

Evaluation of the Effects of Inj Magnesium Sulfate (MgSO₄) 500mg(1ml) and Levobupivacaine 0.5% (19ml) Versus Levobupivacaine 0.5% (20ml) Alone during Ultrasound guided Femoral Nerve Block for Post-Operative Analgesia in patients undergoing Femur Fracture Surgeries

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Abstract

Background and Aim: To promote appropriate healing and functional recovery, femur fractures often require intramedullary nailing, plating, or bipolar surgery. Poor postoperative analgesia might delay recovery and increase morbidity. Regional anesthetic with ultrasound-guided femoral nerve blocks improves analgesia and reduces opioid use. Due to the high occurrence of these injuries and their impact on patient quality of life, this research could dramatically change orthopedic surgery clinical practices and outcomes.

Material and Methods: This double blinded randomized clinical trial included 60 patients aged between 18 to 70 years who are undergoing elective surgical intervention at our institute were parted into two groups (Group A and Group B) which includes 30 patients in either of the two groups. Group A who received Inj MgSO₄ 500mg (1ml) along with Inj Levobupivacaine (0.5%) 19ml and the Group B who received Inj Levobupivacaine (0.5%) 20ml for the USG Guided femoral nerve block after completion of respective surgery.

Results: Over a 24-hour period, both the treatment groups exhibited a statistically significant decrease in VAS scores. However, Inj Levobupivacaine added with MgSO₄ group demonstrated superior efficacy in pain reduction compared to only Inj Levobupivacaine group. Along with VAS score, the two groups (A and B) were also compared as regard time to first rescue analgesia postoperatively, and which showed a statistical difference between the two groups. When the vital data compared, which included Systolic and Diastolic blood pressure, Respiratory Rate and Spo₂ at room air, does not show statistical difference in both groups.

Conclusion: Both Inj Levobupivacaine with MgSO₄ and Inj Levobupivacaine alone produced post-operative analgesia in patients undergoing femur fracture surgery. However, giving Inj Levobupivacaine added with MgSO₄ shown to be more effective in postoperative analgesia during Femoral Nerve Block compared to Inj Levobupivacaine alone.

Keywords: Femur Fracture, Postoperative Analgesia, USG Guided Femoral Nerve Block, MgSO₄, Levobupivacaine.

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Introduction

According to the American Society of Anesthesiologist practice guidelines for acute pain management in the peri-operative setting, acute pain is defined as pain present in a surgical patient after a procedure. The World Health Organization and International Association for the Study of Pain have recognized pain relief as a human right. Poorly managed postoperative pain can lead to complications and prolonged rehabilitation.[1] Peripheral nerve blocks as a part of this approach decreases postoperative pain scores and systemic response while providing effective analgesia with less adverse effects compared to neuraxial

techniques.[2] Magnesium sulfate is a physiological calcium channel blocker and antagonizes the N-methyl d-aspartate (NMDA) receptors. The changes in intracellular calcium levels can affect the excitability of the dorsal horn cells which play an important role in the perception pain. NMDA receptors are found in the peripheral visceral and somatic nociceptors which are responsible from the transmission of nociceptive stimuli and the central nervous system where central sensitization occurs. For decades, magnesium has been used to reduce postoperative pain. In 1996, the first randomized controlled trial

(RCT) used magnesium as an analgesic adjuvant to support the effect of postoperative Analgesia. [1,3] Traumatic pain is an independent risk factor of morbidity and mortality. It can lead to a decompensation of chronic diseases, a worsening of traumatic injuries, and an increase in blood loss through sympathetic activation. That is why, it is widely considered to be the fourth vital sign.

Material and Methods

After obtaining approval from the institutional ethical committee and securing written, valid consent from the patients and their attendants, a total of 60 ASA I–III patients were randomly allocated to either group A, receiving Inj MgSO₄ 500 mg (1 ml) combined with Inj Levobupivacaine (0.5%) 19 ml, or group B, receiving Inj Levobupivacaine (0.5%) 20 ml, for USG-guided femoral nerve block after the completion of surgery performed under spinal anesthesia; randomization was achieved through envelope method with concealed allocation. All patients aged between 18 to 70 years, Patients undergoing elective femur fracture surgery and ASA Physical status I - III were included in this study. Emergency surgery,

Diabetic patients, Uncooperative patients, Patients who had known allergy to study drugs, Patients with uncontrolled infections, Open wound or signs of infection at likely injection site, Patients with Hepatic or Renal impairment, Patients with a history of chronic pain or on chronic pain medication and Pregnant or Lactating women were not included in this study.

Procedure

Patients with femoral fractures scheduled for surgical intervention were transported to the operating theatre, where they were connected to vital sign monitors, including blood pressure, pulse oximetry, and electrocardiography, with baseline measurements recorded prior to the administration of spinal anesthesia. After the surgery got done, we Position the patient into supine with the leg slightly abducted to expose the inguinal region, for Ultrasound-Guided Femoral Nerve Block Technique in the Operating Room.

Medications were prepared and administered by a seasoned anesthesiologist assisting the primary anesthesiologist performing the procedure. Notably, the specific drugs administered were not disclosed to either the anesthesiologist conducting the femoral nerve block or the patient receiving it. Then with the use of a high-frequency linear ultrasound probe, the probe is placed just below the inguinal ligament in a transverse plane to visualize the femoral nerve, artery, and vein. Once identified, the needle is inserted parallel to the long axis of the probe so the entire needle can be visualized. The needle tip is maneuvered to lie immediately

adjacent to the femoral nerve but under the fascia iliaca. The spread of local anesthetic should be seen displacing the nerve or separating the fascial layers. Finally, before injecting the local anesthetic solution, we aspirate the injecting solution to ensure that the needle is not in a blood vessel. Patients were assessed for the duration of analgesia by the return of pinprick sensation and the use of first dose of rescue analgesia as the primary outcomes of the study by anesthetist who had performed the USG guided femoral nerve block. A numerical rating scale from 0 to 10 along with patient's vital data including Systolic and Diastolic Blood Pressure, Respiratory Rate, Pulse Rate and Saturation was used to assess post-operative pain at zero, 2, 4, 6, 8, 12, 24Hr.

Both the procedures were carried out with USG-Guided Femoral Nerve Block after immediate completion of operative procedure. All patients and nursing staff stationed over ward where patient was shifted, were advised to not take any analgesics such as NSAIDs or opioids, non-opioids during our study. When the Visual Analog Scale (VAS) score reached 6 or higher, the patient received an initial dose of rescue analgesia, administered as a 1mg/kg body weight injection of Tramadol. All patients were assessed with VAS score and vital data during the study and were followed up for the next 24 hours post femoral nerve block.

Results

All the subjects finished with 24 hour study period. Most of the patients were in the age group between 50 to 70 years in the both groups who were fit into our criteria mentioned above. Pain was assessed with the help of VAS score with each patient's VAS score measured at zero, 2, 4, 6, 8, 12, 24Hr post femoral nerve block.

VAS scores of each patient of both groups were compared with respect to each group at each period of time and the significance in differences were calculated with applying Student paired T test.

Over a 24-hour period, both the treatment groups exhibited a statistically significant decrease in VAS scores. However, Inj Levobupivacaine added with MgSo₄ group demonstrated superior efficacy in pain reduction compared to only Inj Levobupivacaine group. Along with VAS score, the two groups (A and B) were also compared as regard time to first rescue analgesia postoperatively, and which showed a statistical difference between the two groups.

Among 30 patients in Group A which received Inj Mgso₄ combined with Levobupivacaine, 3 patient's required first dose of rescue analgesia within 12 hours following the USG guided femoral nerve block. Among 30 patients in Group B which received Inj Levobupivacaine alone, 9 patients

required the first dose of rescue analgesia within 8 hours post USG guided femoral nerve block. At the conclusion of our study, a pronounced disparity was evident between the VAS scores of two study

groups. When the vital data compared, which included Systolic and Diastolic blood pressure, Respiratory Rate and Spo2 at room air, does not show statistical difference in both groups.

Table 1: Comparison of VAS score changes from baseline between the two groups

Variables	Mean (SD)		P value
	Group A (n=30)	Group B (n=30)	
VAS			
0 Hr	0.0 (0.0)	0.0 (0.0)	0.6432
2 Hr	0.133 (0.49)	0.26(0.67)	0.4055
4 Hr	0.26 (0.67)	0.53 (0.88)	0.1864
6 Hr	0.66 (0.94)	2.53 (1.35)	0.00048
8 Hr	1.46(1.14)	3.86(1.85)	0.00277
12 Hr	2.26(1.76)	4.8(1.42)	0.0000071
24 Hr	2.93 (1.61)	5.86(1.54)	0.0000014

Data were presented as mean $\pm$ SD. P-value <0.05 is considered as statistically significant. The values above mentioned were calculated based on paired t test. The above graph showing the comparison of

efficacy to reduce pain post operatively, between the Inj Levobupivaine added with MgSo4 and Inj Levobupivacaine alone with time plotted on X axis and Mean of VAS scores plotted on Y axis.

Table 2: Comparison between group A and B as regard Systolic Blood

Systolic Blood Pressure	Group A (n=30)	Group B (n=30)	P value
at 0 hr	127 $\pm$ 14.10	132 $\pm$ 14.31	0.43
at 2hr	128.5 $\pm$ 18.47	130.9 $\pm$ 12.12	0.72
at 4 hr	129.2 $\pm$ 18.34	126.3 $\pm$ 10.13	0.65
at 6hr	126.8 $\pm$ 17.71	125.8 $\pm$ 10.49	0.87
at 8 hr	127.8 $\pm$ 16.12	128.4 $\pm$ 12.05	0.92
at 12 hr	131.1 $\pm$ 17.08	129.7 $\pm$ 12.03	0.82
at 24hr	132.7 $\pm$ 15.26	128.9 $\pm$ 11.36	0.52

The data represented above as mean $\pm$ SD. P value >0.05 is considered to be statistically insignificant.

Table 3: Comparison between group A and B as regard Diastolic Blood Pressure

Diastolic Blood Pressure	Group A	Group B	P value
at 0 hr	77.4 $\pm$ 8.33	78.5 $\pm$ 7.63	0.75
at 2hr	77.8 $\pm$ 10.34	77.9 $\pm$ 9.66	0.98
at 4 hr	75.5 $\pm$ 8.46	74.9 $\pm$ 8.47	0.87
at 6hr	76.2 $\pm$ 10.06	75.3 $\pm$ 4.73	0.79
at 8 hr	80.4 $\pm$ 6.38	77.4 $\pm$ 7.53	0.33
at 12 hr	78.9 $\pm$ 6.94	76.5 $\pm$ 8.44	0.48
at 24hr	82.4 $\pm$ 7.72	77.5 $\pm$ 7.42	0.15

The data represented above as mean $\pm$ SD. P value >0.05 is considered to be statistically insignificant.

Table 4: Comparison between group A and B as regard Respiratory Rate

RR	Group A	Group B	P value
at 0 hr	14 $\pm$ 0.0	14.1 $\pm$ 0.3	0.3
at 2hr	13.9 $\pm$ 0.32	14.1 $\pm$ 0.3	0.15
at 4 hr	14.2 $\pm$ 0.63	14 $\pm$ 0.0	0.3
at 6hr	14.4 $\pm$ 0.70	14.1 $\pm$ 0.3	0.2
at 8 hr	14.6 $\pm$ 0.70	14.3 $\pm$ 0.47	0.25
at 12 hr	14.8 $\pm$ 1.03	14.2 $\pm$ 0.4	0.08
at 24hr	15.1 $\pm$ 1.1	14.9 $\pm$ 0.47	0.07

The data represented above as mean $\pm$ SD. P value >0.05 is considered to be statistically insignificant.

Table 5: Comparison between group A and B as regard Spo2 in % at room air

Spo2	Group A	Group B	P value
at 0 hr	98.2 ± 0.79	98.6 ± 0.67	0.22
at 2hr	98.1 ± 1.1	98.5 ± 0.69	0.32
at 4 hr	98.2 ± 0.79	98.7 ± 0.65	0.12
at 6hr	98.1 ± 0.99	98.6 ± 0.92	0.24
at 8 hr	97.8 ± 0.79	98.1 ± 0.69	0.14
at 12 hr	97.9 ± 0.88	98.5 ± 0.93	0.14
at 24hr	98 ± 0.82	98.2 ± 0.65	0.26

The data represented above as mean ±SD. P value >0.05 is considered to be statistically insignificant.

Table 6: Demographic comparison between Group A and Group B

Variables	Group A Mean (SD)	Group B Mean (SD)	P value
Age	57.5 (7.854)	58.5 (10.144)	0.6710
Gender (M/F)	17/13	16/14	0.566
Weight	62.9 (5.664)	63.7 (5.326)	0.5752

The above data calculated based on t-test. The data represented above as mean ±SD. P value >0.05 is considered to be statistically insignificant. There was no bias involved in respect to Age, Gender and weight in both the groups.

Table 7: Comparison between Group A and B as regard time to first dose of rescue analgesia in hours

Time to first dose of Tramadol (in hours)	Group A	Group B	P value
	19.43 (3.63)	11.8 (4.40)	<0.0001

The above data calculated based on t-test. The data represented above as mean ±SD. P value <0.05 is considered to be statistically significant. The duration for rescue analgesia was significantly more in group A compared to group B.

Discussion

This study primarily sought to assess the efficacy between Inj Levobupivacaine and Inj Levobupivacaine along with added MgSo4. In this study, we determined that incorporating MgSo4 as an adjunct to Levobupivacaine in Femoral Nerve Block for patients who were posted for femur fracture surgery, significantly enhances the quality of post-operative analgesia.

In fact, it reduces the intensity of pain along with quick onset and prolonged duration of time till the need for rescue analgesia and also avoided the need for opioids. In a study conducted by Veerabhadram Garimella et al conducted a study on various approaches for the management of postoperative pain and concluded that each patient is unique in his or her perception of pain allowing for many combinations in the treatment of pain. Pre-emptive analgesia with regional blocks may be beneficial in ambulatory cases. [1]

A study conducted by Chawki Jebali et al concluded that Magnesium sulfate should be considered as an efficient and safe adjuvant to local anesthetics in prehospital FNB. It allows a significant decrease in pain scores and opioid requirements without increase in adverse effects.[4]

In other study, the addition of magnesium to levobupivacaine prolonged the sensorial and motor block duration without increasing the side effect profile and improved postoperative analgesia quality and patient satisfaction; however, the addition of magnesium delayed the time to first mobilisation and decreased the rescue analgesic requirement.[5] In another study, magnesium sulfate and dexamethasone added to bupivacaine in ESP block prolonged the duration of postoperative pain control and decreased the consumption of postoperative analgesia than the bupivacaine alone. There were no major complications recorded in our study in the three groups which solidify the safety of the technique.[6] A study conducted by Jie Zeng et al found that magnesium sulfate enhances the analgesic effects of local anesthetics for nerve and truncal blocks. Individual blocks and that they prolonged duration of the sensory block compared with local anesthetic alone. This provided pain relief for up to 12 hours after surgery however opioid consumption was not different between groups at the 24-hour period after surgery. The addition of magnesium sulfate to local anesthetics reduced the incidence of PONV in patients receiving TAP blocks. Collectively, these results reveal that magnesium may play a critical role in further improving the patients' surgical recoveries and postoperative experiences.[7]

Conclusion

Here we can conclude that both Inj Levobupivacaine with MgSo4 and Inj

Levobupivacaine alone produced post-operative analgesia in patients undergoing femur fracture surgery. However, giving Inj Levobupivacaine added with MgSo₄ shown to be more effective in postoperative analgesia during Femoral Nerve Block compared to Inj Levobupivacaine alone. Finally, this study provides evidence that when Inj Levobupivacaine mixed with MgSo₄, resulted in significant post-operative analgesia.

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