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Original Research Article

EFFICACY OF NALBUPHINE AS AN ADJUVANT TO ROPIVACAINE FOR ULTRASOUND GUIDED COMBINED ADDUCTOR CANAL AND POPLITEAL SCIATIC BLOCK IN HIGH RISK PATIENTS UNDERGOING ELECTIVE DIABETIC FOOT WOUND DEBRIDEMENT: A PROSPECTIVE RANDOMISED DOUBLE-BLIND STUDY

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ABSTRACT

Background: Combined adductor canal block and popliteal sciatic block provide effective surgical anaesthesia for distal leg and foot. It is one of the peripheral nerve block techniques used in high risk surgical patients where other modalities of anaesthesia can pose significant problems. Also, it is an integral component of multi modal approach to perioperative analgesia in surgeries involving distal leg and foot. **Aim:** To compare the efficacy of Nalbuphine as an adjuvant to Ropivacaine in ultrasound guided combined adductor canal and popliteal sciatic block in high risk patients posted for elective diabetic foot wound debridement. **Objectives: Primary:** To compare the duration of Analgesia. **Secondary:** To compare the onset of sensorimotor blockade. To compare the adverse effects in both groups.

Materials and Methods: It is a prospective, randomized, double-blinded study. Following approval from the hospital ethics committee and obtaining written informed consent, we enrolled 100 high-risk patients with ASA physical status III and IV who were scheduled for elective diabetic foot wound debridement in our study. Patients were assigned randomly to one of two groups. Group- A (n=50): Patients received 9ml of 0.375% Ropivacaine plus 1ml of normal saline for adductor canal block (total-10ml) and 14ml of 0.375% Ropivacaine plus 1ml of normal saline for popliteal sciatic block (total-15ml). Group- B (n=50): Patients received 9ml of 0.375% Ropivacaine plus 5mg of Nalbuphine hydrochloride diluted in 1ml of normal saline for adductor canal block (total-10ml) and 14ml of 0.375% Ropivacaine plus 5mg of Nalbuphine hydrochloride diluted in 1ml of normal saline for popliteal sciatic block (total-15ml).

Results: The mean duration of analgesia in group A was 580.4±138.6 mins and in group B it was 800.5±140.6 mins which was statistically significant. The mean time of onset of sensory block in group A was 8.72±0.49 mins and in group B was 4.72±0.49 mins and the difference was statistically significant. Mean time of onset of motor block in group A was 10.72±0.52 mins and in group B was 5.17±0.54 mins with a p-value of less than 0.001. The need for

rescue analgesia was significantly less in group B compared to group A. Group B experienced slightly more incidence of nausea, vomiting and pruritis but was statistically insignificant. Respiratory depression was not observed in both the groups.

Conclusion: This study concludes that Nalbuphine as an adjuvant to Ropivacaine in ultrasound guided combined adductor canal and popliteal sciatic block prolongs the duration of analgesia, with faster onset of sensorimotor blockade and minimal adverse effects.

Keywords: Nalbuphine, Ropivacaine, Adductor Canal Block, Popliteal Sciatic Block and Ultrasound Guided Block.

INTRODUCTION

Perioperative anaesthetic management can pose a huge challenge when dealing with high-risk surgical patients who have serious cardiovascular and other systemic illnesses such as sepsis, multi-organ dysfunction and coagulopathy. Central neuraxial blocks can be catastrophic due to haemodynamic instability and coagulopathy. General anaesthesia can result in high morbidity with significant hypotension, myocardial depression, mechanical ventilation-related complications, and perioperative mortality. Peripheral nerve blocks, with the advent of ultrasound, can offer a safer and more suitable alternative to high-risk surgical patients, improving outcomes and satisfaction1. Diabetes mellitus2 is an increasingly common medical condition affecting approximately 11.4% of Indian population, of which 25% may require surgical intervention. Patients undergoing diabetic foot wound debridement have poor glycaemic control. Despite being a relatively straightforward procedure, anaesthesia for these set of patients has the potential for catastrophic consequences with long term complications. The main anaesthesia goal is to minimise haemodynamic fluctuations and to provide adequate anaesthesia and analgesia intra- and postoperatively.

Spinal anaesthesia with or without adjuvants is a natural choice provided there are no absolute and relative contraindications. Central neuraxial blockade, when administered to patients requiring surgical intervention with diabetic autonomic neuropathy and associated comorbid conditions, may lead to haemodynamic instability resulting in higher morbidity and mortality3. In this set of patients, ultrasound-guided peripheral nerve blocks can be a suitable, safer alternative improving patient outcomes and satisfaction. A combination of popliteal sciatic block and saphenous nerve block can adequately anaesthetize the distal leg and foot4. The popliteal approach is the most distal location for sciatic nerve blockade. About 5-10 cm above the popliteal crease, the sciatic nerve is anesthetized immediately proximal to its division into tibial nerve and the more lateral common peroneal nerve. This can be performed either in the supine, prone or lateral position. The popliteal approach of the sciatic nerve block provides satisfactory anaesthesia of the distal leg and foot, except for a small strip of saphenous nerve sensory innervation5,6. Adductor canal block is an interfascial plane block performed in the mid thigh that anaesthetises saphenous nerve and nerve to vastus medialis. The saphenous nerve is a terminal sensory branch of the femoral nerve. It supplies innervation to the medial aspect of the leg down to the ankle and foot. It also sends infrapatellar branches to the knee joint. A saphenous nerve block is useful as a supplement to sciatic block for foot and ankle procedures that involve the medial aspect of the malleolus and the foot. Ropivacaine is a long-acting local anaesthetic that is less lipophilic and less cardiotoxic. It causes less motor blockade and has potential advantages for peripheral nerve blocks and postoperative pain management due to more rapid recovery of motor function. Nalbuphine is a potent opioid analgesic commonly used as an adjuvant in peripheral nerve blocks9. In our study, we evaluated the efficacy of Nalbuphine as an adjuvant to Ropivacaine in ultrasound guided combined adductor canal and popliteal sciatic block in high risk patients undergoing elective diabetic foot wound debridement.

Aims and Objectives of the Study

To compare the efficacy of Nalbuphine as an adjuvant to Ropivacaine in ultrasound guided combined adductor canal and popliteal sciatic block in high risk patients posted for elective diabetic foot wound debridement. **Primary objective:** • To compare the duration of analgesia. Secondary objectives: • To compare the onset of sensorimotor blockade. • To compare the adverse effects in both groups

MATERIALS AND METHODS

Following approval from the hospital ethics committee (02/GMC/KDP/2023) and registered with the Clinical Trials Registry of India (CRTI/2025/03/083425) and obtaining written informed consent, we enrolled 100 high-risk patients with ASA physical status III and IV who were scheduled for elective diabetic foot wound debridement in our study. Inclusion criteria: Patients aged between 30-80 years of either sex belonging to American society of Anaesthesiologists physical status III and IV posted for elective diabetic foot wound debridement were included in the study. Patients, with known hypersensitivity to study drugs, on medication for chronic pain, neurological

deficits, anti-coagulant therapy, contraindications to Peripheral nerve block, psychiatric and neurological disorders and pregnant patients were excluded from the study.

Preoperative evaluation: The patient's comprehensive medical history, thorough physical examination, and systemic assessment were conducted during pre-anaesthetic evaluation. Standard diagnostic tests including haemoglobin, bleeding and clotting time, blood sugar, blood grouping and typing, blood urea and serum creatinine, chest X-ray, and electrocardiogram (E.C.G.), were performed on all patients as part of routine investigations. Demographic characteristics such as age, sex, height, and weight were documented, and written informed consent was obtained. On the night before surgery, all patients were administered oral doses of Ranitidine 150mg and Alprazolam 0.25 mg. After the patients were shifted to the operating room, standard A.S.A. monitors, such as NIBP, E.C.G., and pulse oximeter (SpO2), were attached. An 18gauge intravenous access was secured. Prior to the procedure, baseline vital parameters such as arterial pressure, heart rate, and Spo2 were measured. Patients were premedicated with Midazolam 0.02 mg/kg IV. All patients received combined adductor canal and popliteal sciatic block under ultrasound guidance with patient in supine position. Group allocation: Patients were assigned randomly to one of two groups. Group- A (n=50): Patients received 9ml of 0.375% Ropivacaine plus 1ml of normal saline for adductor canal block (total-10ml) and 14ml of 0.375% Ropivacaine plus 1ml of normal saline for popliteal sciatic block (total-15ml). Group- B (n=50): Patients received 9ml of 0.375% Ropivacaine plus 5mg of Nalbuphine hydrochloride diluted in 1ml of normal saline for adductor canal block (total-10ml) and 14ml of 0.375% Ropivacaine plus 5mg of Nalbuphine hydrochloride diluted in 1ml of normal saline for popliteal sciatic block (total-15ml). The Ultrasound machine, (Sonosite SII, Fujifilm Sonosite, Inc) was positioned on the contralateral side of the limb requiring the block. A linear probe transducer (6-13 MHz) was utilized and covered with a sterile sleeve.

Adductor canal block (mid-level block): Patient was placed in supine position and the limb to be blocked was slightly flexed at knee joint and externally rotated (frog leg position). The linear transducer was positioned in the antero-medial aspect of middle thigh. The boat-shaped sartorius muscle and the femoral artery were identified. Mid-level block location was determined as the place where the femoral artery was parallel to the medial border of the sartorius muscle, in the middle of the proximal and distal blocks. Following local anaesthetic infiltration, a 21-gauge 80mm nerve block needle was inserted in plane, along lateral to medial orientation and advanced towards the femoral artery. Once the needle tip was visualized anterior to the artery underneath the sartorius muscle, 1ml of the saline was injected to confirm the location and then the study drug was administered after ensuring negative aspiration. Group- A (n=50): Patients received 9ml of 0.375% Ropivacaine plus 1ml of normal saline for adductor canal block (total-10ml) Group- B (n=50): Patients received 9ml of 0.375% Ropivacaine plus 5mg of Nalbuphine hydrochloride diluted in 1ml of normal saline for adductor canal block (total-10ml).

Popliteal sciatic nerve block (lateral approach): The patient was positioned supine for a lateral approach. The limb to be blocked was immobilized by flexing at the knee and resting the foot on an elevated foot rest. High frequency linear probe was used to locate tibial and common peroneal nerves in popliteal fossa, which are situated posterior to the popliteal artery. On proximal movement of the probe tibial and common peroneal nerves unite at a variable location from the popliteal crease visualizing sciatic nerve in Vloka's sheath. The study drug was deposited using a 21gauge 80mm nerve block needle through an in plane approach at the point of bifurcation of sciatic nerve in the Vloka's sheath ensuring negative aspiration. The spread of local anaesthetic in the Vloka's sheath around the sciatic nerve was observed in real-time. Group- A (n=50): Patients received 14ml of 0.375% Ropivacaine plus 1ml of normal saline for popliteal sciatic block (total-15ml). Group- B (n=50): Patients received 14ml of 0.375% Ropivacaine plus 5mg of Nalbuphine hydrochloride diluted in 1ml of normal saline for popliteal sciatic block (total-15ml).

All patients received oxygen supplementation. Sensory assessment was done using pin prick method and motor assessment by observing plantar or dorsiflexion at the Ankle joint. The onset of sensory block and motor block was assessed at regular intervals and the surgery was commenced once complete sensory and motor blockade had been attained.

Haemodynamic parameters, including heart rate, blood pressure, and peripheral oxygen saturation, were assessed at regular time intervals. The time for first rescue analgesic requirement and any associated complications were documented. After the patient was shifted to the post anaesthesia care unit, pain assessment was performed every hour using the visual analogue scale. The VAS is a scale that ranges from 0 to 10, where 0 represents no pain and 10 represents the most intense pain. This assessment persisted until the effects of the anaesthesia subsided. When the VAS score exceeded 4, IV Paracetamol 1gm was administered as rescue analgesic.

RESULTS

Demographic data like age, gender, BMI, duration of surgery, ASA physical status were comparable in both groups.

Table 1: Demographic Data

Demographic data	Group A	Group B	p value
Age [Mean]	60	62	0.749
Gender [M/F]	22/28	25/25	0.545
BMI [kg/m2]	23.58+/-3.25	24.01+/-2.62	0.46
Duration of surgery	24+/-2.06	26+/-3.06	0.09
ASA physical status [III/IV]	29/21	25/25	0.5477

The mean time of onset of sensory block in group A was 8.72±0.49 mins and in group B was 4.72±0.49 mins and the difference was statistically significant (p-value < 0.001). Mean time of onset of motor block in group A was 10.72±0.52 mins and in group B was 5.17±0.54 mins with a p-value of less than 0.001, indicating a statistically significant difference.

Table 2: Comparison of Block Characteristics

Group	Group A	Group B	p value
Onset of sensory block (min)	8.72+/-0.49	4.72+/-0.49	<0.001
Onset of motor block (min)	10.72+/-0.52	5.17+/-0.54	<0.001

The mean duration of analgesia in group A was 580.4±138.6 mins and in group B it was 800.5±140.6 mins with a p-value of less than 0.001. The duration of analgesia was significantly longer in group B compared to group A.

Table 3: Comparison of Duration of Analgesia

Group	Group A	Group B	p value
Duration of Analgesia (min)	580.4+/-138.6	800.5+/-140.6	<0.001

Patients in group B experienced slightly more incidence of nausea, vomiting and pruritis, but it was statistically insignificant (p > 0.05) when compared with group A. Respiratory depression was not observed in either of the groups.

Table 4: Comparison of Adverse Effects

Adverse effects	Group A n(%)	Group B n(%)	Total n(%)	p value
Nausea	7(14)	11(22)	18(18)	0.215
Vomiting	6(12)	8(16)	14(14)	0.233
Respiratory depression	0(0)	0(0)	0(0)	0
Pruritis	1(2)	2(4)	3(3)	0.911

DISCUSSION

In our study, mean time of onset of sensory block among group A was 8.72±0.49 minutes and group B was 4.72±0.49 minutes. Mean time of onset of motor block among group A was 10.72±0.52 minutes and group B was 5.17±0.54 minutes. The onset of sensory and motor block was earlier with Nalbuphine as an adjuvant to Ropivacaine which is statistically significant.

Our findings correlate with previous studies conducted by Prajwal Venugopal et.al., who also observed that onset of sensory and motor blockade is faster in group BN (Bupivacaine + Nalbuphine 10mg) than group A (Bupivacaine + normal saline) in ultrasound guided popliteal nerve block. A study by Nazia Nazir et.al., demonstrated that group N, who received Nalbuphine (10mg) as an adjunct to Bupivacaine in supraclavicular block under ultrasound guidance, experienced a considerably faster onset of both sensory and motor block compared to group C, who received only Bupivacaine. Several studies have reported consistent findings indicating a faster onset of sensory and motor block but without a statistically significant result with Nalbuphine as adjuvant to local anaesthetic in ultrasound guided supraclavicular brachial plexus block. In a study conducted by Shweta Saurin Mehta et.al, it was observed that the onset of sensory and motor blockade was faster in group N receiving Nalbuphine (10mg) as an adjuvant to Bupivacaine as compared to group B receiving normal saline, but without a statistically significant difference. Manojkumar Namdeorao Gajbhare et.al., reported that there was no difference in the onset times of sensory block (p=0.070) and motor block (p=0.666) in their study comparing Tramadol group and Nalbuphine group. The results of Abdelhaq M et al, and Chiruvella S et al, have shown faster onset of sensory and motor block in Nalbuphine group than the control group with no statistical significance. In

a recent study by R. Madhusudhanan et.al., there was a statistically significant difference between the two groups, with group Nalbuphine as adjuvant to Bupivacaine in ultrasound guided supraclavicular brachial plexus block having an earlier onset of sensory (36%) and motor block onset (16%) than control group. Jingyao Jiang et. al., in their study on efficacy of Nalbuphine as adjunct to local anaesthetic for brachial plexus block, observed the shortening of onset time of sensory and motor blockade in Nalbuphine group compared to control group (normal saline).

In our study, we observed that mean duration of analgesia in group A and group B was 580.4±138.6 minutes and 800.5±140.6 minutes respectively. The duration of analgesia was more prolonged with Nalbuphine as an adjuvant to 0.375% Ropivacaine, which is statistically significant ($p< 0.001$), with 42 % longer than in group B than in group A. Chiruvella S et al. investigated the dose dependency of Nalbuphine when combined with Levobupivacaine for peripheral nerve blockade. In their study, all volunteers received supraclavicular brachial plexus block with 29ml 0.375% Levobupivacaine mixed with 5mg (LN5) or 10mg (LN10) Nalbuphine. They observed a significant dose-dependent increase in the mean duration of analgesia with Nalbuphine: LN10: 833.55 ± 141.6minutes, LN5: 698.44 ± 138.6 minutes. Jingyao Jiang et. al., in their study, concluded that perineural use of Nalbuphine as an adjuvant to local anaesthetic prolonged the duration of analgesia in supraclavicular brachial plexus block.

In our study, 7 out of 50 (14%) patients in group A and 11 out of 50 (22%) patients in group B had nausea, whereas 6 patients in group A and 8 patients in group B had vomiting, which was comparable in both groups. There was no incidence ofrespiratory depression in both groups in our study. Incidence of pruritis was 2% in group A and 4% in group B, which was not statistically significant. Kumkum Gupta et. al., and Prabhati Rani Mishra et. al., concluded in their studies that the use of Nalbuphine was not associated with any adverse effects, as Nalbuphine is an agonist to k receptor and antagonist to μ receptors and is devoid of pruritus, nausea, vomiting and respiratory depression. Similarly, Shwetha Saurin et. al., Anjan Das et. al., and Vinod Kumar Yadav et. al., in their studies on Nalbuphine as an adjuvant to local anaesthetic in supraclavicular brachial plexus block, mentioned that no adverse effects occurred with the use of Nalbuphine. Jingyao Jiang et. al., in their study, did not notice any significant differences in adverse effects in both Nalbuphine group and control group. Jitendra Agarwal et.al., concluded that addition of Nalbuphine to Levobupivacaine in sciatic nerve block for post-operative analgesia was associated with minimal postoperative complications.

CONCLUSION

We conclude that the onset of sensory and motor block was earlier and the duration of sensory and motor block was prolonged with 10 mg of Nalbuphine hydrochloride as an adjuvant to 0.375% Ropivacaine than Ropivacaine alone in ultrasound guided combined adductor canal and popliteal sciatic block in high risk surgical patients undergoing elective diabetic foot wound debridement. Nalbuphine as an adjuvant decreases the need for rescue analgesia in the first 24 hours following surgery with minimal adverse effects.

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