

Comparison of Ropivacaine and Levobupivacaine in Supraclavicular Brachial Plexus Block for Fast-track Recovery in Arteriovenous Fistula Creation: A Randomised Double-blind Clinical Study

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ABSTRACT

Introduction: Arteriovenous Fistula (AVF) creation surgery is the standard procedure for establishing durable vascular access in patients with End Stage Kidney Disease (ESKD). Brachial Plexus Blocks (BPB) improve surgical outcomes of AVF by producing sympathetic blockade and vasodilatation. For ambulatory AVF surgery, early motor recovery from regional blocks is desirable to enable early discharge.

Aim: The present study was aimed to compare recovery profile of Ropivacaine and Levobupivacaine in supraclavicular BPB for AVF creation.

Materials and Methods: The present randomised double-blind clinical study was conducted in the department of Anaesthesia at a tertiary care superspeciality teaching hospital, (Institute of Kidney Disease and Research Centre-Institute of Transplantation sciences) Ahmedabad, Gujarat, between September 2022 and July 2024 by enrolling sixty American Society of Anesthesiologists (ASA) III-IV patients with ESKD undergoing AVF creation. Patients received Supraclavicular BPB with either 20 mL of 0.5%

Levobupivacaine (Group L) or 20 mL of 0.5% Ropivacaine (Group R). Motor and sensory block characteristics, postoperative analgesia duration and complications were assessed. Data were analysed using Statistical Package for Social Sciences (SPSS) version 20. Independent t-test and Mann-Whitney U test were applied for continuous variables while Chi-square test for categorical variables.

Results: Both groups were comparable in terms of demographic characteristic. Motor block regression time and total motor block durations were shorter in Group R (225±14.7 minutes; 425.67±82.28 minutes) than Group L (268±14.7 minutes; 606.67±54.73 minutes, $p=0.001$); whereas motor block onset was faster in Group L (14.27±1.01 minutes) than Group R (19.77±1.59 minutes, $p=0.001$).

Conclusion: Levobupivacaine provides prolonged motor and sensory blockade whereas Ropivacaine offers short duration motor block with adequate analgesia. Thus, Ropivacaine is more suitable Local Anaesthetic (LA) to hasten Regional Anaesthesia (RA) recovery in Arterio-Venous Fistula (AVF) creation surgery.

Keywords: Ambulatory surgical procedures, Chronic kidney failure, Motor activity, Regional anaesthesia

INTRODUCTION

The AVF is the most reliable and preferred vascular access for patients with ESKD requiring long term haemodialysis. Compared with central venous catheters and synthetic grafts, AVFs are associated with lower infection rates, improved durability and better long-term outcomes. AVF creation is increasingly being performed as a planned elective procedure, often in ambulatory or day-care settings as it provides additional advantages of reduced risk of hospital acquired infection in immunocompromised ESKD patients and increased patient satisfaction [1,2]. The anaesthetic technique significantly influences intra-operative conditions, postoperative recovery, patient satisfaction and discharge timings in day care AVF creation surgery [2,3].

In ambulatory settings, RA is considered as most suitable and practical alternative to general anaesthesia due to limited peri-operative fasting times, avoidance of airway manipulation, extended superior postoperative analgesia with less systemic side-effects of opioids and other anaesthetic drugs (nausea, vomiting, respiratory depression, sedation, urinary retention) and haemodynamic stability. BPB are being widely utilised for RA of the upper limb including AVF creation surgery. BPB induces sympathetic blockade, leading to vasodilatation of the upper limb vessels. The resultant increase in arterial inflow and venous distensibility enhance immediate fistula blood flow and maturation [3-6]. Real time brachial plexus blocks

under Ultrasonography (USG) guidance allow dynamic visualisation of surrounding structures (blood vessel, pleura) and needle path and increase safety in case of anatomical variations. USG guidance increases the success rate and allows rapid onset of block even with reduced dosage of LA [7,8] benefitting the high-risk surgical population (patients with cardio-respiratory compromise, obesity, difficult airway, renal failure). Advantages of ultrasound-guided supraclavicular BPB for AVF surgery has been substantiated by many studies [4,6].

The ideal LA for brachial blocks should provide rapid onset and recovery, sufficient intraoperative anaesthesia, prolonged postoperative analgesia and haemodynamic stability. Additionally, choice of LA for patients with ESKD also depends on safety margin for LA dosage and recovery of sensory and motor function in presence of renal failure. In ambulatory AVF surgery; quick action of LA helps with the rapid turn-over time whereas early recovery of finger movements helps with the teaching and performance of isometric exercises like ball squeezing for fistula maturation [9]. Quick recovery of sensory and motor function increases patient's satisfaction by relief from the immobility; commonly described as "the dead arm" and enables early discharge in presence of adequate limb support at home [10].

Both Ropivacaine and Levobupivacaine are frequently used for peripheral nerve blocks because of their improved safety profiles

compared with racemic Bupivacaine. Theoretically, greater degree of sensory-motor separation and less intense motor block achieved using comparable concentration of Ropivacaine than Levobupivacaine make it a more suitable option for ambulatory surgery and this formed the basis of the research hypothesis for the present study. [11]. Existing comparative studies between these two have largely been conducted in orthopaedic or general upper limb surgeries [11-15] and reported varying findings regarding block characteristics and analgesia. Limited literature specifically evaluates these agents in the context of AVF creation, where it is beneficial both ways (to provide excellent surgical conditions and favourable outcomes as well as analgesia). Furthermore, many previous investigations [4-6,16] have focused predominantly on analgesic duration and sympatholytic vasodilation rather than functional recovery endpoints such as time to motor block regression, which are crucial in ambulatory surgery. Given the growing emphasis on fast-track anaesthesia and early discharge pathways, it is important to determine which LA agent better balances effective analgesia, prompt motor recovery and superior safety profile in high-risk ESKD population presenting for low-risk day care AVF surgery. However, due to gaps in current literature, clear evidence favouring one agent over the other in these patient cohorts is lacking and underscores the need for focused comparative evaluation.

By emphasising functional recovery alongside analgesic efficacy, the present randomised double blind study aimed to provide clinically relevant evidence to guide LA selection in ESKD patients presenting for superficial ambulatory surgery like AVF creation. The primary objective was to compare motor block regression time between the two groups. Secondary objectives were comparison of onset and duration of motor block, onset and duration of sensory block, duration of postoperative analgesia. Haemodynamic parameters and complications were also monitored.

MATERIALS AND METHODS

The present randomised double-blind clinical study was conducted in the department of Anaesthesia at a tertiary care super-speciality teaching hospital, (Institute of Kidney Disease and Research Centre-Institute of Transplantation sciences) Ahmedabad, Gujarat, between September 2022 and July 2024. Enrolment of study participants was carried out only after approval from the Institutional Ethics Committee (GUTS/4th/EC/Approved/53/2022). Written informed consent was obtained from all patients.

Sample size calculation: A pilot study was conducted on ten patients to estimate the mean and Standard Deviation (SD) of motor block regression time. The pilot data showed a mean regression time of 225 minutes in the ropivacaine group and 268 minutes in the levobupivacaine group, with a pooled SD of 14.7 minutes. Although the observed difference between groups in the pilot study was 43 minutes, a conservative and clinically meaningful difference of 11 minutes was considered for the purpose of sample size estimation to avoid overestimation of effect size associated with small pilot samples. Assuming a two-sided alpha error of 0.05 and power of 80%, the minimum required sample size was calculated to be 28 patients per group. To account for an anticipated dropout rate of approximately 15% and to enhance the robustness of the present study, the sample size was increased to 33 patients per group. Therefore, a total of 66 patients were enrolled in the present study.

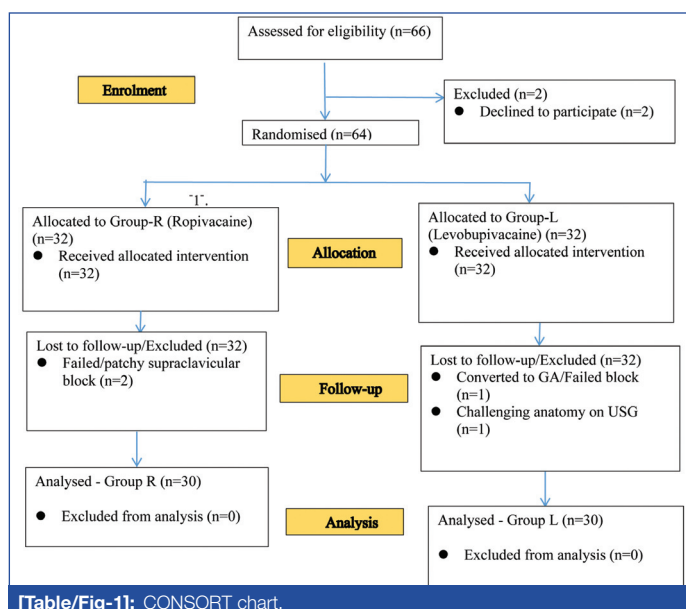
Inclusion criteria: Patients aged between 18-60 years with ESKD stage II to V and classified as ASA physical status III or IV were included. Patients with ESKD and comorbidities such as diabetes mellitus, hypertension, and ischemic heart disease were also included. A total of 66 patients were included in the study and 60 patients were analysed.

Exclusion criteria: Patients with coagulation disorders, allergy to LAs, pre-existing neuropathy or local site infection. Out of 66

eligible patients enrolled for the present study, two patients refused to participate and were excluded. Out of 64 enrolled patients, two patients in Group R and one patient in Group L were excluded from analysis due to a failed block. Also, one patient from Group L excluded due to technical difficulty in performing block (challenging regional anatomy for brachial block).

Study Procedure

All patients posted for AVF creation underwent pre-operative USG doppler evaluation to assess eligibility and measure the diameters of the brachial artery, radial artery and cephalic vein as per institutional protocol. Principles of declaration of Helsinki (2013) were followed during each step. All eligible patients were randomly divided into two groups using a sealed envelope technique: Group R and Group L by an anaesthesiologist who was not involved in patient enrolment or outcome assessment [Table/Fig-1]. The study was conducted in a double-blind manner. The anaesthesiologist performing the block was aware of the group allocation but was not involved in data collection or postoperative assessment. The study drug was prepared in identical syringes by an independent anaesthesiologist not involved in the study observations. The patients and the investigator assessing block characteristics and outcomes were blinded to group allocation and drug preparation. On the day of surgery, post-dialysis fitness was assessed and intravenous lines were secured. Baseline vital parameters, including Mean Arterial Pressure (MAP) (mmHg), Heart Rate (HR), and Oxygen Saturation (SpO₂) were recorded at zero minute. Patients were positioned supine, with the head turned to the opposite side and a pillow placed under the head. The ipsilateral arm was kept adducted. Under aseptic precautions, a high-frequency linear probe (18L5, GE/Philips) was placed in the supraclavicular fossa in the coronal oblique plane for proper visualisation of the brachial plexus, first rib, and subclavian artery. The needle was inserted in-plane from lateral to medial, targeting the nerve bundle (characteristically appearing as a "bunch of grapes") located superolateral to the subclavian artery [17]. Group R received 20 mL 0.5% ropivacaine and Group L received 20 mL 0.5% levobupivacaine [4,16]. The block was performed by an anaesthesiologist experienced in over 50 supraclavicular blocks. Haemodynamic parameters were closely monitored immediately after the block and at 15-30 minutes intervals thereafter. Motor block was assessed using a 3-point modified Bromage scale (Grade 0-full motor function of elbow, wrist, and finger movement, Grade 1-decreased motor strength with movement of fingers only, Grade 2- complete motor block with no finger movement) [18]. Onset of motor blockade (Time to reach grade 2), regression of



motor blockade (Time required for grade2 to return to grade 1) [19] and duration of motor blockade (Time required for grade 2 to return to grade 0) were recorded. Sensory block was assessed by pinprick test using 3 point scale (grade 0- normal sensation, grade 1-loss of sharp sensation of pinprick, grade 2-complete loss of sensation to touch) by 24G hypodermic needle every two minutes in areas innervated by the median, ulnar, and radial nerves comparing with the contralateral side.

Study Outcomes: Primary outcome was the motor block regression time. Secondary outcomes were onset and duration of sensory blockade, onset and duration of motor blockade, duration of analgesia and postoperative pain scores assessed using the Visual Analogue Scale (VAS).

If adequate sensory anaesthesia was not achieved within 30 minutes, the block was considered failed and excluded from the analysis. Patients were monitored for intraoperative haemodynamics and complications such as haematoma, nerve injury, circumoral numbness, dizziness, seizures, haemodynamic instability, signs of Local Anaesthetic Systemic Toxicity (LAST), phrenic nerve palsy, and pneumothorax. Provisions were made to address any perioperative complications immediately. Pain was assessed using a VAS, 0-10 every two hours till 10 hours. When VAS score was >3, rescue analgesia (Inj. Tramadol 2 mg/kg) was administered. Duration of analgesia was defined as the time from block administration to the time VAS exceeded three. Postoperatively; patients were monitored as per institutional protocol. At the end of surgery, the AVF was examined for thrill and patency and advised isometric exercise.

STATISTICAL ANALYSIS

Using a standardised proforma, data were recorded in Microsoft Excel 2021 and analysed using SPSS version 20 software. Continuous data were expressed as mean±SD for both parametric and non-parametric variables. Categorical (non-continuous) data were expressed as frequency and percentage. An independent t-test and Mann-Whitney U test were used to determine statistical significance for continuous variables, depending on the data distribution. The Chi-square test was used to assess significance in categorical variables. A p-value of <0.05 was considered statistically significant.

RESULTS

The two groups were comparable in terms of demographic characteristics [Table/Fig-2].

Haemodynamic parameters (HR, MAP and SpO₂) were assessed every 15 minutes intraoperatively and it remained within 20% of the baseline [Table/Fig-3]. The onset of sensory blockade was comparable between both the groups (p=0.095) while motor block onset time was significantly longer in Group R [Table/Fig-4].

Shorter regression time with Ropivacaine indicates early recovery of finger movements. There was significant difference in VAS score between two groups at eight hours and at 10 hours [Table/Fig-5]. No significant intraoperative or postoperative complications were noted in either group [Table/Fig-6].

DISCUSSION

Use of local infiltration anaesthesia in AVF creation surgery is associated with the risk of sympathomimetic vasospasm induced early thrombosis [3]. Supraclavicular brachial plexus block due to its wider anatomical coverage as compared to other approaches allows on table change of surgical plan for vascular access [17], use of tourniquet etc., and supports the dynamic nature of AVF surgery with single injection. Moreover, use of single point injection using supraclavicular approach better justify comparative evaluation of recovery profile of Ropivacaine and Levobupivacaine in this study.

Therefore, in the present randomised double-blind clinical study 0.5% Ropivacaine and 0.5% Levobupivacaine were compared in USG guided supraclavicular brachial plexus block to evaluate their motor and sensory block characteristics mainly recovery profile.

Onset of sensory block and motor block: In the present study, time for sensory block onset is comparable between Group R and Group L; whereas motor block onset time is significantly longer for Ropivacaine than Levobupivacaine. Various studies [12,13] in general upper limb/ortho surgery also had reported prolonged onset time (both motor and sensory) with Ropivacaine(R) compared to Levobupivacaine (LB). Contrary to these findings, Thalamati D et al., and Sarma R et al., reported shorter onset time (both sensory and motor) with Ropivacaine as compared to Levobupivacaine [14,15].

The relatively slower establishment of motor block with Ropivacaine may be attributed to its lower lipid solubility and reduced penetration into large myelinated motor fibers [20]. In settings of superficial surgery like AVF; awake co-operation by patient can circumvent such issues due to rapid onset time of sensory block [12-15] compared to motor block and hardly significant clinically.

Motor block regression time and total duration of motor block: The most important finding of current study is shorter motor block regression time and total duration of motor block with Ropivacaine compared to Levobupivacaine and signifies suitability of Ropivacaine for ambulatory settings. Similar to findings of current study; shorter motor block duration with Ropivacaine (R) compared to Levobupivacaine (LB) had been reported by many authors [12-14]. Two meta-analyses also reported faster motor recovery with Ropivacaine (irrespective of type of motor block and concentration employed) compared to Levobupivacaine and attributed this to greater affinity of Levobupivacaine for tetrodotoxin resistant sodium channels, resulting in sustained neuronal conduction inhibition [11,21].

Patient characteristics	Group R (N=30) (mean±SD)		Group L (N=30) (mean±SD)		p-value
Age (years)	39.37±10.37		48.97±5.67		0.060
Weight (kg)	56.97±6.36		59.83±6.31		0.085
Duration of surgery (min)	40.50±6.99		42.53±2.10		0.132
Gender distribution (%)	Male 20 (66.6%)		Male 19 (63.3%)		0.787
	Female 10 (33.3%)		Female 11 (36.6%)		
Co-morbidity	n (%)		n (%)		0.06
HTN	23 (76.7%)		26 (86.7%)		
DM	4 (13.3%)		0		
HTN+DM	1 (3.3%)		4 (13.3%)		
Smoker	2 (6.7%)		0		
Type of fistula (%)	Brachiocephalic 28 (95%)	Radiocephalic 2 (5%)	Brachiocephalic 29 (98%)	Radiocephalic 1 (2%)	

[Table/Fig-2]: Demographic characteristics of patients.

HTN -Hypertension; DM -Diabetes Mellitus

Time (min)	Parameters	Group R (n=30)	Group L (n=30)	p-value
0	HR (beats/min)	82.43±10.71	81.27±3.77	0.576
	MAP (mmHg)	88.20±9.93	85.33±5.86	0.184
	SpO ₂ (%)	99.10±0.76	99.30±0.47	0.224
15	HR (beats/min)	83.60±9.38	82.53±5.01	0.598
	MAP (mmHg)	88.33±9.66	86.50±5.32	0.21
	SpO ₂ (%)	99.20±0.61	99.30±0.49	0.28
30	HR (beats/min)	82.73±8.56	82.47±4.75	0.882
	MAP (mmHg)	89.93±10.65	87.20±4.66	0.19
	SpO ₂ (%)	99.17±0.59	99.33±0.48	0.236
45	HR (beats/min)	82.60±8.65	82.47±3.35	0.938
	MAP (mmHg)	90.67±10.23	87.80±4.76	0.16
	SpO ₂ (%)	99.20±0.61	99.40±0.50	0.170
60	HR (beats/min)	82.67±8.70	84.20±3.03	0.366
	MAP (mmHg)	90.80±9.66	88.30±4.33	0.17
	SpO ₂ (%)	99.20±0.71	99.30±0.47	0.523
75	HR (beats/min)	82.93±9.09	83.67±2.78	0.674
	MAP (mmHg)	91.90±9.62	89.20±4.23	0.15
	SpO ₂ (%)	99.57±0.50	99.37±0.49	0.125
90	HR (beats/min)	82.13±9.44	82.93±4.19	0.673
	MAP (mmHg)	91.50±9.60	89.20±4.00	0.18
	SpO ₂ (%)	99.43±0.50	99.30±0.47	0.292

[Table/Fig-3]: Haemodynamic parameters.

Parameters	Group R	Group L	p-value
Onset of sensory block (min)	8.50±0.90	8.90±0.92	0.095
Onset of motor block (min)	19.77±1.59	14.27±1.01	0.001
Motor block regression (min)	225±14.7	268±14.7	0.001
Duration of sensory block (min)	455.00±85.73	649.33±50.58	0.001
Duration of motor block (min)	425.67±82.28	606.67±54.73	0.001
Duration of analgesia (min)	443.67±91.90	631.33±51.64	0.001

[Table/Fig-4]: Comparison of Sensory and Motor characteristics.

Time (Hours)	Levobupivacaine (Mean± SD)	Ropivacaine (Mean± SD)	p-value
0	0.40±0.62	0.47±0.66	0.68
2	1.18±0.88	1.29±0.92	0.63
4	2.26±1.05	2.41±1.10	0.57
6	3.08±1.21	3.25±1.27	0.59
8	3.82±1.18	4.45±1.20	0.03
10	4.36±1.22	5.02±1.25	0.02

[Table/Fig-5]: Comparison of VAS score.

Adverse effects	Group R (n=30)	Group L (n=30)
Bruising	2 (6.66%)	1 (3.33%)
Nausea and vomiting	3 (10%)	2 (6.66%)

[Table/Fig-6]: Adverse effects.

As a promising alternative to Ropivacaine; Hull J et al., have used 1% and 2% lignocaine respectively in supraclavicular block in interventional AVF surgery/AVF creation surgery and reported relatively shorter (99±40.5 minutes) duration of motor block [22]. But lack of control group and retrospective nature of the study make the results inconclusive.

Duration of sensory block and Postoperative analgesia: The reported duration of sensory block and postoperative analgesia is significantly longer for Levobupivacaine compared to Ropivacaine in this study. These findings are in congruence with other studies [12-15]. Parallel to the findings established by Kulkarni SB et al., this study also reported significant difference in VAS score between

two groups at eight hours and at 10 hours [Table/Fig-5] [12]. Even though, Alharran AM et al., reported no significant difference in rescue analgesia rate between two in meta-analysis [11]. In superficial surgery like AVF creation the need for analgesia is less pronounced and relatively shorter duration of analgesia does not greatly affect the overall recovery and patient's satisfaction.

Complications: No major complications either related to procedure/ LA agents reported in this study. Ropivacaine is recognised to have a relatively favourable cardiotoxic and neurotoxic profile compared with racemic Bupivacaine. In real world clinical practice both LAs (Ropivacaine and Levobupivacaine) are well tolerated and present study also supports its suitability in high-risk ASA III-IV patients [11,21]. Although Ropivacaine and its metabolites get excreted via renal pathways; its pharmacokinetics remain largely unaffected in chronic renal failure due to compensation by non-renal elimination [23].

This is the first study which evaluated the effect of choice of LA on recovery of RA especially in ESKD patients undergoing superficial surgery (AVF creation). Comparison of motor block regression time signifies a more patient centric approach as it denotes reduced physical dependence of patients for routine everyday activities after early discharge.

Limitation(s)

Short-term and long-term outcomes like vasodilation, primary patency rate, failure rate, and maturation time were not evaluated. Only fixed volume and concentration were assessed for both LAs. Different dosing strategies may yield different recovery profile. Haemodynamic parameters in both groups were not compared statistically as additives were not used.

CONCLUSION(S)

Both 0.5% Levobupivacaine and 0.5% Ropivacaine are safe and effective in patients with ESKD. Use of Ropivacaine in USG guided brachial block facilitates fast-tracking of recovery pathways with satisfactory analgesia and represents a shift towards more efficient patient centred peri-operative care (e.g., early exercise for fistula maturation, less physical dependency) in ambulatory AVF creation surgery. In contrast, Levobupivacaine provides extended analgesia which may enhance postoperative comfort but could be associated with delayed motor recovery.

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PLAGIARISM CHECKING METHODS: [\[Jain H et al.\]](#)

- Plagiarism X-checker: Feb 14, 2026
- Manual Googling: Apr 02, 2026
- iThenticate Software: Apr 04, 2026 (1%)

ETYMOLOGY: Author Origin**EMENDATIONS:** 6**AUTHOR DECLARATION:**

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

Date of Submission: **Jan 20, 2026**Date of Peer Review: **Feb 16, 2026**Date of Acceptance: **Apr 06, 2026**Date of Publishing: **Jun 01, 2026**