RESEARCH

A RANDOMIZED CLINICAL TRIAL COMPARING EFFICACY AND SAFETY OF 0.5% ROPIVACAINE AND 0.5% BUPIVACAINE PREOPERATIVELY IN FEMORAL NERVE BLOCK FOR PAIN RELIEF AND POSITIONING IN CONDUCTING REGIONAL ANESTHESIA IN CASES OF INTER-TROCHANTERIC FRACTURES OF FEMUR.

Arpita Jena[1], Rashmi Ranjan Mohanty[2], Ranjan Kumar Mohanty[3], Pritam Mohanty[4], Debadas Biswal[5]

[1]Assistant Professor, Department of Anesthesiology, FM Medical College, Balasore, Odisha, India.
[2]Assistant Professor, Department of Orthopaedics, PRM Medical College, Baripada, Odisha, India.
[3]Assistant Professor, Department of Cardiology, SCB Medical College, Cuttack, Odisha, India.
[4]Senior Resident, Department of Anesthesiology, FM Medical College, Balasore, Odisha, India.
[5]Associate Professor, Department of Anesthesiology, SLN Medical College, Koraput, Odisha, India.

Received : 02/05/2022
Received in revised form : 07/07/2022
Accepted : 25/08/2022

Keywords:
Inter-trochanteric fracture,
Femoral block,
Ropivacaine,
Bupivacaine.

Corresponding Author:
Dr. Debadas Biswal,
Email. debadasbiswal@gmail.com
ORCID: 0000-0002-8531-9330

DOI: 10.47009/jamp.2022.4.4.26

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2022; 4 (4); 122-126

Abstract

Background: Adequate perioperative pain relief forms an integral part of good anesthesia practice. Peripheral nerve blocks are ideally suited for extremities because of the peripheral location of the surgical sites and the potential to block the pain pathways at multiple levels. Nerve blocks provide perioperative analgesia and reduce hemodynamic and pulmonary complications. In this study the analgesic effect of ropivacaine is compared with bupivacaine in femoral nerve block (FNB) for positioning of patient for neuraxial block in patients with inter-trochanteric fractures of femur. **Materials and Methods:** 60 patients in the age group 25 to 80 years with inter-trochanteric fractures of femur were randomly allocated into two groups of 30 each. All the patients received femoral nerve block for positioning and regional anaesthesia. Group A received 0.5 % 20 ml bupivacaine and Group B received 0.5% 20 ml ropivacaine. The pain score during patient positioning and the time of onset and peak of sensory block was measured. **Result:** Patients in group B (receiving ropivacaine) had a mean onset time of the sensory block of 3.57 mins and in group A (receiving bupivacaine) it was 3.93 mins. The mean time taken to achieve the peak of sensory block between the two groups was statistically significant (P< 0.0001). The mean time taken to achieve the peak of the sensory block in group B (receiving ropivacaine) was 17.47 mins as compared to 22.53 mins. in group A. The difference between the mean onset times of sensory block between the two groups was not statistically significant. (p= 0.0896). At the peak of the sensory block the difference of the mean pain scores between the two groups was not statistically significant.(p=0.8003) the mean of the pain scores (NRS) for group A was 2.00 while the mean of the pain scores(NRS)for group B was 2.03. **Conclusion:** 0.5% 20ml of ropivacaine in femoral nerve block is a safe dose allowing anesthetist to produce a fast onset of sensory block, providing quicker and favourable positioning to conduct neuraxial block.

INTRODUCTION

Peripheral nerve blocks are ideally suited for lower extremity fractures for the peripheral location of surgical site and the potential to block pain pathways at multiple levels. In contrast to systemic analgesics, a properly conducted peripheral nerve block avoids hemodynamic instability and pulmonary complications, helps achieve adequate preoperative and post-operative analgesia and facilitates timely discharge.[1] It is generally not contraindicated in patients on anticoagulants,[2,3] extended for surgical anesthesia, used in patients having lumbo-sacral diseases and circumvents the need for airway instrumentation.

Nerve blocks reduce the quantity of parenteral analgesia to control pain or dulcify pain levels.[4] Peripheral nerve blocks can also be used for comfortable positioning of patients for the conduct of neuraxial anesthesia as a part of management of

fracture of femur.[5] Various pharmacological agents have been used to conduct peripheral nerve blocks, bupivacaine being the most popular due to its longer duration of action.[6] Ropivacaine, a newer local anesthetic agent with greater selectivity for sensory blockade and lower cardiovascular and neurological toxicity seems to be an attractive alternative.[7,8] Studies had compared safety and efficacy of bupivacaine and ropivacaine for inter scalene block, brachial plexus block, lumbar pelvic block & sciatic nerve block, however few studies had compared in femoral nerve block to provide analgesia for positioning before subarachnoid block in patients with fracture femur. The present study is designed to compare bupivacaine with ropivacaine in femoral nerve block (FNB) to provide analgesia for positioning before performing subarachnoid block in the sitting position in patients with inter-trochanteric fractures of femur.

MATERIALS AND METHODS

This was a prospective single blind two arm randomized clinical trial conducted during the period of December 2020 to March 2022. 60 patients of 25 to 80 years with inter-trochanteric fracture of femur were randomly divided into two groups of 30 each. Patients who refuse for consent, hypersensitivity to local anesthetics, unable to score pain, local infection, neurological and coagulation disorder were excluded from the study.

Group A: receiving 0.5% 20 ml Bupivacaine

Group B: receiving 0.5% 20 ml Ropivacaine

Pain was assessed before the block using a Numeric Rating Scale along with pulse, blood pressure and oxygen saturation monitoring. Femoral Block was performed in the recovery room 30 mins before the surgery. Both the groups received single shot femoral block using bupivacaine or ropivacaine in the above-mentioned doses using nerve stimulator & 50 mm 22G stimuplex nerve locator needle. The patient lies in the supine position with both legs extended with a clear view of the patella. Femoral artery was palpated just below the inguinal ligament. Needle insertion site was labeled immediately lateral to the pulse of the femoral artery. Local anesthetic was infiltrated subcutaneously at the estimated site of needle insertion. The nerve stimulator was initially set to deliver 1.5mA (2 Hz, 100µsec). A visible or palpable twitch of the quadriceps muscle (patella twitch) at 0.4 – 0.6mA current is the optimal response. After a negative aspiration for blood, 0.5 % 20 ml of either bupivacaine or ropivacaine was slowly injected.

Time 0 mins was recorded after the completion of the injection of local anesthetic. Pulse rate, systolic and diastolic blood pressures, oxygen saturation were monitored regularly at every 5 min. intervals. Sensory block assessment was done every 1 min till the onset of sensory block and thereafter at every 2 min. interval till the peak block was obtained. Subjective analgesia score using Numeric Rating Scale (NRS) was recorded before the block, at the peak of the sensory block and during positioning for neuraxial block. When the peak of the sensory block was achieved the pain score was noted and the patient was shifted to the operation theatre and was given sitting position for subarachnoid block. If any patient in either group, reported pain scores > 4 during positioning, Inj. Fentanyl 0.5 mcg/kg iv every 5 min was supplemented until the pain scores≤ 4. However these patients were excluded from this study. Subarachnoid block was performed at L2-L3 or L3-L4 level using 3 ml, 0.5% heavy bupivacaine.

Any treatment required and complications if any were recorded till 30 min after FNB. Pulse rate less than 60 was considered as bradycardia and treated with Inj. Atropine 0.6 mg iv. Blood pressure less than 90mmHg or 20% below the baseline considered hypotension and treated with intravenous fluid, colloid or Inj. Ephedrine 5 mg iv.

Assessment of sensory block (assessed with pin prick to 23 G hypodermic needle)

0 - Sharp pains on pin prick

1 - Touch sensation on pin prick

2 - Not even touch sensation

Assessment of Onset and Peak of Sensory Block (Sensory block assessment was done over the antero-medial aspect of the thigh and knee, and the medial border of the leg and medial malleolus)

Onset of sensory block - Time duration from the end of injection to dull response to pin prick

Peak of sensory block - Time duration from the end of injection to no response to pin prick

NRS (Subjective analgesia score)

Collected data were tabulated and analyzed using Graph Pad Prism online calculator. The mean values with standard deviation (SD) were calculated for all the parameters and comparison between the two groups was made using unpaired student's t-test. The difference between the two groups was said to be statistically significant if p value is <0.05.

RESULTS

The age and sex distribution between the two groups are comparable. [Table 1]

There is no difference in mean time for onset of sensory block, NRS score during the peak of sensory block and during positioning for neuraxial block were not statistically significant. But the mean time for peak of the sensory block was significant showing that there was earlier onset of peak of sensory block in patients receiving ropivacaine for femoral block. [Table 2]

ISSN (O): 2687-5365; ISSN (P): 2753-6556

The difference in mean systolic blood pressure between the two groups was not statistically significant throughout the study. [Table 3]

The difference in mean diastolic blood pressure between the two groups was not statistically significant throughout the study. [Table 4]

Table 1: Demographic Profile

	Group A(Bupivacaine)	Group B (Ropivacaine)	P-Value
Age	57.67±12.152	58.00±11.564	0.914
Male	12 (40%)	12 (40%)	1.000
Female	18 (60%)	18 (60%)	

Table 2: Sensory block and NRS score following Femoral Nerve block.

Nerve block profile	Group-A (Bupivacaine)	Group-B (Ropivacaine)	P-Value
Mean time for onset of sensory block (Min)	3.93±0.78	3.57±0.86	0.0896
Mean time for the peak of the sensory block (Min)	22.53±2.78	17.47±1.74	<0.0001
NRS score during the peak of sensory block	2±0.53	2.03±0.49	0.8003
NRS score during positioning for neuraxial block	2±0.53	2.03±0.49	0.8003

Table 3: Systolic Blood Pressure

Time	Group-A (Bupivacaine)	Group-B (Ropivacaine)	P-Value
0 min	146.63±8.211	149.33±8.413	0.213
5 min	146.30±8.289	149.33±8.413	0.165
10 min	146.07±8.233	149.33±8.413	0.134
15 min	143.87±8.165	144.43±8.752	0.796
20 min	139.80±7.667	142.90±8.155	0.135
25 min	139.00±7.557	142.10±8.181	0.133
30 min	137.23±7.137	140.93±7.922	0.062

Table 4: Diastolic Blood Pressure

Time	Group-A (Bupivacaine)	Group-B (Ropivacaine)	P-Value
0 min	91.90±4.596	92.73±6.011	0.549
5 min	91.80±4.544	92.40±6.157	0.669
10 min	91.80±4.544	92.40±6.157	0.669
15 min	87.17±4.669	86.13±5.406	0.431
20 min	86.27±5.037	84.37±4.895	0.144
25 min	85.60±5.008	83.17±4.778	0.059
30 min	85.53±5.002	83.17±4.778	0.066

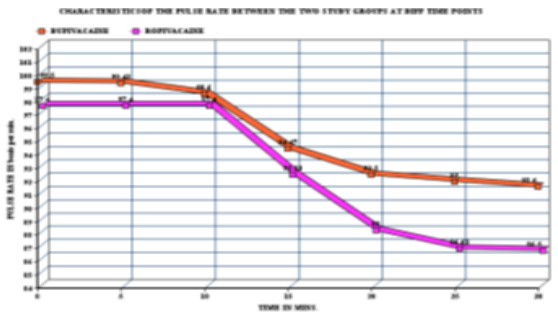

Figure 1: Mean Pulse Rate Trends Between the Two Groups

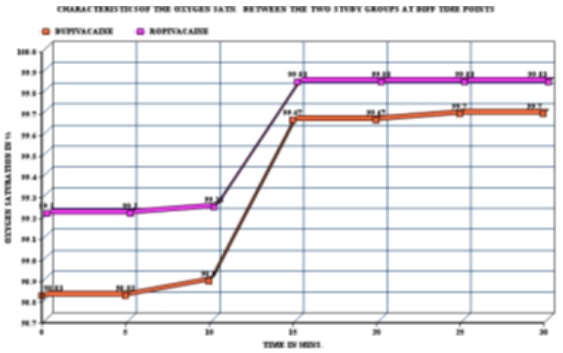

Figure 2: Mean Oxygen Saturation Trends Between the Two Groups.

The difference in mean pulse rate between the two groups was not statistically significant at 0, 5, 10, 15 minutes. Patients who received bupivacaine had significantly higher pulse rate than ropivacaine at 20, 25, 30 minutes. [Figure 1]

Patients who received bupivacaine had significantly lower SPO2 than ropivacaine at 0, 5, 10 minutes but the difference in the mean SPO2 between the two groups was not statistically significant at 15,20,25,30 minutes. [Figure 2]

DISCUSSION

Bupivacaine has been the most popular local anesthetic for peripheral nerve blocks but with a wide and unpredictable latency of nerve block and enhanced neuro and cardio toxicity.[9] Ropivacaine, showed a remarkable safety profile,[7] greater degree of separation between motor and sensory blockade in extradural block.[10] It has reduced toxic potential as compared with bupivacaine not only at equivalent but also at equipotent doses.[11] Femoral nerve block is effective in relieving pain and muscle spasm caused by fractured bone and help for positioning during conduct of regional anesthesia even when patient's legs are placed in traction.[1] As the patients of femur fractures are elderly, it is better

ISSN (O): 2687-5365; ISSN (P): 2753-6556

to avoid systemic analgesics which have more side effects compared to peripheral nerve block.

Onset time of the sensory block: The patients in group B(receiving ropivacaine) had a mean onset time of the sensory block of 3.57 mins which was slightly faster than group A(receiving bupivacaine) 3.93 mins (p value of 0.0896). The difference between the mean onset times of sensory block between the two groups was not statistically significant. Trivedi L et al compared ropivacaine and bupivacaine in femoral nerve block concluded that the mean onset time for sensory block was less than 5 mins[5]. Klein et al compared the same volume of 0.5% bupivacaine, 0.5% ropivacaine, and 0.75% ropivacaine for inter scalene block and concluded that the onset time of sensory block was <6 mins. in all the three groups.[12] Ramamurthy studied the onset times of sensory block between ropivacaine and bupivacaine in brachial plexus block and concluded that the onset times of sensory block were comparable in both the groups.[13] But in a study done by Tripathy D comparing ropivacaine and bupivacaine in supraclavicular block, the onset time of sensory block in the ropivacaine group was achieved in less than 5 mins but it was 13.83±3.49 mins in the bupivacaine group.[14] However this could have been due to the lesser concentration of bupivacaine 0.5% vs 0.75% for ropivacaine.

Time for the peak of the sensory block: In group B the mean time taken to achieve the peak of the sensory block was 17.47 mins as compared to 22.53 mins. in group A. The mean time taken to achieve the peak of sensory block between the two groups was statistically significant(P < 0.0001). Similar results were obtained by; Trivedi L et al found that the mean time for the peak of sensory block was earlier in the ropivacaine group compared to the bupivacaine group.[5] Tripathy D et al found that the mean time taken to reach the peak of the sensory block in the ropivacaine group was faster as compared bupivacaine group.[14]

Subjective analgesia was evaluated and compared at two time points, during the peak of the sensory block and during positioning before the conduction of neuraxial block. At the peak of the sensory block the mean of the pain scores (NRS) for group A was 2.00 while the mean of the pain scores (NRS) for group B was 2.03, with a p = 0.8003, which was not statistically significant. During positioning for neuraxial block the mean of the pain scores for group A was 2.00 while for group B was 2.03 with a p value of 0.8003 again, not being statistically significant. Trivedi L et al comparing subjective analgesia measured by VAS found that both ropivacaine and bupivacaine provided adequate pain relief (both study groups had a mean vas score <4) that facilitated sitting position to conduct subarachnoid block and both the groups were comparable to one another[5]. Lima R et al investigated the effect of single injection femoral nerve block in post operative pain relief after total knee replacement and anterior cruciate ligament repair with 0.25% ropivacaine and 0.25% bupivacaine with epinephrine concluded that patients in both the groups had effective post-operative analgesia and both the groups were comparable in terms of subjective analgesia.[15] The sensory block distributions were similar in both the groups.

Wulf et al compared 0.2 and 0.75 % Ropivacaine vs. 0.25 % Bupivacaine in femoral nerve block for post-operative pain relief in anterior cruciate ligament reconstruction found that both the drugs provided effective and comparable post-operative analgesia as measures by VAS.[16,17,18] Casati et al found that the intensity of anesthesia provided by ropivacaine and bupivacaine were similar.[19] Kuthiala G found that the quality of anesthesia provided by ropivacaine and bupivacaine were similar.[17] However these studies had not taken into account subjective analgesia and described the quality in terms of the objective assessment of the characteristics of sensory and motor blockade after nerve block. The patients in both the groups are comparable to each other in terms of subjective analgesia. This allowed transport of patients to the operation theatre and facilitated positioning for the conduct of neuraxial anesthesia. In the absence of enough published literature for subjective analgesia, it was difficult to conclusively say whether ropivacaine was more effective in relieving preoperative pain after femoral nerve block as compared to bupivacaine. Moreover considering the subjectivity of the pain assessment it was difficult to compare the quality of analgesia provided by ropivacaine and bupivacaine.

Though bupivacaine was claimed to be more cardiotoxic and neurotoxic there was no reported complications in either of the groups.[9] The pulse rate, systolic and diastolic blood pressures and oxygen saturation were stable throughout the study. These parameters were comparable between the two study groups. The difference in the mean pulse rates between groups A and group B was not statistically significant except at 20, 25 and 30 mins. This was probably due to the slightly higher baseline pulse rate in the subjects of Ropivacaine group to start with. However the pulse rate remained stable and comparable to the base line throughout the study. The difference in the mean oxygen saturation between group A and group B was not statistically significant except at 0,5,10 mins. This was probably because of pain and discomfort due to the traction and movement during transportation stimulated the sympathetic system affecting normal breathing. But the saturation remained stable and comparable to the baseline in both groups. In a study by Trivedi L et al,[5] the hemodynamic parameters remained fairly stable and comparable to the baseline as well as to each other throughout the study duration. Hamaji et al in brachial plexus block foundd that the hemodynamic parameters remained stable and the incidence of supra ventricular arrhythmias were not different before or after the plexus blockade.[18] But he did find a decrease in heart rate during the 24

ISSN (O): 2687-5365; ISSN (P): 2753-6556

hour holter monitoring for both the groups which could well be due to pain relief following the block. Tripathy D et al,[9] also concluded that the hemodynamic parameters remained stable and comparable to each other as well as to the base line in his study comparing ropivacaine and bupivacaine in supraclavicular block.

CONCLUSION

Femoral nerve block is a simple, effective and cheap method to provide analgesia in patients with fracture femur for positioning before neuraxial block. 0.5% 20ml of ropivacaine in femoral nerve block is safe dose allowing anesthetist to produce a fast onset of sensory block, providing quicker and favorable positioning to conduct neuraxial block. Ropivacaine has similar onset and level of sensory analgesia as compared to bupivacaine. Both the drugs have stable hemodynamic profile without any adverse effects. So either of the two drugs could be used for peripheral blocks but considering the increased safety profile of ropivacaine it can be used as a safer alternative to bupivacaine, especially in compromised cardiovascular patients.

Limitations of this Study

The ultrasonography could be used for more accuracy but considering the constraints of availability and technical expertise required to operate the equipment, it could not be used. Motor effects were not evaluated to avoid painful stimuli and possible further displacement of fractures. The assessment of analgesia was subjective and hence it was difficult to compare the analgesic potency between the two drugs. Evaluation of motor blockade could have provided a better understanding of the quality of anesthesia. Total duration of the block could not be evaluated because the definitive management of fractures was done under neuraxial block before the effect of femoral block weaned out.

REFERENCES

1. Kullenberg B, Ysberg B, Heilman M, Resch S. Femoral nerve block as pain relief in hip fracture. A good alternative in perioperative treatment proved by a prospective study. Lakartidningen. 2004;101(24):2104-7.
2. Chelly JE, Schilling D. Thromboprophylaxis and peripheral nerve blocks in patients undergoing joint arthroplasty. J Arthroplasty. 2008;23(3):350-4. doi: 10.1016/j.arth.2007.05.045.
3. Horlocker TT, Wedel DJ, Rowlingson JC, Enneking FK, Kopp SL, Benzon HT, et al. Regional anesthesia in the patient receiving antithrombotic or thrombolytic therapy: American Society of Regional Anesthesia and Pain Medicine Evidence-Based Guidelines (Third Edition). Reg Anesth Pain Med. 2010;35(1):64-101. doi: 10.1097/aap.0b013e3181c15c70.
4. Parker MJ, Griffiths R, Appadu BN. Nerve blocks (subcostal, lateral cutaneous, femoral, triple, psoas) for hip fractures. Cochrane Database Syst Rev. 2002;(1):CD001159. doi: 10.1002/14651858.CD001159.
5. Jadon A, Kedia SK, Dixit S, Chakraborty S. Comparative evaluation of femoral nerve block and intravenous fentanyl for positioning during spinal anaesthesia in surgery of femur fracture. Indian J Anaesth. 2014;58(6):705-8. doi: 10.4103/0019-5049.147146.
6. Parker MJ, Handoll HH, Griffiths R. Anaesthesia for hip fracture surgery in adults. Cochrane Database Syst Rev. 2004;(4):CD000521. doi: 10.1002/14651858.CD000521.pub2.
7. Parker MJ, Urwin SC, Handoll HH, Griffiths R. General versus spinal/epidural anaesthesia for surgery for hip fractures in adults. Cochrane Database Syst Rev. 2000;(2):CD000521. doi: 10.1002/14651858.CD000521.
8. Knudsen K, Beckman Suurküla M, Blomberg S, Sjövall J, Edvardsson N. Central nervous and cardiovascular effects of i.v. infusions of ropivacaine, bupivacaine and placebo in volunteers. Br J Anaesth. 1997;78(5):507-14. doi: 10.1093/bja/78.5.507.
9. Watanabe K, Tokumine J, Lefor AK, Moriyama K, Sakamoto H, Inoue T, et al. Postoperative analgesia comparing levobupivacaine and ropivacaine for brachial plexus block: A randomized prospective trial. Medicine (Baltimore). 2017;96(12):e6457. doi: 10.1097/MD.0000000000006457.
10. McClure JH. Ropivacaine. Br J Anaesth. 1996;76(2):300-7. doi: 10.1093/bja/76.2.300.
11. Dony P, Dewinde V, Vanderick B, Cuignet O, Gautier P, Legrand E, et al. The comparative toxicity of ropivacaine and bupivacaine at equipotent doses in rats. Anesth Analg. 2000;91(6):1489-92. doi: 10.1097/00000539-200012000-00036.
12. Klein SM, Greengrass RA, Steele SM, D'Ercole FJ, Speer KP, et al. A comparison of 0.5% bupivacaine, 0.5% ropivacaine, and 0.75% ropivacaine for interscalene brachial plexus block. Anesth Analg. 1998;87(6):1316-9. doi: 10.1097/00000539-199812000-00019.
13. Hickey R, Hoffman J, Ramamurthy S. A comparison of ropivacaine 0.5% and bupivacaine 0.5% for brachial plexus block. Anesthesiology. 1991;74(4):639-42. doi: 10.1097/00000542-199104000-00002.
14. Nallam SR, Chiruvella S, Karanam S. Supraclavicular brachial plexus block: Comparison of varying doses of dexmedetomidine combined with levobupivacaine: A double-blind randomised trial. Indian J Anaesth. 2017;61(3):256-261. doi: 10.4103/ija.IJA_700_15.
15. de Lima E Souza R, Correa CH, Henriques MD, de Oliveira CB, Nunes TA, Gomez RS. Single-injection femoral nerve block with 0.25% ropivacaine or 0.25% bupivacaine for postoperative analgesia after total knee replacement or anterior cruciate ligament reconstruction. J Clin Anesth. 2008;20(7):521-7. doi: 10.1016/j.jclinane.2008.05.016.
16. Wulf H, Löwe J, Gnutzmann KH, Steinfeldt T. Femoral nerve block with ropivacaine or bupivacaine in day case anterior crucial ligament reconstruction. Acta Anaesthesiol Scand. 2010;54(4):414-20. doi: 10.1111/j.1399-6576.2009.02200.x.
17. Kuthiala G, Chaudhary G. Ropivacaine: A review of its pharmacology and clinical use. Indian J Anaesth. 2011;55(2):104-10. doi: 10.4103/0019-5049.79875.
18. Hamaji A, de Rezende MR, Mattar R Jr, Vieira JE, Auler JO Jr. Comparative study related to cardiovascular safety between bupivacaine (S75-R25) and ropivacaine in brachial plexus block. Braz J Anesthesiol. 2013;63(4):322-6. doi: 10.1016/j.bjan.2012.06.001.
19. Klein SM, Greengrass RA, Steele SM, D'Ercole FJ, Speer KP, Gleason DH, et al. A comparison of 0.5% bupivacaine, 0.5% ropivacaine, and 0.75% ropivacaine for interscalene brachial plexus block. Anesth Analg. 1998;87(6):1316-9. doi: 10.1097/00000539-199812000-00019.

ISSN (O): 2687-5365; ISSN (P): 2753-6556