscalene block. Steroids induce a degree of vasoconstriction and act by reducing local anaesthetic absorption, they also increase the activity of inhibitory K^+channels on nociceptive C fibres, thus decreasing their activity and modifying the membrane lipid phase equilibrium.

Recent heed has been given to magnesium sulphate (MgSO4) as a supplement to improve and prolong local anaesthesia postoperatively. MgSO4 is thought to reduce pain via antagonism of N-methyl-D-aspartate (NMDA) receptors. A local mechanism of action on peripheral rather than central NMDA receptors is supported by studies showing that despite providing pain relief, peripherally administered MgSO4 does not increase cerebrospinal fluid concentrations of magnesium, implying that it cannot cross the blood-brain barrier to enter the central nervous system. Magnesium is the second most intracellular cation present in the body in abundant quantities after potassium. It competitively

blocks the entry of calcium in presynaptic nerve endings leading to reduced release of acetylcholine from nerve endings and can produce similar effects like calcium channel blockers. Magnesium also antagonize NMDA (N-methyl D-aspartate) receptors and thereby augment antinociceptive effect. Many authors in their studies have demonstrated the decreased requirement of anaesthetics during general anaesthesia and postoperative analgesic consumption after magnesium administration [6-8]. Magnesium also results in decreased postoperative opioid consumption when administered through epidural route [9]. So, due to these analgesic properties it can be tried as an adjuvant with local anaesthetics to prolong the duration and intensity of nerve blocks.

Magnesium sulphate has been used as an adjuvant to bupivacaine in peripheral nerve blocks including interscalene, axillary, femoral, and supraclavicular nerve blocks. It caused significant prolongation of analgesic duration without reported side effects [8-9].

The value of using ultrasound in this study are; facilitates more rapid block onset and the added advantages of a decrease in drug dosage and a reduction in the incidence of LA toxicity.

Supporting the results of the present study was the results of Hossam A et al., done to study the analgesic effect of Magnesium, which showed a significant prolongation of femoral nerve block. Similar results were shown in study done by Lee et al., Magnesium was used in interscalene block. Many studies done previously have proved the efficacy of using dexamethasone and magnesium sulphate as additive to local anaesthesia, showing the comparison.

Anupreet et at [16], concluded that the onset of action of sensory and motor block was early in ropivacaine group with faster recovery of motor functions as compared to bupivacaine group. Hence, we chose ropivacaine as a primary drug.

Regarding the duration of sensory block, our study showed that both dexamethasone and magnesium sulphate prolong the post-operative analgesia, with mastery over dexamethasone. Our results are in accordance with work of Raghavan et al [17]., comparing effects of dexamethasone against magnesium sulphate as additive to local anaesthetic in supraclavicular block showing the paramountcy of dexamethasone. A study done by Santoshilaxmi CD et al. [18], showed that early onset and better coverage of analgesia with magnesium sulphate group than dexamethasone but prolong analgesia with dexamethasone.

Regarding postoperative analgesia and total rescue analgesic consumption, our study showed significantly prolonged duration of postoperative analgesia and less requirement of rescue analgesia in dexamethasone group compared to magnesium sulphate. Similar results were found in the study done by Michael et al., with remarkably lower VAS score in dexamethasone group compared to magnesium sulphate.

All the patients in both groups were satisfied with amount of analgesia provided by the block, but more number of patients in RD group were highly satisfied with the prolongation of analgesia as compared to that in RM group.

We also evaluated the duration of motor block with assessing the toe movement. We observed that, toe movement was delayed with the dexamethasone than that of magnesium sulphate group.

We did not encounter any side effects of both the drugs during the study. All the patients in both the groups were stable hemodynamically.

Conclusion

In conclusion, the result of the clinical study shows that, both magnesium sulphate and dexamethasone when added to local anaesthetic during FSNB provides profound prolongation of analgesia, with significant decrease in postoperative pain and total dose of rescue analgesic consumption. When concerned with early ambulation, magnesium sulphate is preferred over dexamethasone.

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