COMPARATIVE STUDY OF EFFECT OF REGIONAL VS LOCAL ANESTHESIA IN AVF CREATION AND IN PREDICTION OF SUCCESSFUL HEMODIALYSIS BASED ON POSTOPERATIVE FLOW RATES.

By

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Dissertation submitted to the National Board of Examinations, New Delhi.

In partial fulfillment of the requirements for the degree of

DNB Super-specialty

In

PERIPHERAL VASCULAR AND ENDOVASCULAR SURGERY

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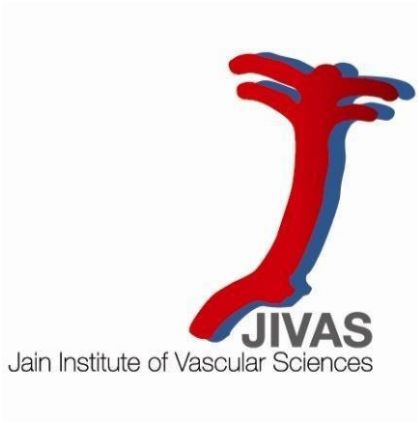
Comparative study of effect of regional vs local anesthesia in AVF creation and in prediction of successful hemodialysis based on postoperative flow rates.

Dissertation submitted to the National Board of Examinations, New Delhi, in partial fulfilment of the requirements for the award of the Diplomate of National Board in the super specialty of Peripheral Vascular Surgery



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I Dr.Pavan B K, hereby declare that this thesis entitled "**COMPARATIVE STUDY OF EFFECT OF REGIONAL VS LOCAL ANESTHESIA IN AVF CREATION AND IN PREDICTION OF SUCCESSFUL HEMODIALYSIS BASED ON POSTOPERATIVE FLOW RATES.**" is 'bonafide' in nature and was carried out by me for under the guidance and supervision of my guide Dr Vishnu M. The interpretations put forth are based on my reading and understanding of the original texts and they are not published anywhere in the form of books, monographs or articles. The other books, articles and websites, which I have made use of are acknowledged at the respective place in the text. For the present thesis, which I am submitting to the National Board of Examinations, New Delhi, no degree or diploma or distinction has been conferred on me before elsewhere.

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Abbreviations

AVF-Arteriovenous fistula

RC AVF –Radiocephalic arteriovenous fistula

BC AVF-Brachiocepahilc arteriovenous fistula

B MCV AVF- Brachio-median cubital vein arteriovenous fistula

CKD-Chronic kidney disease

ESRD-End stage renal disease

ESKD-End stage kidney disease

GFR-Glomerular filtration rate

LA-local anaesthesia

RA-Regional anaesthesia

BPB-Brachial plexus block

ABSTRACT

Background - The main treatment options for ESRD are haemodialysis, peritoneal dialysis and renal transplantation. Hemodialysis is the commonest renal replacement therapy in the management of ESKD.[3] Arteriovenous fistulas (AVFs) are the preferred hemodialysis access for such patients due to their, lower risk of systemic sepsis and of all causes of cardiovascular mortality, comparably low morbidity and fairly good long-term patency..

Objectives - To determine if the postoperative flow rates , of AV Fistula created under local vs regional anesthesia, is a predictor of successful hemodialysis function**.**.

Results – In the present study a total of 72 patients underwent AVF creation, 37 in local anesthesia group and 35 in regional anesthesia group. The mean age was 49.8 years with no significant differences in the baseline demographics and co-morbidities between the two groups.The majority of the AVFs created were left BC AVFs, 17 in each of the groups. Flow rate at 1 month was 639.85 $\pm$ 228.49 ml/min and 631.64$\pm$ 221.21ml/min among two groups and this difference was not statistically significant (p=0.884). Flow rate at 3 months was 1047.33 $\pm$ 274.96 ml/min and 990.17 $\pm$ 278.67 ml/min among two groups and this difference was not statistically significant(p=0.734).At the end of 6 months, among all the study participants, 51(70.83%) had functional AVF present. In group 1, 26 patients (70.27%) had functional AVF and in Group 2, 25 patients (71.43%) had functional AVF .This difference was not statistically significant. Of the 17 participants, who had non functional AVF at the end of 6 months, mean flow rates of 6 patients in group 1, who had patent AVF at end of 1st month was 392.28±82.99 ml/min. Of the 8 patients in group 2 , mean flow rates of 5 of these patients who had patent AVF at the end of 1st month was 431.2±52.70 ml/min.This difference was not statistically significant.

Conclusion – In this study it was found that flow rates of <480ml/min for BC AVF and <330ml/min for RC AVF at the end of 1st month showed more likelihood of non maturation and these values should be considered as markers to predict poor hemodialysis function at the end of 6 months.There was no difference of statistical significance, in effect of local anesthesia or regional anesthesia in the primary patency of AVF at the end of 6 months.

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Key words – Hemodialysis , Arterio venous fistula, local anesthesia, regional anesthesia .

INTRODUCTION

End-stage kidney disease (ESKD) occurs when the kidneys are no longer able to function at a level needed for day-to-day life.[1] The three main treatment options for ESRD are haemodialysis, peritoneal dialysis and renal transplantation.[2] Hemodialysis is the commonest renal replacement therapy in the management of ESKD. Considerable morbidity exists when dealing with vascular access (VA) creation.[3] Arteriovenous fistulas (AVFs) are the preferred hemodialysis access for such patients due to their, lower risk of systemic sepsis and of all causes of cardiovascular mortality, comparably low morbidity and fairly good long-term patency. Good quality, stable vascular access is a major factor in determining survival of these patients.[3,4,5]

General anesthesia, local anesthetics infiltrations with sedations and regional anesthesia in the form of brachial plexus block (BPB) are the three main anesthetic techniques used to conduct vascular access surgery. It has long been postulated that anaesthetic techniques may affect the rate of blood flow through AVFs and the subsequent success rate.[6] The radiocephalic arteriovenous fistula (RC-AVF) was envisioned and first created by James Cimino and Kenneth Appell respectively. It is now widely recommended as the first choice for hemodialysis vascular access.[7]

Regional anaesthesia, such as a brachial plexus block (BPB), involves injection of local anesthetic around nerves to specifically 'block' the motor and sensory nerves that supply the operative site, avoiding the need for general anaesthesia.[8] The benefits of regional block are well documented and include anesthesia of the entire upper extremity, block of motor function during the procedure, and venodilation. Regional block, unlike local anesthesia, results in reduced tissue edema resulting in improved electrocautery efficiency and reduced risk of infection. A review of the literature published in 2009 indicates better postoperative analgesia and faster recovery from anesthesia. Shorter time for surgery and reduced intraoperative pain

are also observed, compared to local anesthesia. Increased blood volume through the extremity and perioperative venodilatation, even if short-lived, may play an important role in the early remodeling of a newly formed fistula.[5]

BPB can be performed under ultra- sound guidance, allowing for more accurate placement of the injection needle as well as more rapid onset and longer duration of the block, reduced vascular and neurological complications, and minimization of the volume of local anesthetic required.[9,10] The use of this non-invasive technology to view nerve bundles while performing nerve blocks has significantly improved the success rate of the block as well as the safety of the procedure.[11,12]

Long-term functional patency is the ultimate goal of vascular access surgery, reducing both the need for further vascular access procedures and complications.[13]

Vascular surgical patients and especially those with end-stage renal disease are exposed to a high risk of preventable adverse events. Typically, a combination of organizational and technical deficiencies, human error or ineptitude and patient comorbidity leads to inadvertently poor outcome.[14] AVF is often at risk for nonmaturation, stenosis, thrombosis, infection, aneurysm formation, and steal syndrome.[3] Failure of an AVF not only interrupts a functional access but also reduces the number of sites at which another access can be made.[15]

A permanent vascular access is considered adequate when it has sufficient size (i.e. greater than 0.6 cm) for easy cannulation and a flow rate of approximately 600 mL/min for dialysis.[3]

Fistula maturation is related to pre-operative (arterial and venous diameter), post-operative (blood flow through the AVF), patient, and surgeon related factors.[16] Postoperative ultrasound measurements have been used to predict AVF clinical maturation in several small, single-center series, using brachial or radial artery, or AVF vein inner diameter measurements, and blood flow measured in varying locations of these arteries or the AVF vein, limiting comparability.[17,18]

Use of regional nerve block for dialysis access creation has been shown to increase vessel diameter and perioperative flow rates through the fistula; however, there has been much discussion about whether this translates to improved outcomes.[19]

The present study was conducted to compare the effect of regional anesthesia with that of local anesthesia in creating arteriovenous fistula and also in the prediction of successful hemodialysis based on postoperative outflow vein flow rates

Aims and objectives

Aim: to assess the effect of type of anesthesia for primary radiocephalic or brachiocephalic AVF creation on subsequent success rate of hemodialysis.

Objectives:

To determine if the postoperative flow rates , of AV Fistula created under local vs regional anesthesia, is a predictor of successful hemodialysis function**.**

MATERIALS AND METHODS

Study Setting: The study was conducted at single centre in the Department of Vascular Surgery, Jain Institute of Vascular Sciences (JIVAS), Bhagwan Mahaveer Jain Hospital, Vasanth Nagar, Bengaluru.

Study Duration: The study was conducted for a period of 16 months from November 2019 to March 2021.

Study Design: A prospective randomised comparative observational study.

Study sample: All patients presenting to the vascular surgery department aged 18 years and above with intent to create primary Radiocephalic (RC) or Brachiocephalic (BC) AVF were screened for eligibility to this trial.

Recruitment period : November 2019 – October 2020

Follow up period: October 2020-March 2021

Sample size:

Sample size was calculated using the formula:

$$n=\left(\frac{Z_{1-\alpha/2}\,\sigma}{d}\right)^2$$

σ-the standard deviation 3.32[16]

Z- Z score from the tables 2.58 at 1%level of significance

d-desired margin of error 2%

α-level of significance

n-sample size

Calculation with the above formula revealed that minimum sample size required for statistically significant results was 60.

Patients were categorized based on their residence into regional and local. 30 patients from each category were selected for the study.

Inclusion criteria:

All patients aged 18 years and above with intent to create primary RC or BC AVF.

Exclusion criteria:

- Infection at the site of creation.
- Allergy to anesthetic drugs.
- Radial artery <1.8 mm ; Brachial artery <3mm and/or cephalic vein <2 mm at the wrist or <2.5 mm at the elbow on pre-operative ultrasound*.

*Robbin ML, Chamberlain NE, Lockhart ME, et al. Comparison of arteriovenous fistulas and arteriovenous grafts in patients with favorable vascular anatomy and equivalent access to health care: Hemodialysis arteriovenous fistula maturity: US evaluation. Radiology 2002;225:59e64

Methodology:

- All patients who meet eligibility criteria were enrolled in the study.
- The study participants underwent clinical examination and preoperative AVF screening Doppler to assess the diameters of the cephalic vein/median cubital vein and radial/brachial artery and arterial peak systolic velocities.
    - Study group 1: patients undergoing AVF creation under Local anesthesia
    - Study group 2: patients undergoing AVF creation under regional anesthesia

For Group 1, the local infiltration group, the surgical site was infiltrated with local anesthetic agent subcutaneously.

In group 2, patients received ultrasound guided supraclavicular brachial plexus block .

Standardized surgical technique was employed with minimal dissection of the radial/brachial artery and cephalic/Median cubital vein with an end to side or side to side anastamosis.

Flow rates and vessel diameters were assessed at the end of 1 and 3 months to compare whether AVFs created in regional or local anaesthesia have better patency in terms of flow rates.

Definition:

AVF maturity will be defined as an average cephalic luminal diameter of 4 mm and outflow vein blood flow rate of 500 mL/min via color doppler at the end of 4 weeks[5].

Follow up :

Postoperative doppler were performed at 1 and 3 months and the flow rate readings were measured in the arterialized cephalic vein 5 cms proximal to the AVF site.

Ethical Consideration

Ethical clearance was taken from Ethical Committee of Bhagwan Mahaveer Jain hospital, Bengaluru, before conducting the study. Patients were provided with the patient information sheet and informed consent of the patients was obtained prior to the procedure.No additional financial burden was incurred by the patient.

Statistical Analysis

The data was entered in excel spread sheet and analysis was done using IBM SPSS Version 23.0 software (SPSS, Chicago, Illinois).

Normally distributed data means was compared by using Student's t-test.

For skewed data or for scores, a Mann–Whitney test was applied for the two groups.

A p-value of less than 0.05 was considered to be statistically significant

REVIEW OF LITERATURE

End stage renal disease:

Patients with end-stage renal disease and its comorbidities have a high risk of suffering adverse events during their continuous treatment as in- or outpatients. Furthermore, dialysis access creation and maintenance are prone to complications.

Kidney failure is becoming increasingly common and is associated with poor health outcomes and high medical expenditures

CKD is kidney damage for 3 or more months, as defined by structural or functional abnormalities of the kidney, with or without decreased glomerular filtration rate (GFR), manifested by pathologic abnormalities or markers of kidney damage, including abnormalities in the composition of the blood or urine or abnormalities in imaging tests or GFR <60 ml/min/1.73 m^2 for 3 months or more, with or without kidney damage.

Progression of CKD toward end-stage renal disease (ESRD) is common in CKD patients, and once significant impairment of renal function has occurred, it tends to progress irrespective of the underlying kidney disorder.

It is important to identify patients who may eventually require renal replacement therapy since adequate preparation can decrease morbidity and perhaps mortality. Early identification enables dialysis to be initiated at the optimal time with a functioning chronic access.[14]

Hemodialysis:

The first dialysis treatment on a human was performed in October 1924 by the German physician Georg Haas. Dialysis was performed for 15 minutes as an attempt to prevent a boy from dying of uraemia. The next ground-breaking step in history was when the physicians Brescia, Cimino and Apell developed the AV-fistula in the mid- 1960s. By surgical ligation, they transposed a cephalic vein to the radial artery of the lower arm by a side-to-side technique.[20]

CKD is considered a public health problem worldwide and about 50 million people suffering from chronic kidney disease worldwide. African Americans, American Indians, Hispanics, and South Asians, specifically, people from Pakistan, Sri Lanka, Bangladesh, and India, are at great possibility of experiencing CKD.[21]

The three principal forms of chronic hemodialysis access are arteriovenous (AV) fistulas, AV grafts, and hemodialysis catheters.[22,23]

Dialysis access procedures, from central venous catheter insertion to arteriovenous fistula and grafts placement, are performed in patients with different degrees of renal insufficiency, including patients with acute kidney injury (AKI) and chronic kidney disease (CKD) in different stages.[14]

Hemodialysis access is most commonly attained using vessels in the upper extremities. The lower extremity is a less commonly used initial access site.[24]

Arteriovenous fistula:

Arteriovenous fistula (AVF) is an established term to characterize a special kind of vascular access in patients on hemodialysis. An AVF is defined as an autogenous anastomosis between an artery and a vein.[25]

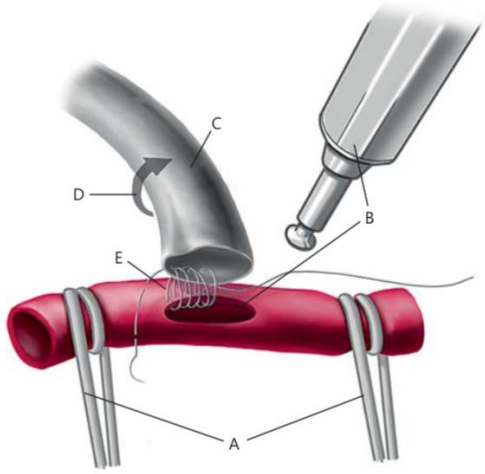


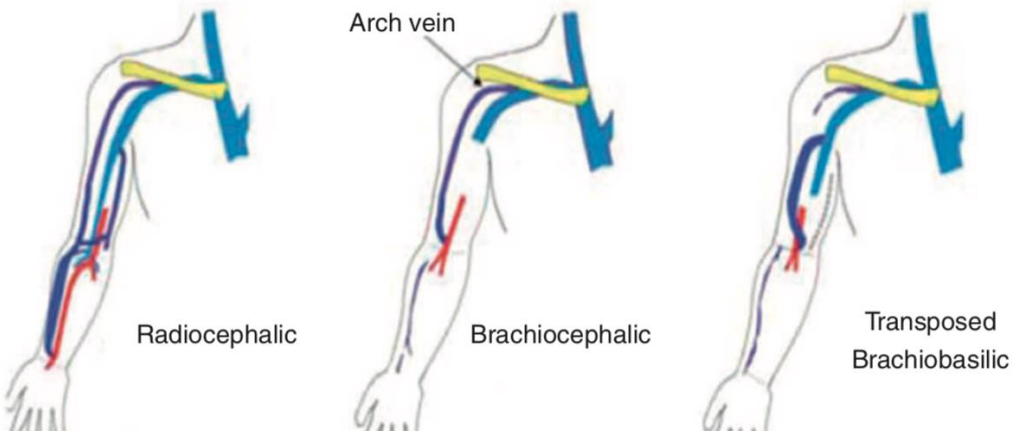
Fig. 2. Safe creation of an arteriovenous anastomosis. A = Control of inflow and outflow using clamps, vessel loops or tourniquets; B = incision of the artery and creating round ends using a punch; C = instillation of heparinized saline solution to check the outflow of the vein and enlarge the vein so it can be marked; D = mild outward rotation of the vein; E = running suture inside artery out in parachute technique.

Arteriovenous fistulas remain the preferred form of dialysis vascular access due to their superior long-term patency and lack of infection.

The AV-fistula (AVF) is, in normal circumstances cannulated with two separate needles, each one connected with a hose to the extracorporeal circuit and pump-system on the dialysis machine. Through this bloodline system, the blood is pumped from the arterial needle placed in the AVF, through a dialysis filter (dialyser) of the dialysis machine and returned via the second needle to the venous circulation at the arm of the patient. Within the filter, uremic blood meets balanced salt and ultra clean water (dialysate), and there the exchange of waste products into the dialysate as well as removal of excess water (ultrafiltration) occurs.[20]

These may be formed by any artery and vein but the most common types are:

- Radiocephalic: This is often the preferred first line and preserves proximal locations for later use.
- Brachiocephalic: It is more proximal and therefore higher flow could be achieved.
- Brachiobasilic transposition: This type is more difficult to create. Due to relative inaccessibility and therefore reduced frequency of prior access, vein may be better preserved at formation of fistula. Often used after multiple failed distal fistulas. And has the highest risk of steal syndrome.[26]



Common upper limb AV fistula

The main disadvantage of AVFs is a very high incidence of maturation failure, which is defined as the inability to use the AVF for dialysis due to inadequate flow and diameter, likely due to a combination of neointimal hyperplasia and inadequate outward remodeling in the perianastomotic region.[27,28]

A long period of AVF maturation, however, often results in risks of infection, thrombosis and central vein stenosis.[29,30]

<u>Anesthetic techniques in AVF creation</u>

Local anesthetics (LA) are indispensable in contemporary regional anesthesia and pain management. Introduced in Western medicine in the late 19th century, the prototype substance cocaine had been widely used by South American cultures for thousands of years.[31]

The discovery of the topical numbing properties of cocaine led to the development of regional anesthesia in its modern form, with the basic principle that injection of cocaine next to nerves produces a transient and reversible interruption of pain propagation, sensory and motor function.

The introduction of the first short-acting amide-type local anesthetic, lidocaine, in 1947, and the standard long-acting amide-type local anesthetic, bupivacaine, were pharmacological milestones in regional anesthesia.[32]

Stephan Kapral and Peter Marhofer described the guidance of the regional anesthesia needle by ultrasound, sparking renewed interest in regional anesthesia techniques.[33]

The majority of AVFs in the forearm or in the antecubital fossa can easily be performed under local anaesthesia using lidocaine or bupivacaine. Regional anaesthesia such as axillary or brachial block takes more time and usually requires the services of an experienced anaesthetist but has the advantage of causing significant vasodilatation, which some surgeons find helpful and increases the proportion of distal AVFs in their hands. [34,35]

Although local, general or regional anesthesia are acceptable modalities for arteriovenous fistula formation, the accumulation of evidence suggests that regional anesthesia in the form of a brachial plexus block is associated with significantly increased blood flow through the arteriovenous fistula as well as higher primary functional rates in the first 3 months compared with local anesthetic infiltration.[36]

Moukuet et al indicated a significant increase in blood flow in the brachial artery after block

anesthesia, compared with local anesthesia.[37]

Predictors of successful hemodialysis

A multitude of factors has been identified to affect patency of AVF. Results from a recent review show that nonmodifiable patient factors such as age, diabetes, peripheral vascular disease, predialysis hypotension and vessel characteristics (<2 mm diameter, reduced distensibility) negatively influence patency. When it comes to modifiable factors, smoking, early referral, ultrasound imaging, anastomosis type, vascular staples/clips, flow assessments, antiplatelet therapy, and timing of first cannulation have an effect on patency. Systemic heparin use, cannulation technique and fistula surveillance do not alter the rate of fistula patency according to latest data.[38]

AVF maturation can be predicted by intraoperative blood flow measurement. Low flow calls for immediate revision. Minimal flow values needed for radiocephalic fistulae are 120 ml/min and for brachiocephalic fistulae 310 ml/min. When reaching these values during fistula creation, one can expect maturation.[39]

Prolonging the patency and limiting the complications of a functioning hemodialysis (HD) access require a multidisciplinary approach.[20]

Kelsey Gray, MD et al., conducted a retrospective study titled between January 2011 and June 2016 to assess radiocephalic fistula creation, rate of early thrombosis and clinical maturation in patients with radiocephalic fistula. Results showed that 2.8% had early thrombosis and 91.3% achieved maturation. There were 14.9% patients that received regional anesthesia and 85.1% that received local anesthesia. There was no difference between local and regional anesthesia in the rate of early thrombosis (2.7% vs 3.3% p=0.7) or maturation (91.5% vs 90.0% p=0.6). There was also no difference between the groups in radiocephalic fistula creation (28.7% vs 22.2% p=0.2). Despite the promising physiologic changes observed with the use of a

regional nerve block for dialysis access creation, there is no improvement in rate of early thrombosis or clinical maturation when compared to local anesthesia.[40]

A meta analysis conducted by Chen Gao et al., demonstrates that regional anesthesia is associated with higher AVF primary patency rates and improved local blood flow compared with local anesthesia. It was also observed that operation duration and the use of painkillers was significantly reduced with regional anesthesia versus local anesthesia. The authors concluded that BPB anesthesia techniques in AVF construction could contribute to vessel dilation and reduced vasospasm via sympathectomy-like effects, increasing fistula blood flow, reducing fistula maturation time, and improving the success rates of vascular access procedures.[41]

Sahin L, et al., conducted a study in 2011 to compare the effects of ultrasound-guided, infraclavicular brachial plexus block and local infiltration anesthesia on blood flow in the radial artery and AVF during the early and late postoperative periods. After anesthesia, preoperative radial arterial flow was 56 ± 8.6 mL/min in the patient group who were given infraclavicular brachial plexus block vs 40.7 ± 6.11 mL/min in control group ($P < .0001$). Blood flow in the fistula, measured in mL/min at 3 hours, 7 days, and 8 weeks postoperatively, was also greater in the group that received infraclavicular brachial plexus block. Further the study concluded that BPB provides higher blood flow to the radial artery and AVF compared to infiltration anesthesia.[42]

A study conducted by Elizabeth B Malinzak and Tong J Gan suggested that use of a regional block, compared with other anesthetic techniques, resulted in significantly increased fistula blood flow in the intraoperative and postoperative periods. The greater sympathetic block contributed to vessel dilation and reduced vasospasm. Use of regional techniques in AVF construction yielded shorter maturation times, lower failure rates, and higher patency rates.[43]

W H Nofal et al., conducted a study in 2017 to compared ultrasound-guided axillary brachial plexus block versus local infiltration anesthesia for arteriovenous fistula creation at the forearm for hemodialysis in patients with chronic renal failure. The study showed that there were significant increases ($P < 0.05$) in the AVF blood flow in the AxBP block group compared to local infiltration group. However, the primary failure rate between the groups did not show a difference that is statistically significant.[44]

In a study by Reynolds et al. aimed to assess the effect of regional block anesthesia on vein diameter, type of AVF placement, and fistula size and flow volume, the rate of native AVF placement was found to improve from 89% to 93% with regional block and concluded that the vein diameter increases significantly in the basilic and cephalic veins following regional block anesthesia and may improve the rate of native fistula placement. However, propensity to dilate after regional block anesthesia does not predict size of the fistula.[45]

A systematic review and meta-analysis was conducted by R Cerneviciute et al. in 2017 to assess the effect of anaesthesia type for autologous primary radiocephalic or brachiocephalic AVF creation on subsequent fistula failure rates. The results showed that there was a significantly lower failure rate with regional anesthesia compared with local anaesthesia (OR 0.28, 95% CI 0.14-0.57) among patients undergoing primary forearm AVF formation for haemodialysis.[46]

A research study conducted by António Pedro da Silva Pinto Gomes of Lisbon Medical School in 2018 suggests that presence of a temporary catheter or a long-term catheter for vascular access was a risk factor for AVF surgery due to venous drainage obstruction, pro-thrombotic, inflammatory and infectious milieu or association (confounding) with blood pressure liability and post-dialytic hypotension. The study also showed that immediate pre- operative systolic blood pressure was an independent predictor of AVF patency at 48h, with an optimized cut-off of 154mmHg. Vein diameter with tourniquet was an independent predictor of 6 weeks and 12 weeks AVF success with an optimized cut-off of 3.9mm.[47]

Emma Aitken et al. 1n 2020 conducted an observer-blinded randomized controlled trial at three university hospitals in Glasgow, United Kingdom to study the effects of regional versus local anesthesia on longer-term AVF patency. At 12 months, it was found that higher primary patency among patients receiving regional versus local anesthesia (79%] versus 59%) patients with an odds ratio of 2.7; 95%; as well as higher functional patency (68% versus 49%) patients (OR, 2.1; 95% CI, 1.5 to 2.7; P50.008). Results were robust after extensive sensitivity and scenario analyses. It was further concluded that compared with local anesthesia, regional anesthesia significantly improved both primary and functional AVF patency at 1 year and is cost-effective.[13]

In a prospective study conducted by Eric Pillado et al., it was noted that an RC-AVF flow rate of 400 mL/min in the first month predicted more successful HD than low flow (<400 mL/min) (81% vs. 62%). Without intervention, low flow rates did not improve significantly and maturation was unlikely. The authors recommended imaging for all patients at 30 days to identify and promptly correct stenosis in those with low flow rates.[48]

A randomized controlled trial conducted by Laura M. Dember et al. in 2016 showed that fistula thrombosis occurred in 12.2% participants assigned to clopidogrel compared with 19.5% participants assigned to placebo (relative risk, 0.63; 95% confidence interval, 0.46–0.97; P = .018). and it was concluded that clopidogrel reduces the frequency of early thrombosis of new arteriovenous fistulas but does not increase the proportion of fistulas that become suitable for dialysis.[49]

Yong Pey See et al. conducted a multi-center, double-blind, multinational, randomized placebo-controlled trial in 2020 evaluating the effect of fish oil and/or aspirin in preventing AVF failure in patients receiving hemodialysis. On univariable logistic regression, female sex, older age,

non-Malaysian region of recruitment, absence of hypertension, lower DBP and mean arterial pressure, higher parathyroid hormone level and open labelled (i.e. medically required) aspirin use were statistically significantly associated with increased odds of AVF failure. The association between female sex and higher risk of AVF failure was also reported previously.[50]

Benjamin Gavish and Joseph L Izzo Jr in 2016 suggested that lower diastolic pressure may lead to venous stasis thereby predisposing to early AVF thrombosis and may also reflect reduced vascular compliance associated with a wider pulse pressure, both impairing vascular remodelling and maturation. [51]

A review article by Radojica V. Stolić et al. in 2021 suggests that regional block anesthesia provides reduced vasospasm of blood vessels, provokes venodilatation and complete sensory and blockade of motor neurons, which affects the increase in flow rate, and of initial functioning of the arteriovenous fistula. Further, the authors concluded that the choice of anesthesia method is determined by several interrelated factors, anesthesiologist, patient and the surgeon, which implies expertise, inclination, habits, practicality, and norms.[5]

'Clinical aspects of Arteriovenous Fistula use in a haemodialysis population'-Results based on retrospective and interventional studies by Anna Wärme concluded that the AVF patency among HD patients is limited. Risk factors for AVF dysfunction are high doses of ESA (Erythropoiesis stimulating agent) and iron and for arterial lesions those with diabetic nephropathy and interstitial nephritis. FIR (Far Infrared illumination) light may improve the maturation and patency of the AVF as prevention, and readiness for repeated radiological interventions helps to prolong AVF patency.[20]

Shyam Meena et al. conducted a randomized controlled trial in 2015. It was shown that primary patency rate was 100% in the brachial plexus block group whereas there was 10% fistula failure rate in the local infiltration group (p-value = 0.237). Diameter of the vessels, peak systolic velocity, mean diastolic velocity, and blood flow at 30 minutes, 48 hours, 2 weeks, and 6 weeks after the fistula creation was significantly greater than the preoperative diameter in all patients (p-value < 0.05). Intergroup comparison revealed that vascular parameters were significantly better in the brachial plexus analgesia group versus local infiltration group at all observation points up to and including six weeks post fistula creation (p-value < 0.05). Thus it was concluded that brachial plexus anaesthesia significantly dilates the vessel diameter and increases blood flow whereas local infiltration has a negligible effect on vessel diameter and blood flow.[2]

A retrospective study conducted by Mbengono Junette Arlette et al. at the anaesthesiology and haemodialysis units of Douala General Hospital among patients with primary AVF creation surgery between January 2015 and December 2018 showed a significant association between the type of anaesthesia and the proportion of patients who had a primary patency six weeks after the operation was found (83.8% for USRA and 63.9% for GA; p = 0.006). The patency three months after the surgery was significantly associated with the type of anaesthesia (USRA 82.3% vs GA 55.4%; p < 0.004). Regarding the complications encountered, only thrombosis was significantly associated with the anaesthesia type. Significantly fewer patients in the USRA group suffered from thrombosis than in the GA group.[26]

In a prospective, randomized single-center clinical trial by Subin Heo et al. in 2019 to evaluate the efficacy and safety of the ultrasound-guided supraclavicular brachial plexus block (BPB) during angioplasty of dysfunctional arteriovenous access, the BPB group showed a lower average pain score than the control group (mean ± SD, 0.9 ± 1.9 vs 6.4 ± 2.5; P < .001). Participant satisfaction (mean ± SD, 2.8 ± 0.5 vs 2.1±0.8; P < .001) was also higher in the BPB group. Six-month patency was 65% in the BPB group and 59% in the control group, with no

significant difference between the 2 groups. No major immediate or delayed complications were observed. Further it was concluded that ultrasound-guided BPB is highly effective in reducing pain during angioplasty of dysfunctional arteriovenous access with an acceptable safety profile.[53]

Michelle L. Robbin et al. conducted a seven-center prospective cohort study between March 2010 and August 2013. At each ultrasound measurement time, AVF blood flow, diameter, and depth each predicted in a statistically significant manner both unassisted and overall clinical maturation. Neither the remaining ultrasound parameters nor case-mix factors were associated with clinical AVF maturation after accounting for blood flow, diameter, and depth, although maturation probabilities differed among clinical centers before and after accounting for these parameters. It was concluded that AVF blood flow, diameter, and depth moderately predicted unassisted and overall AVF clinical maturation. The other factors considered did not further improve AVF maturation prediction.[54]

Mohamed A. Elsharawy and Roshdi Al-metwalli conducted a prospective study between September 2004 and September 2007 to assess the effect of regional anesthesia on the outcome of elbow arteriovenous fistula (AVF). There were no instances of systemic toxicity, hematomas, or nerve injury from the regional block. No major complications were reported from the general anesthesia. There was no significant difference between both groups regarding early failure of AVF (P= 0.80). No significant advantage of regional over general anesthesia in terms of early outcome of AVF was seen in this study.[55]

Harold I Feldman et al. conducted a prospective cohort study with 348 hemodialysis patients receiving an AVF and followed them until ascertainment of successful AVF maturation. A total of 55.5% of AVFs successfully matured. A history of stroke or transient ischemic attack,

increasing age, and dependence on dialysis at the time of access placement were associated with lower probabilities of maturation. Of potentially modifiable variables, maturation was associated with greater intraoperative doses of heparin, use of large-diameter veins, and mean arterial pressure of 85 mm Hg or greater. Using optimal surgical technique, the probability of successful AVF maturation would have been as high as 84%. A predictive logistic regression model had moderate ability to predict AVF maturation under optimal surgical therapy with an area under the ROC curve of 0.69. It was concluded that surgical technique potentially may be modified to yield a greater probability of successful AVF maturation. Predictive probabilities of successful AVF maturation under optimal surgical technique reinforce the view that functioning AVFs can be achieved in a large proportion of hemodialysis patients, consistent with experience in selected regions of the United States and abroad.[56]

A comparative study was conducted by Naida M Cole et al. The National Surgical Quality Improvement Project database was accessed to identify a cohort of 3199 patients undergoing arteriovenous fistula surgery from 2007 to 2015. Patients who received regional anesthesia had the shortest postoperative length of stay compared to monitored anesthesia care/intravenous (IV) sedation and general anesthesia. Administration of regional anesthesia was associated with a shorter length of stay compared to general anesthesia (odds ratio [OR]: 0.55, P = .001). Patients who received monitored anesthesia care/IV sedation had a lower risk of reoperation compared to general anesthesia (OR: 0.65, P = .012) but not compared to regional anesthesia (OR: 0.89, P = .759). Anesthesia type had no significant effects on other measured postoperative complications. Predictors of the type of anesthesia were age and surgical procedure (P < .001). Further, the study concluded that use of regional anesthesia is associated with a shorter postoperative length of stay after arteriovenous fistula surgery and lower risk of reoperation compared to general anesthesia or monitored anesthesia care/IV sedation. Regional

anesthesia may be an excellent choice for arteriovenous fistula surgery to reduce postoperative length of stay and risk of reoperation.[57]

Emma Aitken et al. in a larger trial randomly assigned 126 adults receiving primarily radiocephalic or brachiocephalic fistulas to local anesthesia (0.5% L-bupivacaine and 1% lidocaine injected subcutaneously) or brachial plexus block anaesthesia (0.5% L-bupivacaine and 1.5% lidocaine with epinephrine). For the entire group, primary patency at three months was significantly higher in the brachial plexus block group compared with local anaesthesia. Assisted primary patency and secondary patency rates were not reported, but initial patency has been correlated with improved outcome. No complications related to brachial plexus block occurred in this study. Further, the authors concluded that compared with local anaesthesia, BPB significantly improved 3 month primary patency rates for arteriovenous fistulae.[58]

RESULTS

In our study, 72 patients underwent AVF creation. For 37 participants (Group 1) local anesthesia (LA) was given and for 35 participants (Group 2) regional anesthesia was given.

Table 1: Socio-demographic characteristics of study participants

VARIABLE		Group 1(LA) N=37	Group 2(Regional) N=35	Total N=72	
AGE	21-30 yr	2 (5.41%)	1 (2.86%)	3 (4.16%)	0.429
	31-40 yr	3 (8.11%)	5 (14.28%)	8 (11.11%)	
	41-50 yr	8 (21.62%)	13 (37.14%)	21(29.17%)	
	51-60 yr	13 (35.13%)	10 (28.57%)	23 (31.95%)	
	>60 yr	11 (29.73%)	6 (17.15%)	17 (23.61%)	
Mean age(SD)		52.54(12.45)	50.37(11.71)	51.49(12.06)	0.449
Mean Hemoglobin		9.32(1.02)	9.30(1.01)	9.31(1.01)	0.51
Gender	Female	10 (27.03%)	13 (37.14%)	23 (31.95%)	0.358
	Male	27 (72.97%)	22 (62.86%)	49 (68.05%)	
Diabetes mellitus	yes	24 (64.86%)	21 (60%)	45 (62.5%)	0.67
	no	13 (35.14%)	14 (40%)	27 (37.5%)	
Ischemic heart disease	yes	9 (24.32%)	5 (14.28%)	14 (19.45%)	0.28
	no	28 (75.68%)	30 (85.72%)	58 (80.55%)	
Hypertension	yes	23 (62.16%)	22(62.86%)	45 (62.5%)	0.95
	no	14 (37.84%)	13(37.14%)	27 (37.5%)	

Figure 1: Bar graph showing age distribution

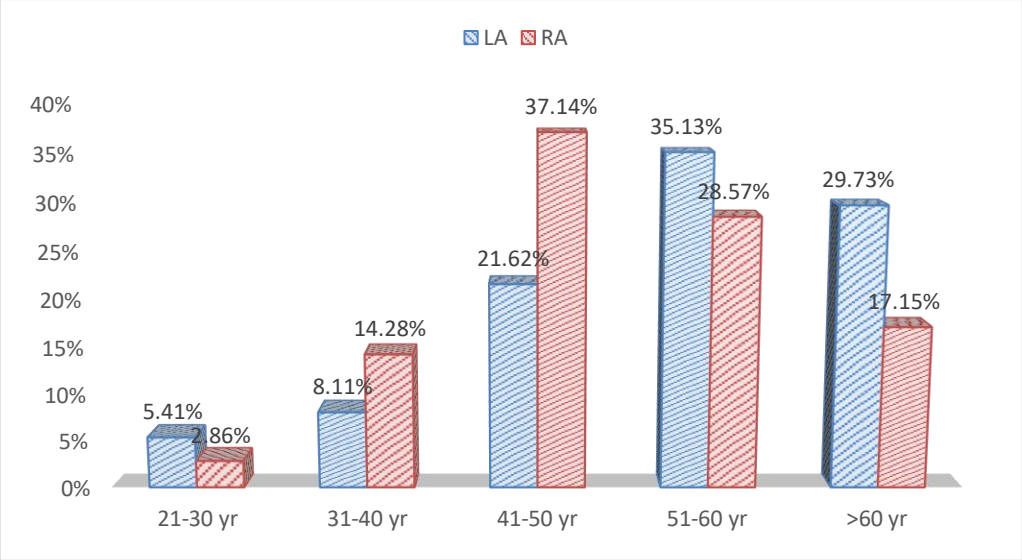
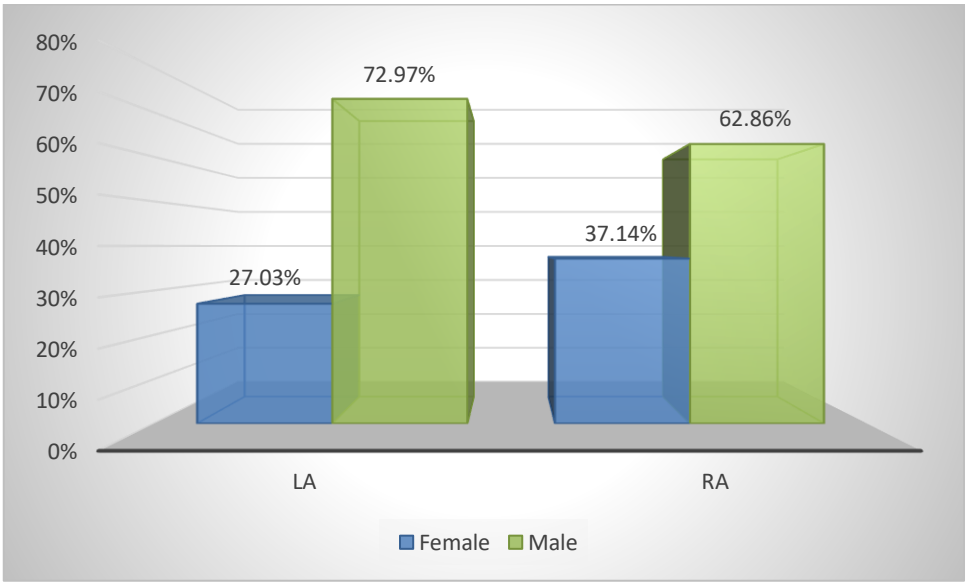


Figure 2: Bar graph showing sex distribution

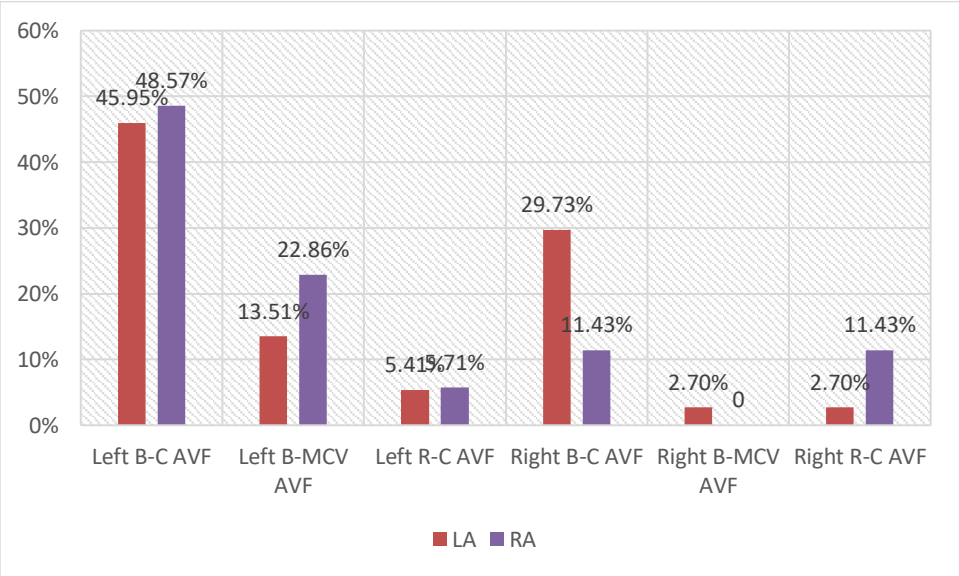


Among 72 study participants, majority belonged to the age group of 51-60 years (31.95%) followed by 41-50 years (29.17%). Mean age was 51.49 years with SD of 12.06 years. Among these study participants most of them were males (68.05%). 45(62.5%) had history of diabetes and hypertension. 14 patients (19.45%) had history of ischemic heart disease. (Table 1)

Table 2: Site and type of fistula created for the study participants

	Group 1(LA) N=37	Group 2(Regional) N=35	Total N=72
Left B-C AVF	17 (45.95%)	17 (48.57%)	34
Left B-MCV AVF	5 (13.51%)	8(22.86%)	13
Left R-C AVF	2 (5.41%)	2 (5.71%)	4
Right B-C AVF	11 (29.73%)	4 (11.43%)	15
Right B-MCV AVF	1 (2.70%)	0	1
Right R-C AVF	1 (2.70%)	4(11.43%)	5

Figure 3: Bar chart showing site and type of fistula



Among the participants for whom local anesthesia was given, for 17(45.95%) participants left B-C AVF was created and for 11 (29.73%) right B-C AVF was created. Whereas for whom regional anesthesia was given, 17(48.57%) had left B-C AVF followed by left B-MCV AVF.

Table 3: Comparison of Doppler findings between the groups

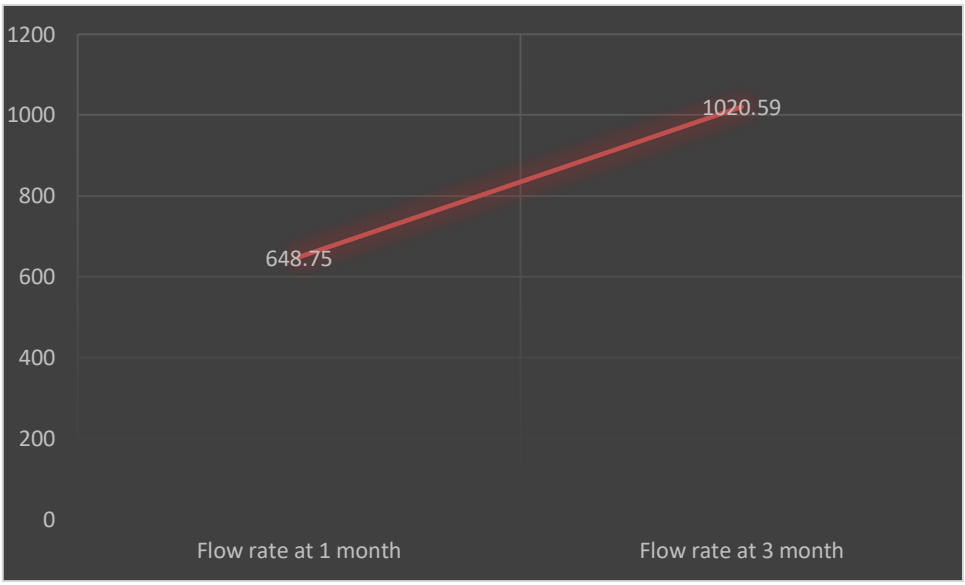
	Group 1(LA) N=37	Group 2(Regional) N=35	P value
Pre-op cephalic vein diameter(mm)(at elbow)	2.87(0.49)	2.83(0.45)	0.729
Pre op cephalic vein diameter(mm)(at wrist joint)	2.08(0.26)	2.01(0.28)	0.628
Pre-op brachial artery diameter(mm)	4.14(0.84)	4.14(0.89)	0.988
Outflow vein peak systolic velocity at 1 month(cms/sec)	59.44(5.78)	58.00(8.41)	0.421
Outflow vein diameter at 1 month(cms)	0.50(0.05)	0.48(0.06)	0.259
Flow rate at 1 month(ml/min)	639.85(228.49)	631.64(221.21)	0.884
Outflow vein peak systolic velocity at 3 month(cms/sec)	61.36(5.40)	61.62(7.16)	0.873
Outflow vein diameter at 3 month(cms)	0.59(0.07)	0.57(0.06)	0.347
Flow rate at 3 month(ml/min)	1047.33(274.96)	990.17(278.67)	0.42

AV fistula was created for hemodialysis. Pre-operatively distal arm cephalic vein diameter was measured, in group 1 where local anesthesia was given mean diameter was 2.87mm with SD of 0.49 which was almost same in group 2 i.e 2.83 $\pm$ 0.45mm. Brachial artery diameter among two groups was 4.14 $\pm$ 0.84mm and 4.14 $\pm$ 0.89mm respectively.Radial artery diameters wwre 2.4±0.34 and 2.2±0.52. After fistula creation outflow vein diameter at 1 month among two groups was 0.50 $\pm$ 0.05mm and 0.48$\pm$ 0.06mm respectively. Flow rates were measured at 1 month and 3 month after surgery. Flow rate at 1 month was 639.85 $\pm$ 228.49 ml/min and 631.64$\pm$ 221.21ml/min among two groups and this difference was not statistically significant. (p=0.884) Flow rate at 3 month was 1047.33 $\pm$ 274.96 ml/min and 990.17 $\pm$ 278.67 ml/min among two groups and this difference was not statistically significant.(p=0.734)

Table 4: Comparison of flow rates at 1 month and 3 months among study participants.

	Mean(SD)	p value
Flow rate at 1 month	648.75(219.37)	<0.01
Flow rate at 3 month	1020.59(275.92)	

Figure 4: Line graph showing flow rates at 1 month and 3 months

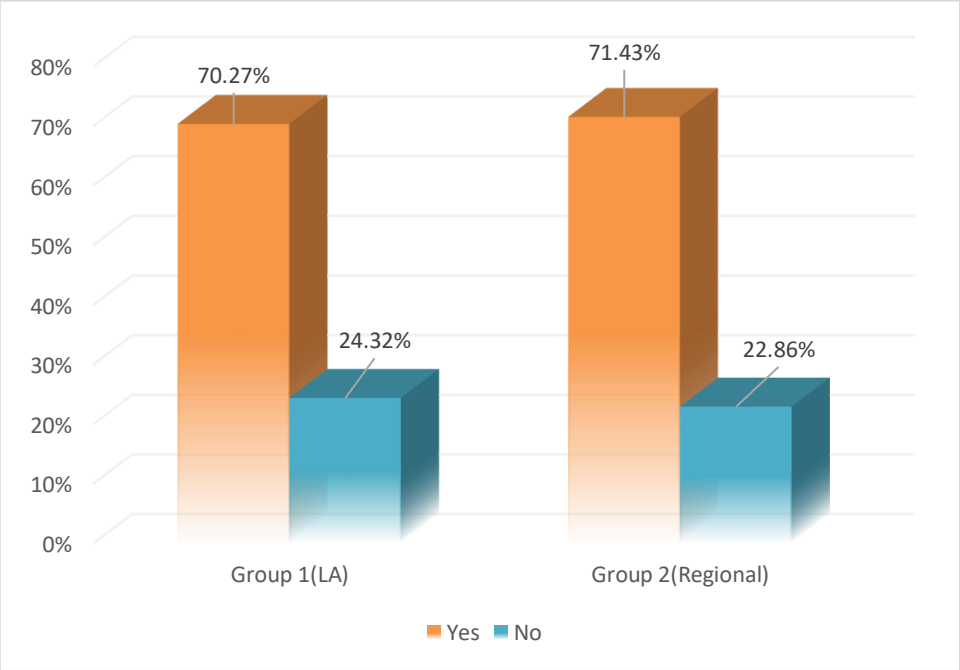


Flow rates were measured at 1 month and 3 months after follow up. It was found that at 1 month mean flow rate among patients with patent AVF was 648.75 ± 219.37 ml/min and at 3 months it increased to 1020.59± 275.92ml/min. This difference was statistically significant ($p<0.01$).

Table 5: Functional AVF at the end of 6 months among study participants

Functional AVF at the end of 6 months	Group 1(LA) N=37	Group 2(Regional) N=35	Total	p value
Yes	26 (70.27%)	25 (71.43%)	51 (70.83%)	0.771
No	9 (24.32%)	8 (22.86)	18 (25%)	
Mortality*	2 (5.41%)	2 (5.71%)	3 (4.17%)	

Figure 5: Bar graph showing Functional AVF at the end of 6 months



Among all the study participants 51(70.83%) had functional AVF present. Among group 1, 26(70.27%) had functional AVF and in group 2, 25(71.43%) had functional AVF. This difference was not statistically significant.

Among all the participants the cut off value of flow rates at the end of one month for BC AVF is 519 ml/min at 100% sensitivity and 90% specificity. Cut off value of flow rates at the end of one month for RC AVF is 415 ml/min at 100% sensitivity and 100% specificity.Of the 17 participants, who had non functional AVF at the end of 6 months, mean flow rates of 6 patients in group 1, who had patent AVF at end of 1st month was 392.28±82.99 ml/min. Of the 8 patients in group 2 , mean flow rates of 5 of these patients who had patent AVF at the end of 1st month was 431.2±52.70 ml/min.This difference was not statistically significant.

DISCUSSION

AVF is considered to be the preferred mode of hemodialysis access with relatively lower morbidity and mortality rates.[59,60] Patients with chronic kidney disease frequently demonstrate arterial narrowing and calcification, especially in the presence of diabetes and hypertension.[61] Many factors could affect the outcome of AVF, such as old age, female gender and underlying diseases like diabetes, hypertension, peripheral vascular diseases, or coronary artery diseases.[38]

Advanced age is assumed to be a risk factor for AVF failure. However, most studies are not consistent in the definition of advanced age. It was noted that distal AVF has a greater likelihood of being unsuccessful in an elderly population.[62,63] In our study majority of the subjects belonged to the age group of 51-60 years followed by 41-50 years and the mean age was 51.49 years. Similar findings were reported by Mittal et al.,[64] and Agarwal[65] for patients with chronic renal failure.

The association between female sex and higher risk of AVF failure has been reported previously.[67,68,69,70]

However the biological process underpinning this observation remains uncertain. In our study, most of the particicpants were male, 62.5% of them had history of diabetes and hypertension. Of the 17 patients who had a non functional AVF at the end of 6 months, 6 were female patients. A previous study reported that there were no relationship between duration of maturation period and diabetes mellitus, sex and age.[8] This was a similar finding in our study also. In the present study 4 patients had expired at the time of 6 months follow up.17 of the 72 patients had a non functional AVF at the end of 6 months,8 in the group who received local anesthesia and 9 in the group,where regional anesthesia was given.This difference was not statistically significant.

In our study, 93 patients underwent AV access surgeries during the study period, of which 72 patients were included in the study and 21 patients were excluded in view of non fulfillment of inclusion criteria. Left brachiocephalic fistula was the commonest of all the AVF procedures performed, so as to use the non dominant hand for AV access ,as is the protocol adopted by several practicing vascular surgeons. BC AVF was mostly done due to the poor caliber of the cephalic vein in the distal forearm. RC AVF was done in 9 of the 72 patients(12.5%).

Impaired blood flow as a result of local handling of vessels and enhanced sympathetic nervous system activity makes the vascular surgical procedures prone to vessel occlusion[70] which is of particular significance in ESRD patients undergoing vascular surgery because of underlying arterial calcification and/or narrowing.[71] One of the major determinants of success of an AVF is adequacy of blood flow in the perioperative period.[72]

AVF blood flow, diameter, and depth could moderately predict the unassisted and overall AVF clinical maturation.[54] In this study standardized surgical technique was employed with minimal dissection of the radial/brachial artery and cephalic vein with an end to side anastamosis.

A recent study reported that BPB would provide higher blood flow to the radial artery and AVF[42] given the sympatholytic effect, producing significant vasodilatation, decreased vascular resistance,[43] and increased local blood flow, seen more in the immediate peri operative period. In the present study, there was no statistical significance between the groups with LA and RA with respect to flow rate at 1 month and at 3 months, which shows that the immediate short term effects that regional blocks might offer do not necessarily translate to improved long term patency and flow rates. In the present study, at the end of 6 months follow up there were 17 patients with non functional primary AVF , 8 in the local anesthesia group and 9 in the regional anesthesia group, which goes on to further prove that the beneficial effects of regional blocks , might be short lived and has no additional beneficial effect in the long term when compared to AVFs created under local anesthesia.

Malovrh and colleagues reported a mean preoperative flow rate of 54.5 ml/min in vessels with a successful outcome and a mean flow rate of 24.1 ml/min in those that failed[73]Lock- hart et al. found no differences in AVF maturity considering preoperative artery and vein diameters or radial artery flow rates greater or less than 500 mL/min.[48] In contrast, results of the present study indicate that the outflow vein diameter and flow rates at the end of 1 month can better predict the outcome.Venous diameter is found to be a consistent predictive factor of AVF quality. The minimal venous diameter value predictor of radiocephalic fistulas success is 2.5mm and a mean venous diameter of 2.2mm has been associated to the failure of proximal AVF (p=0.001).[74,75,57]

Study by Pillado E et al.[48] found that the cutoff for blood flow rate could be lowered to 400 mL/min where those with 400 mL/min had similar successful fistula maturation compared with those with 500 mL/min in a prior study. Blood flow rate of 350 mL/min is considered the lowest a fistula could have to support successful HD without collapsing.[2] Cut off value of flow rates in our study at the end of one month for BC AVF is 519 ml/min at 100% sensitivity and 90% specificity and the cut off value of flow rates at the end of one month for RC AVF is 415 ml/min at 100% sensitivity and 100% specificity. In our study, at 6 months follow up, 51 patients had functional AVF, who had flow rates of 639.85 $\pm$ 228.49 ml/min and 631.64$\pm$ 221.21ml/min ,at the 1st month,among two groups and this difference was not statistically significant. (p=0.884) Flow rate at 3 month was 1047.33 $\pm$ 274.96 ml/min and 990.17 $\pm$ 278.67 ml/min among two groups and this difference was not statistically significant.(p=0.734).In contrast to the study by Pillado et al,in our study the cut off value of flow rate to better predict the

likelihood of maturation was at a higher value close to 5ooml/min as compared to 400ml/min quoted by them.

In our study it was found that amongst the patients with non functional AVFs at the end of 6 months: Out of 9 patients in local anesthesia group, mean flow rates of 6 patients who had patent AVF at end of 1st month with was 392.28±82.99 ml/min, however these patients had occluded AVFs on subsequent follow up visits. The other 3 patients had occluded AVF before the 1st month .Out of 8 participants in regional anesthesia group, mean flow rates of 5 patients who had patent AVF at the end of 1st month was 431.2±52.70 ml/min. This difference was not statistically significant. These flow rates when considered in the context of predicting successful hemodialysis ,provides us with threshold values of 480ml/min for BC AVFs and 330 ml/min for RC AVF ,values below which, serve as a marker of poor hemodialysis function in such patients. These group of patients who have flow rates below the threshold values, as mentioned in our study, warrant further imaging to identify the underlying cause, which can be resolved to further prolong the patency of AVF and salvage a failing AVF.

CONCLUSION

Failure of AVF is a major barrier to the successful establishment of hemodialysis access and can be a source of economic and personal distress in patients with ERSD. Numerous techniques have been employed to improve the patency of AVF, one such technique described in literature, is the beneficial effect of regional anesthesia in improving the flow dynamics . In our study we found that there was no difference of statistical significance, in the effect of local versus regional anesthesia in primary patency of AVFs at the end of 6 months, by which we can conclude that the benefits of regional block for AVF creation are short lived and has no effect on the long term patency of AVFs.

In this study it was found that flow rates of <480ml/min for BC AVF and <330ml/min for RC AVF at the end of 1st month showed more likelihood of non maturation and these values should be considered as markers to predict poor hemodialysis function at the end of 6 months.

LIMITATIONS

The major limitations of the study was that the number of subjects included in the study were small in number . The flow rate measurement were operator dependent and that might have led to some degree of bias.

SUMMARY

This study is a single centre, prospective,randomized, observational, comparative study performed with the objectives of determining if the postoperative flow rates , of AV Fistula created under local vs regional anesthesia, is a predictor of successful hemodialysis function**.**

Patient demographics, co morbidities ,pre operative measurements of cephalic vein and brachial artery/radial artery diameters were recorded.

There was no significant difference in patient demographics, personal history and baseline co-morbidities of diabetes, hypertension, cardiac issues between the two groups.

The study included 72 patients who underwent primary AVF creation procedure fulfilling the inclusion criteria, of which 37 patients received local anaesthesia and 35 patients received regional anaesthesia (Brachial plexus block). The majority of the AVFs created were left BC AVFs, 17 in each of the groups. The patients were followed up for a period of 6 months.

Parameters evaluated at subsequent follow up at 1st and 3rd months were outflow vein diameter , peak systolic velocities and flow rates. Functionality of AVF was recorded at 6 months follow up.

There was an increase in the flow rates at 3 months when compared to flow rates at 1st month, which was statistically significant, in patients who underwent HD via mature AVF at 6 weeks , in both the groups. Mean flow rates at 1st and 3rd month were nearly similar in both the groups and no difference of statistical significance was noted.

At the end of 6 months, among all patients, 51(70.83%) had a functional AVF present. In group 1, 26 patients (70.27%) had functional AVF and in Group 2, 25 patients (71.43%)

had functional AVF .This difference was not statistically significant.

In our study we found that the patients who had 1st month flow rates flow rates of less than 480ml/min for a BC AVF and less than 330ml/min for a RC AVF, had non functional AVF on subsequent follow ups.

This study shows that there is no difference on the primary patency of AVFs created under local anaesthesia versus regional anaesthesia at the time of 6 months follow up.

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ANNEXURE-I

PATIENT INFORMATION SHEET

Title: Comparative study of effect of regional vs local anesthesia in AVF creation in prediction of successful hemodialysis based on postoperative flow rates

Patient name: Address:

Age: IP no.:

Sex:

In patients with who require hemodialysis (HD) for end-stage renal disease(ESRD), arteriovenous fistulas (AVFs) are the preferred method of AV access given their longer patency fewer reinterventions, and lower morbidity and mortality rates compared with arteriovenous grafts and central venous catheters (CVCs).Regional and local anesthesia are both accepted safe modalities in AVF creation. This is a comparative study between regional anesthesia and local anesthesia in creation of AV fistula and how it helps in predicting successful hemodialysis based on postoperative flow rates. Patients will be divided into two groups based on the mode of anesthesia. There will be no additional cost that u will incur as part of being the study in either of the groups.

Person for contact for queries: Dr. Pavan B K

Jain Institute Of Vascular Sciences

Sri Bhagwan Mahaveer Jain hospital

PATIENT CONSENT FORM

TITLE Comparative study of effect of regional vs local anesthesia in AVF creation in prediction of successful hemodialysis based on postoperative flow rates

I have been explained about the nature of the study. I have understood about the two different modes of anesthesia, local anesthesia and regional anesthesia, being used in the study and my allotment into one of the groups, and the means of randomization employed for the study.I have been given the opportunity to not consent to the randomization technique employed.I have been explained about the benefits and complications of both local and regional anesthesia in creation of AV fistula. Complications such as pain ,bleeding, infections, hematoma, failure of fistula , nerve injury , upper limb ischemia ,venous hypertension have all been explained to me.

I have or have been read to about and understand the purpose of the study, type of study, risk and benefits associated with my involvement. I have been given the opportunity to ask questions regarding various aspects of the study.I understand that confidentiality is maintained in patient details. The information collected is only for research. I also understand that I am free to withdraw from the study at any point of

time and standard of care provided to me does not change if I am quitting/not willing to take part in the study.

I the undersigned agree to voluntarily participate in this study and authorize the collection of clinical information for the purpose of research.

Subject name and signature/ thumb impression: Date:

Name and signature/ thumb impression of witness: Date:

Name and signature of person obtaining consent: Date

ANNEXURE -2

STUDY PROFORMA

DEMOGRAPHIC DATA

NAME :

ADDRESS :

AGE/SEX :

HOSPITAL No. :

TELEPHONE :

DATE OF ADMISSION :

Comorbidities :

Hypertension ☐ Yes ☐ No

IHD ☐ Yes ☐ No

Diabetes Mellitus ☐ Yes ☐ No

Laboratory Investigations :

Hb, PCV	
Creatinine	
Serum electrolytes	
PT-INR,APTT	

Pre operative AV mapping

Size (mm)	**Cephalic vein**	**Basilic vein**	**Radial artery**	**Brachial Artery**
Site				
Distal forearm				
Mid Forearm				
Elbow				

Procedure performed-

FOLLOW UP

Study group 1: Patients receiving local anaesthesia for AVF creation

Study group 2: Patients receiving regional anaesthesia for AVF creation

Post op	**Outflow vein diameter(mm)**	**Outflow vein Peak velocity (cm/sec)**	**Flow rate (Velocity x area of vein x ∏{radius}^{2}] x 60 (ml/min)**
1 month			
3 months			

Functional AVF at 6 months

Ye s ☐ **No** ☐

ANNEXURE –3

SCIENTIFIC COMMITTEE APPROVAL

ETHICAL COMMITTEE APPROVAL