"ROLE OF COLOR DOPPLER ULTRASOUND IN ASSESSMENT OF COMPLICATIONS OF ARTERIOVENOUS HEMODIALYSIS FISTULA ACCESS: ONE YEAR HOSPITAL BASED OBSERVATIONAL STUDY"

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With reference to the above, we wish to inform you that your proposed research project titled **"ROLE OF COLOR DOPPLER ULTRASOUND IN ASSESSMENT OF COMPLICATIONS OF ARTERIOVENOUS HEMODIALYSIS FISTULA ACCESS: ONE YEAR HOSPITAL BASED OBSERVATIONAL STUDY"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

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LIST OF ABBREVIATIONS

GLOSSARY	ABBREVIATIONS
HD	Hemodialysis
AVF	Arteriovenous fistula
DUS	Doppler ultrasonography
DOQI	Disease outcome quality initiative
A-V	Arterio-venous
PSV	Peak systolic velocity
CDUS	Color doppler ultrasound
MDCT	Multidetector computed tomography
DSA	Digital substraction angiography
PPV	Positive predictive value
NPV	Negative predictive value
CFDU	Color flow doppler ultrasonography
CE-MRA	Contrast enhanced magnetic resonance angiography
CI	Confidence interval
MRA	Magnetic resonance angiography

ABSTRACT

Background: End stage renal disease is a major life-threatening disease in which most of the complications arise due to hemodialysis vascular access procedures. The best modality used for hemodialysis access is native arteriovenous fistula (AVF) which has lower rates of thrombosis, longer survival and good patency rate as compared to grafts.

Color doppler ultrasonography is a noninvasive diagnostic test that is used to monitor blood flow through an AVF and detect probable causes of vascular access malfunction. This study was done to know about the complications related to the arteriovenous hemodialysis fistula access by utilising colour Doppler ultrasound and thus help in early intervention to resolve hemodynamic problems and prolong the access patency.

Objectives: To determine the role of color doppler ultrasonography in assessment of complications of arteriovenous hemodialysis fistula access.

Materials and methods: A hospital based observational study was done on 35 patients with arteriovenous hemodialysis fistula dysfunction who were referred to the Department of Radiodiagnosis for color Doppler ultrasonography at KLE’s Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi. The study included 35 patients who satisfied the inclusion criteria. All the patients underwent color doppler ultrasonography on GE VOLUSON 8 machine (GE Healthcare, USA) fitted with a linear array transducer of 7.5-12 MHz high frequency. The findings of the Doppler ultrasound were assessed and analyzed. Descriptive analysis was carried out for the quantitative data. Data was represented using appropriate diagrams like bar diagram and charts.

Results: This study shows that among the total sample size, complications were detected by color doppler ultrasonography in 71.4%. There was male (57.1%) predominance, with the maximum number of cases between the age group of 41 to 50 years (31.4%). Among the 35 cases, 22.9% presented with symptoms of upper limb oedema without pain. Radiocephalic fistula (40%) was the most commonly observed fistula. Color doppler ultrasonography done in the present study shows adequate blood flow rate at AVF in maximum no of patients (45.7%), with thrombosis (28.6%) being the most common observed complication.

Conclusion: Color doppler ultrasonography is a noninvasive diagnostic test that enables early identification of AVF issues, helps to monitor blood flow through an AVF and improves patient outcomes. Because it is easily accessible and has a low cost, it ought to be the imaging technique of choice for an AVF that is not operating well. This study underlines the importance of color doppler ultrasonography in early detection of complications associated with vascular access, therefore leading to early intervention and prevention of mortality and morbidity.

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INTRODUCTION

Hemodialysis patients with chronic kidney failure need properly positioned vascular access to improve their chances of survival and maintain a decent quality of life[1,2]. Arteriovenous fistulas, have now become the method of choice for hemodialysis (HD) patients as their patency rates is higher as compared to prosthetic arteriovenous grafts [3,4]. Arteriovenous grafts, on the other hand, continue to have a place in clinical practise for patients who cannot receive AVFs and possibly for members of certain demographics, such as the elderly [5,6]. The process of creating and maintaining an AVF that is patent and fully functioning has grown increasingly complex for nephrologists and vascular surgeons [7,8]. In patients with progressive renal disease the most common cause of morbidity is due to the complications that are caused by the vascular access used in hemodialysis.[9,10]. However, the timely construction of AVFs was responsible for a 1.72 times reduction in the mortality rate [11].

Hemodialysis patients should choose for arteriovenous fistulas constructed with native arteries since they have a lower risk of complications and a higher survival rate at comparable blood flow rates [12,13]. Doppler ultrasound (DUS) has made it possible to map and identify eligible veins before surgery [14,15]. This has greatly expanded the range of situations in which surgeons doing vascular access surgery can construct AVFs from the patient's own native veins. The capacity to diagnose and treat difficulties after surgery more rapidly has also contributed to an increase in the percentage of AVF patients who survive the procedure.

Alterations in hemodynamics can be brought on by access flow. Some of these changes are arterial steal syndrome, venous hypertension, and high-output heart failure [16,17]. Even though illnesses such as diabetic and uremic neuropathy are quite common, they have the potential to hide the diagnosis of other, more curable disorders. These include compression neuropathy and ischemic neuropathy. To put it another way, the most common reasons for access failure are thrombosis at the anastomotic site or stenosis of the outflow vein [18,19]. Either the functionality must be restored through the use of multiple rescue processes, or new access must be created. The failure rate of access could be decreased through the early discovery of malfunction and subsequent rectification of the problem. Due to the fact that they are so superficial, AVFs are easily identifiable through the use of a Doppler ultrasonography (DU) [20]. An examination that is focused on the patient should place a priority on DU. In addition to being portable, inexpensive, and non-invasive, it offers morphological and physiological details on the access flow, including surveillance, vascular mapping, and maturation evaluation. Problems with the AVF can be recognised, and intervention strategies can be directed, in order to enhance hemodynamics and maintain access patency.

In patients undergoing haemodialysis, it is now standard practise to anticipate issues including arteriovenous fistulas[21]. After receiving haemodialysis treatment for more than two years, 72 percent of patients in the United States had been hospitalised owing to access-related issues[22]. Failure of the fistula to function normally is the worst potential consequence, and it is caused by thrombosis that is brought on by stenosis[19,23]. In the 1970s, the yearly thrombosis rate per patient was 0.58 [24]. Today, that number has increased significantly. After using cutting-edge procedures for fistula assessment and endovascular therapy, the rate reduced to 0.15, which is equivalent to the thrombosis rate reported in persons who do not have stenosis. Various scientist came to the conclusion that there is a correlation between the ultrasonographic parameters and the complications that occur in early fistula. After surgery, the participants in the study had their arteriovenous fistulas examined 1 and 4 weeks later.

For Hemodialysis, it's important to have a vascular access method that can resist frequent puncture and yet allow for a healthy amount of blood to flow through. It's essential for safe, effective dialysis. Vascular access should also be of sufficient quality to withstand repeated insertion of catheters. The most serious complications that can arise from having a fistula due to Hemodialysis include lymphedema, infection, aneurysm, stenosis, congestive heart failure, steal syndrome, ischemic neuropathy, and thrombosis [25,26,27].

This study will allow us to know the allocation by age, gender distribution, location of the fistula and complications related to the arteriovenous hemodialysis fistula access by utilising colour Doppler ultrasound and thus help in early intervention to resolve hemodynamic problems and prolong the access patency.

AIMS AND OBJECTIVES

- To assess the complications associated with hemodialysis arteriovenous fistula access with the help of color doppler ultrasonography.

REVIEW OF LITERATURE

In patients undergoing hemodialysis, the implantation of fistulas is strongly recommended according to national recommendations. People with either acute kidney injury or chronic kidney disease, in which renal function is lost suddenly or gradually over time, need dialysis to maintain homeostasis. When the kidneys are no longer functioning properly, the patient undergoes hemodialysis, in which a machine removes waste products, salts, and fluid from the blood. The best modality used for hemodialysis access is native arteriovenous fistula (AVF) which has lower rates of thrombosis, longer survival and good patency rate as compared to grafts. Any abnormal connection between an artery and a vein is called an arteriovenous (AV) fistula. AVFs may be induced during surgery, developed naturally due to a genetic abnormality, or arise from an iatrogenic injury or trauma. A fistula between the arterial and venous systems may have serious pathologic consequences on the body because of the pressure difference between the two systems. When used to treat advanced kidney failure, hemodialysis (he-moe-die-AL-uh-sis) may allow to maintain an active lifestyle. In addition to differences in the manner in which hemodialysis is administered from one place to the next, the popularity of fistulas among hemodialysis patients also shows the demographic and clinical characteristics of the individual patients themselves. In order to maintain the hemodialysis more fistulas need to be implanted, fresh fistulas need to mature more quickly, and the patency of mature fistulas needs to be improved over the long term so that dialysis can be performed through them. When a patient is referred for dialysis and vascular access, a fistula may or may not be placed depending on several factors, including person's vascular anatomy, the kind of fistula used, patient characteristics, the dialysis nurses' and nephrologists' preferences, and the surgeon's skill[28]. That's why we need to determine whether fistula that has been established is suitable for dialysis, additional factors such as vessel adequacy, surgeon specialist knowledge, skills and expertise, individual characteristics, clinical and caregiving skills, the lowest required blood flow for dialysis, and the outcomes of efforts to correct immature fistulas. Patency of a fistula in long term depends on early assessment, treatment and prevention of thrombosis. Good results can be obtained if the patient is referred early when the vascular access is placed and a routine checkup is done regarding the vessels of the patients. Nephrologists are the medical professionals who diagnose and treat kidney disease. The implementation of these measures is anticipated to result in an increase in the proportion of dialysis centres that make use of fistulas. On the other hand, variations between dialysis centres are likely to persist because of the demographic differences that exist between patients in terms of their gender, race, and comorbidities.

Anatomy of upper limb:

Arterial supply of upper limb:

There are five major arteries (from proximal to distal) that give blood to the upper extremity.

1. Subclavian artery
2. The axillary artery
3. Brachial artery
4. Radial artery.
5. Ulnar artery

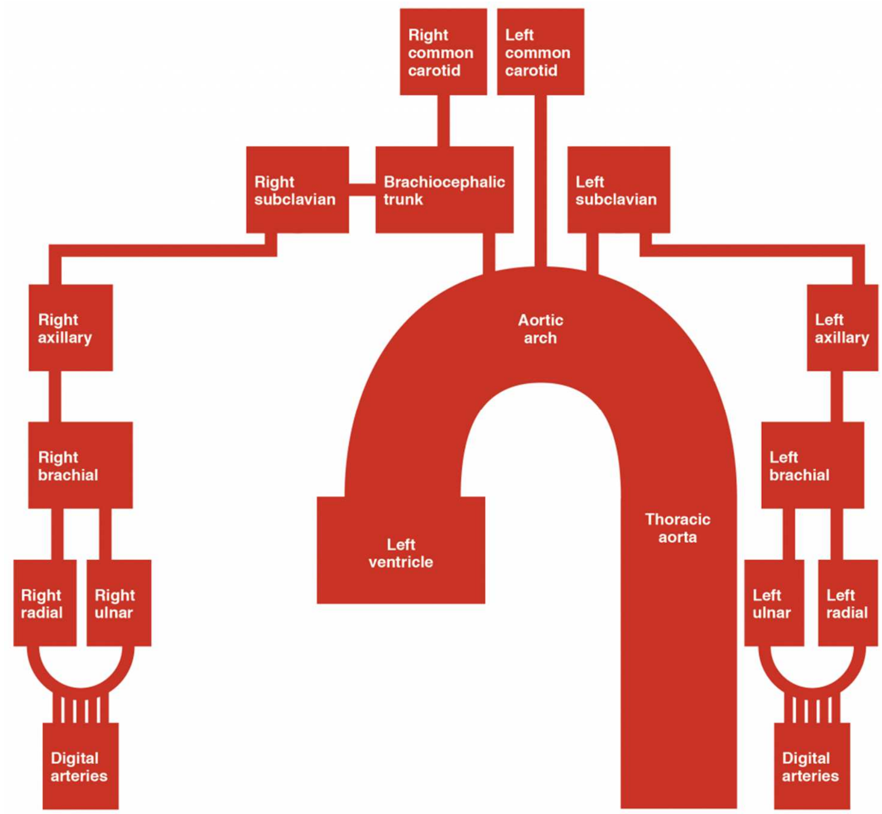

Figure 1: Diagram showing the arteries which supply the upper limb.

Subclavian Artery:

The subclavian artery is the primary artery that supplies blood to the upper body. The subclavian artery branches on the left side from aortic arch and from the brachiocephalic trunk on the right side of the body.

It is anterior to vein in the supraclavicular fossa and its path is lateral. It forms axillary artery when it is beyond the first rib lateral margin.

Axillary Artery:

It has a medial path and it runs over humeral head proximal part. It forms brachial artery at the lower margin of teres major muscle.

Brachial artery:

It has a medial course in the arm and it further forms the radial, ulnar and smaller interosseous arteries at the level of antecubital fossa.

Radial and ulnar arteries:

Both the arteries run towards the wrist along either side of the forearm. Arterial anastomoses of the elbow is formed by the recurrent arteries which arise from the radial and ulnar arteries.

An interosseous branch arise from the ulnar artery which further divides into anterior, posterior and recurrent branches.

Blood supply to the thumbs and fingers is provided by the branches which arise from superficial and deep palmar arch which are formed by ulnar and radial arteries respectively.

Venous supply of upper limb:

Veins for the upper limb carry blood from the hand, wrist, forearm, upper arm, and shoulder and finally drain into the ipsilateral central thorax veins and the superior vena cava.

Venous system is divided into a superficial and deep venous system.

Superficial venous system forms an important means of drainage in the hand, forearm, and upper arm whereas the smaller deep veins exits as pairs and they follow their respective arteries.

Deep venous system:

- It has the paired radial and ulnar veins in the forearm, which unite distal to the level of the elbow to form the brachial veins.

- The teres major muscle forms the landmark where the upper arm brachial veins join the basilic vein.
- Brachial veins after joining the basilic veins forms the axillary vein, which runs from the teres major muscle till the first rib.
- The axillary vein then forms the lateral portion of the subclavian vein after crossing the first rib.
- The brachiocephalic(innominate) vein is formed by the subclavian vein whose medial portion receives blood from the external and internal jugular veins.

Superficial venous system:

- Important superficial veins are cephalic and basilic veins.
- Cephalic vein is present laterally and joins the axillary vein which is present in the lateral chest by coursing through the shoulder.
- Basilic vein is runs medially and then it combines with the brachial veins to finally form the axillary vein.
- Median cubital vein connects the basilic and cephalic vein in cubital fossa, superficial to the biccipital aponeurosis.

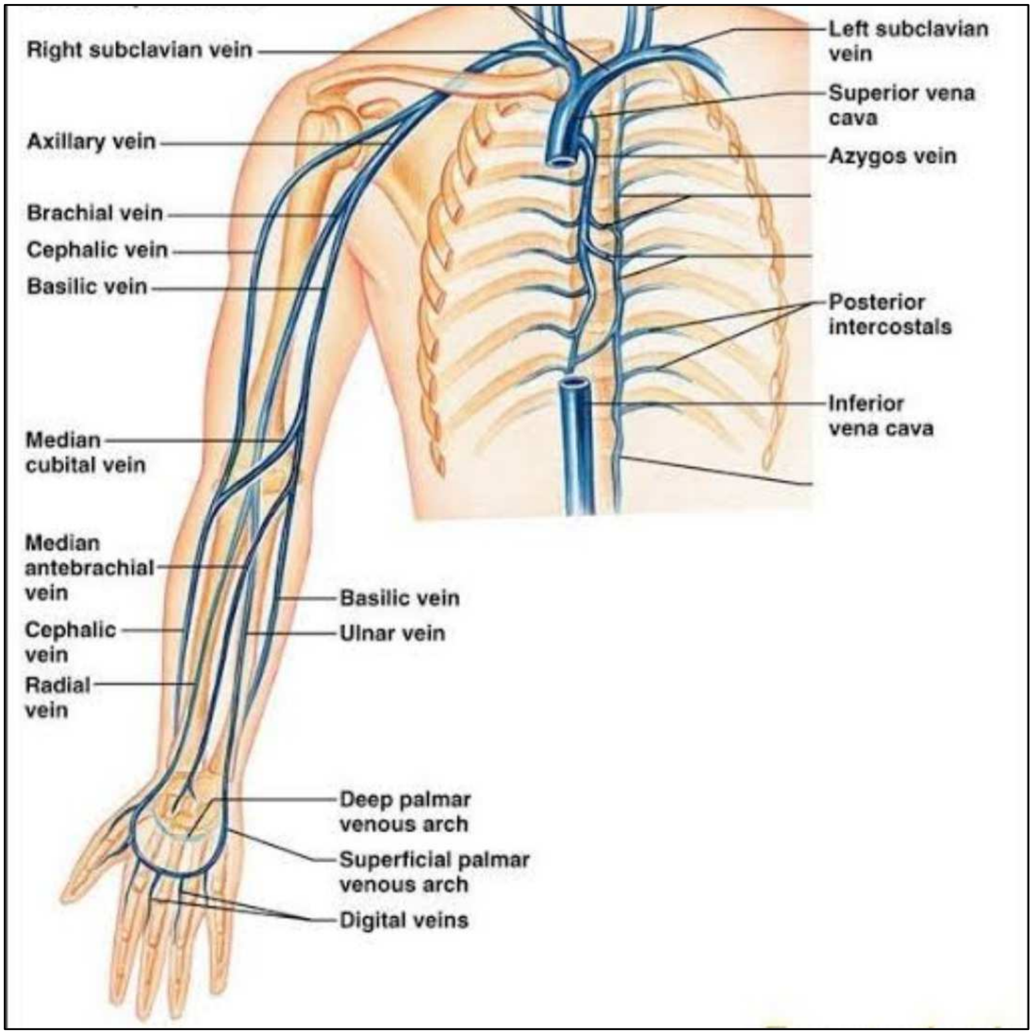

Figure 2: Diagram showing the superficial and deep venous system of upper limb.

Types of AV fistula

Three primary types of AV fistula are:

1. Radiocephalic fistula
2. Brachiocephalic fistula
3. Transposed Brachiobasilic fistula

All have common features and qualities. All AVF fistulas need time to mature so that the vessel walls may expand and thicken.

The most challenging fistula to construct is the radial cephalic fistula. This operation involves severing the cephalic vein and grafting it onto the radial artery. While the radiocephalic's blood flow is smaller than the other two methods, it does save the upper arm's arteries and veins in case further surgery is required. For hemodialysis, the radiocephalic arteriovenous fistula in the wrist is the preferred entry point.

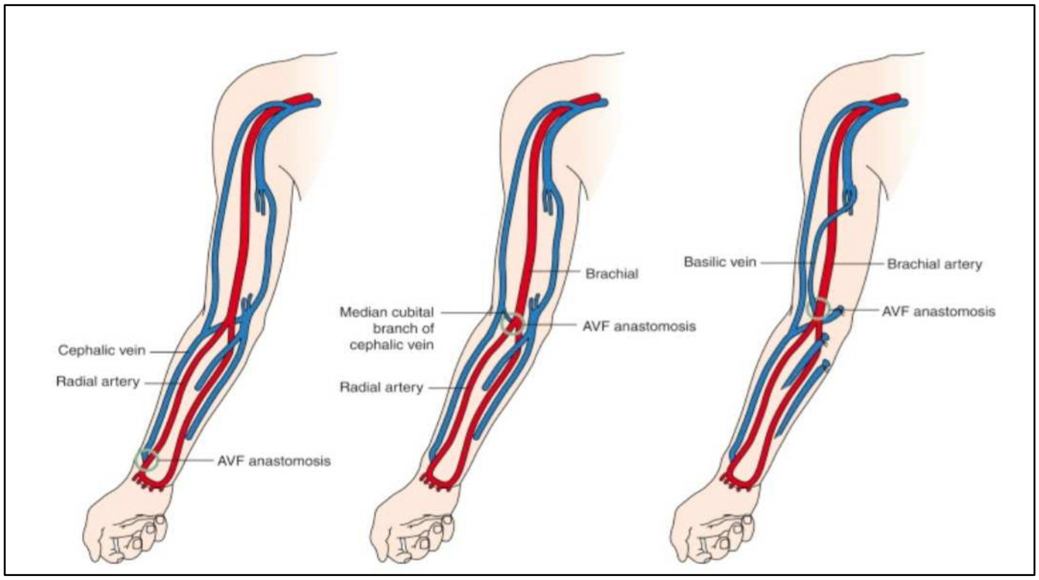

Figure 3: Diagram showing common types of arteriovenous fistulas. left, RADIOCEPHALIC FISTULA. middle, BRACHIOCEHALIC FISTULA. Right, BRACHIOBASILIC TRANSPOSITION.

Since the blood vessels in the upper arm are bigger, the Brachiocephalic Fistula is the simplest fistula to make. This fistula is formed by connecting the cephalic vein in the upper arm to the brachial artery. When compared to the brachial-basilic fistula, it is less invasive to create, can be catheterized more quickly, and offers more cannulation options. While the increased blood flow is beneficial, the brachiocephalic fistula is associated with a slightly greater risk of developing steal syndrome.

However, the Brachiobasilic Fistula is more difficult to establish since it involves transposing the vein and elevating it to get vascular access. An activated vein in the deeper tissue is linked to a channel in the skin. The brachiobasilic fistula is linked to higher patient morbidity but has a higher rate of survival. Steal syndrome is more common and cannulation of the brachiobasilic fistula is more challenging due to its shorter length. Patients with a history of unsuccessful access operations are often candidates for this kind of access.

Epidemiology and pathophysiology

When comparing different vascular access options for hemodialysis, the native arteriovenous fistula (AVF) is preferred because of its higher success rate and reduced risk of complications. To better vascular access outcomes, primary AVF failure owing to early failure or lack of maturation is now regarded an important field of inquiry. Multidisciplinary treatment seems to be the best way to handle the many facets of end-stage renal disease care and improve outcomes, according to recent research and experience in the United States.

More than twenty percent of all kidney patients who require hospitalisation in the United States each year do so as a direct result of complications arising from vascular access procedures. For better patient outcomes following vascular access procedures, the National Kidney Foundation developed the DOQI (Disease Outcome Quality Initiative) guidelines in 1997[29]. These guidelines are a compilation of evidence-based and expert-opinion suggestions for optimal vascular access management [30,31]. These guidelines were developed in an effort to raise the number of patients who survived their dialysis treatments. The many epidemiologic and clinical investigations that were inspired by the DOQI guidelines are largely responsible for the increased knowledge that has been gained regarding vascular access. According to the recommendation of an important DOQI guideline, patients undergoing dialysis ought to be encouraged to use arteriovenous (A-V) fistulas rather than grafts [32,33].

By the middle of the 1990s, just 19% patients undergoing dialysis in the US were doing so via fistulas [34]. Recently, A-V fistulas have seen a rise in popularity due to the fact that in comparison to A-V grafts, they carry a lower risk of developing stenosis, thrombosis, and infection. In view of this, the DOQI vascular access recommendations recommended, coordinated action to raise the number of dialysis patients who use fistulas. In these guidelines, it is recommended that at least half of all patients have an attempt at fistula placement. A-V grafts are to be reserved for those individuals whose vascular architecture does not allow for the development of a native A-V fistula [35]. Fistula placement should be attempted in at least half of all patients. The DOQI criteria indicate that this strategy would result in forty percent of patients who are now undergoing dialysis needing a fistula.

The most common cause for the formation of venous stenosis is venous neointimal hyperplasia and is seen in both AV grafts and fistulas. In case of AV grafts the segment of vein which is involved is the graft and juxta-anastomotic one which are the most common sites of venous stenosis. The failure of an AV fistula often results from two different causes: immature development and venous stenosis that develops later. The location of stenosis in each situation is determined by the kind of AV fistula present. Generally speaking, stenosis within the peri-anastomotic area is the leading cause of failure for radiocephalic fistulas, whereas juxta-anastomotic narrowings are the most prevalent cause of failure for brachiocephalic fistulas. Proximal stenoses are possible in both conditions, but are more common in brachiocephalic fistulas (cephalic arch stenosis).

The method of determining the AVF flow volume using DUS is easy to follow, does not take more than a few minutes to finish, and consistently provides accurate results. The formula that is used to determine flow volumes requires three inputs: the cross-sectional area (in square centimetres), red blood cell mean velocity (in centimetres per second) calculated from recorded Doppler trace at area measuring site, and 60 seconds. Hemodialysis requires puncturing an arterialized vein, so the most important place to assess the volume of vascular access flow forms the outflow vein of the AVF [36]. In addition, the mean velocity of the blood flowing through the venous side of the AVF becomes difficult to know because the venous side has a turbulent flow[37]. Consequently, the most precise measurements of flow volume should be taken at the level of the input artery. When the volume of a distal AVF is measured at the level of the radial artery it is inaccurate as some amount of blood may flow from the fistula approximately “25-30%” and can go to the ulnar artery through palmar arch.[38,39]. If the anastomotic part becomes greater to the artery which is supplying it, there may be a risk of reverse blood flow. [38]. For these reasons, the most important vessel for assessment of blood volume is brachial artery. [39,41]. This is possible because the prosthetic conduit has a more uniform diameter and is, as a result, more resistant to the pressure that is applied by the transducer than a native outflow vein. Thrombosis can occur in either the native or the prosthetic AVF; for this reason, flow measurement is best. In any kind of AVF, decrease in the flow volume is an indicator for thrombosis. DUS, when compared to other technologies, has both advantages and disadvantages: In cases when low AVF flow volumes are present, this tool can be used to document the problem and investigate its root cause, but it cannot be utilised during haemodialysis. According to the findings of the research on the assessment of DUS flow volume, a healthy AVF will have a flow rate that falls anywhere between 700 and 1,300 ml/min[42]. A value that is less than 500 ml/min suggests that the access is dysfunctional[43], whereas a value that is less than 300 ml/min suggests that thrombosis is imminent [44]. Calculating the AVF flow volume with DUS is one way to determine whether or not a treatment intervention that was attempted to repair a problem was successful.

Complications:

Complications arising from hemodialysis vascular access are one of the most common reasons for morbidity. Following complications may be associated with vascular access. Among them are:

Thrombosis: Arteriovenous anastomosis forms the most common site of thrombosis in AVF and usually occurs on venous. Hypoechoic or echogenic thrombus which fills the lumen and absence of flow detected by the color doppler gives the diagnosis of thrombosis.

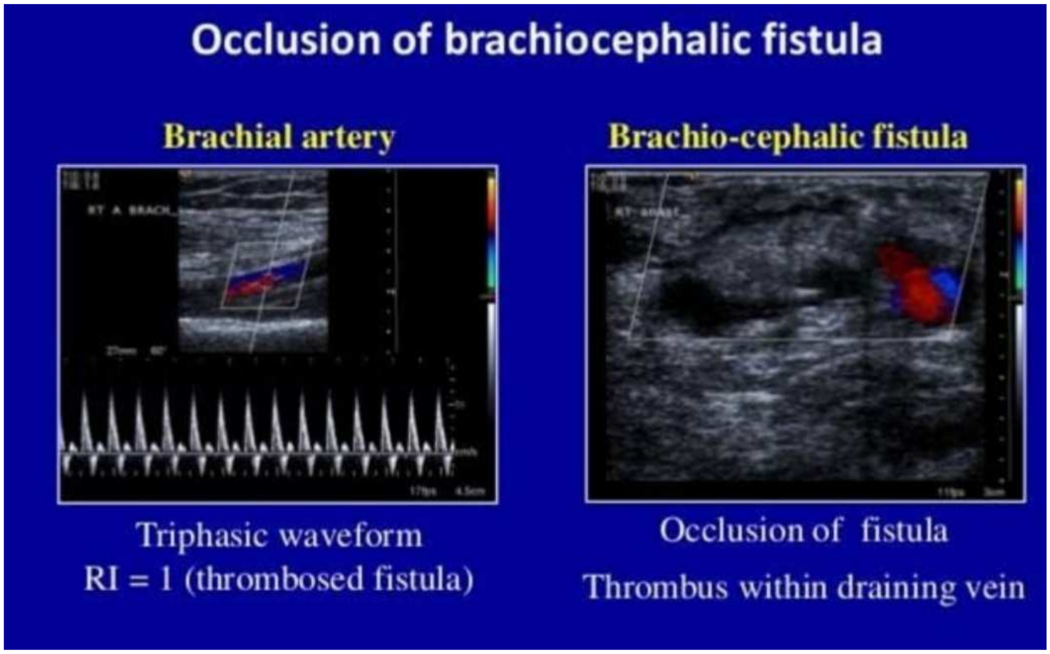

Figure 4: USG image showing the presence of thrombus within the draining vein

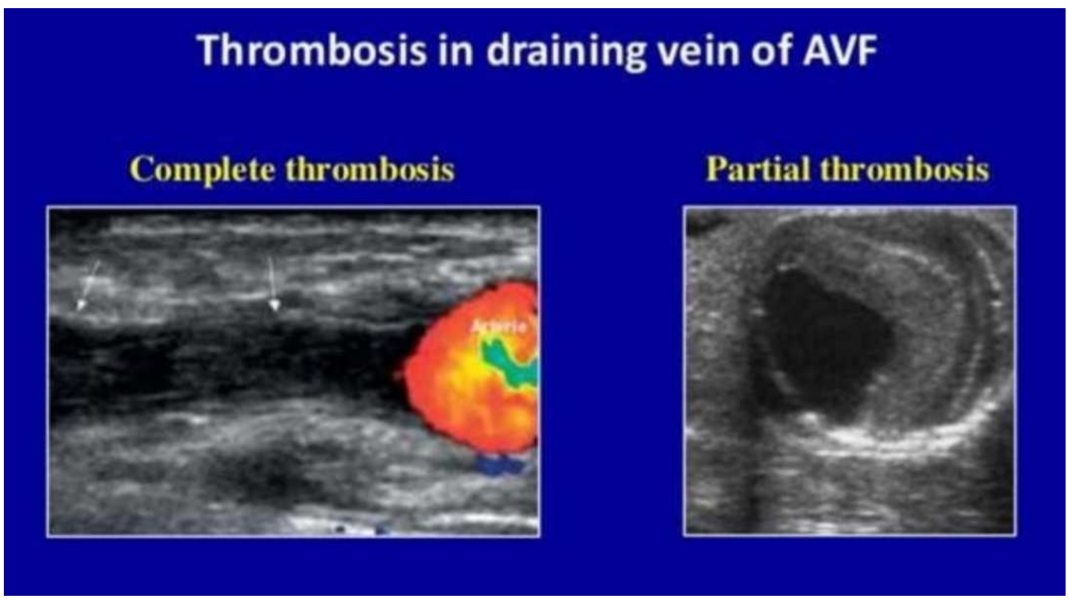

Figure 5: USG image showing complete and partial thrombosis

STENOSIS: Is one of the most common complication. It may further lead to formation of thrombosis and patency of the access may be lost. Juxta-anastomotic region is the main site of stenosis in AVF other than this feeding artery, draining and central veins forms the other sites. The criteria for stenosis include-

- Greater than 50% of visual narrowing seen on ultrasound.
- Greater than or equal to 3:1 PSV ratio (this ratio consists of the PSV which is recorded at or distal to the stenosis to the PSV which is recorded 2 cm upstream from stenosis site)

Early intervention can be done and the patency of AVF can be maintained if stenosis can be detected early before formation of thrombosis. In AVF, stenosis is caused by the intimal or fibromuscular hyperplasia secondary to endothelial damage because of the pressure increase in the venous system.

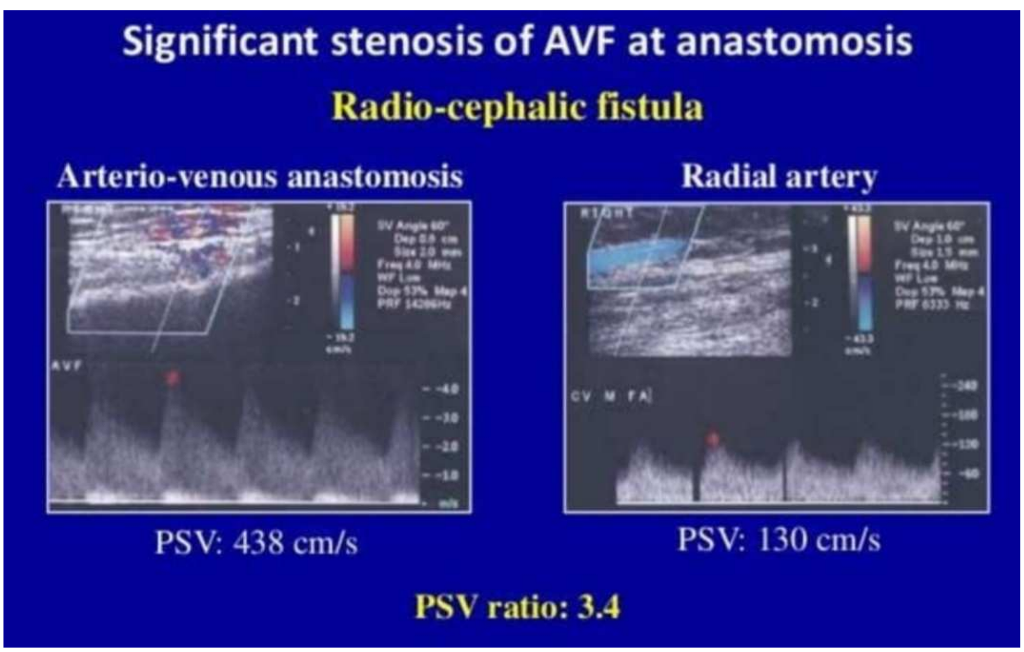

Figure 6: USG image showing stenosis at AVF site with raised PSV

FALSE OR PSEUDOANEURYSMS: They usually occur at the anastomoses or the site of puncture. Prolonged bleeding as a result of puncture at the site of dialysis or due to some intervention procedure can result in pseudoaneurysm formation. Diagnosed as well defined anechoic/hypoechoic outpouching from the fistula, with swirling bidirectional to and from flow on color doppler study.

- It reveals 'yin-yang' pattern in color doppler ultrasound.
- Color doppler ultrasound (CDUS) shows the degree of thrombosis and also the size of the aneurysm. It is also helpful in differentiating it from hematomas as they have a 'to-and-fro' pattern.

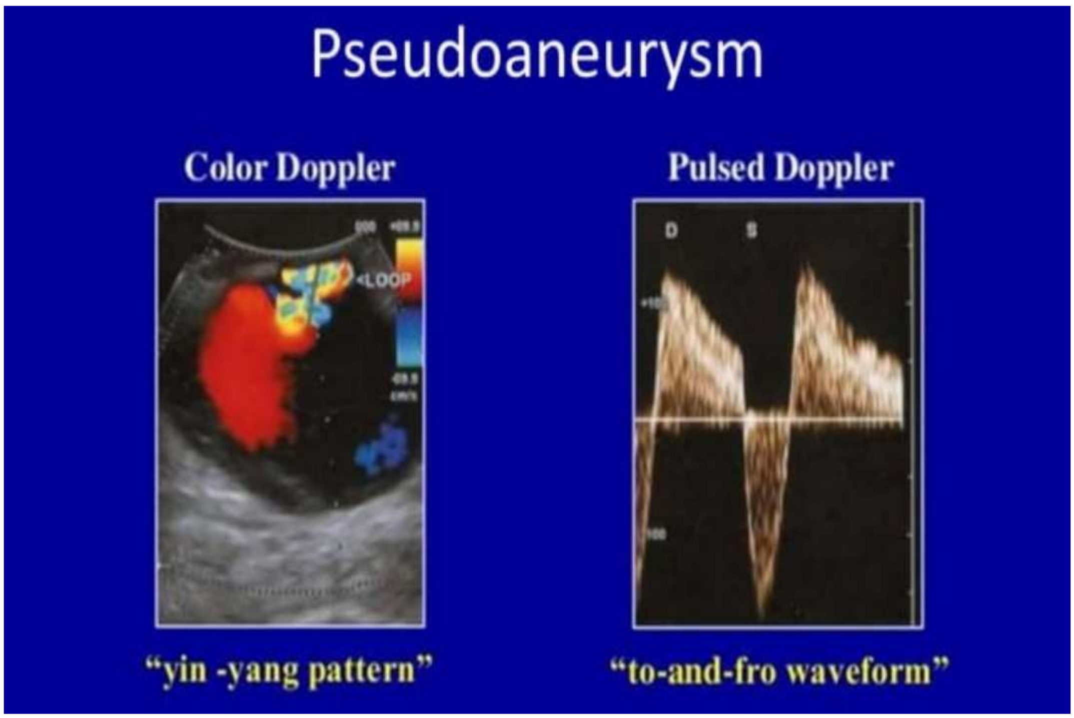

Figure 7: USG image showing characteristic features of pseudoaneurysm

HEMATOMA: They are localised collection which are hypoechoic and have no vascularity. They are found adjacent to the AVF or graft. If gas is seen in the collection abscess should be taken into consideration.

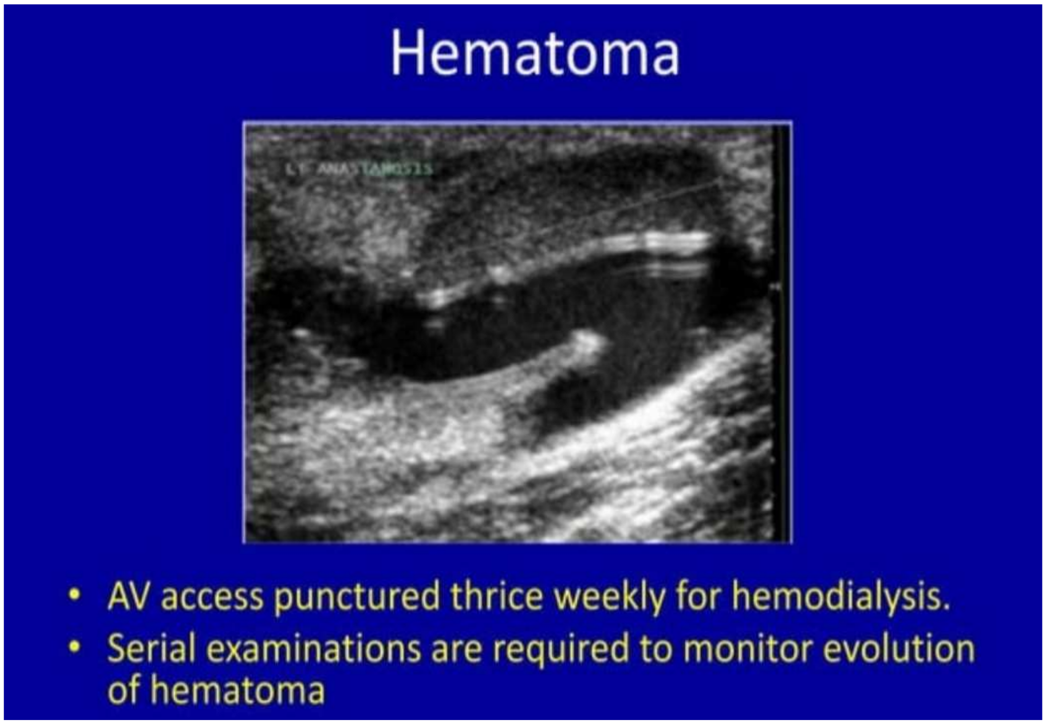

Figure 8: USG image showing hematoma formation at AVF site

ARTERIAL STEAL SYNDROME: is defined as flow reversal in the native artery caudal to the anastomosis. It may be asymptomatic or associated with clinical findings such as hand pain and paresthesias that can worsen during hemodialysis. In severe cases, ischemia or tissue necrosis of the fingers can occur. Ultrasound shows reversal of flow in the distal artery, and rarely shows an arterial occlusion.

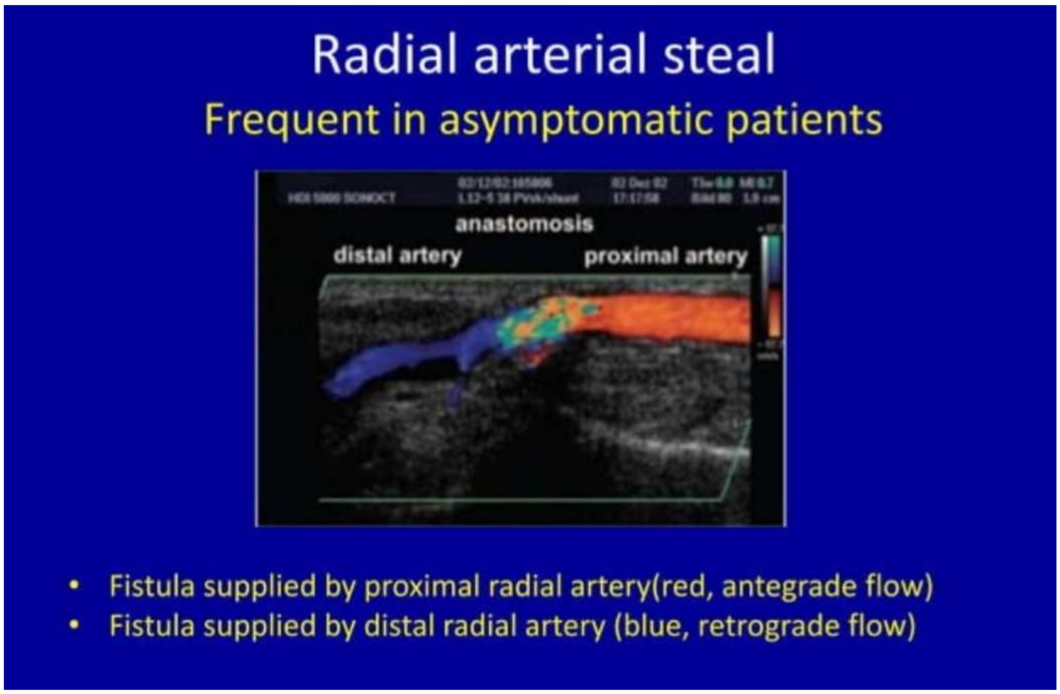

Figure 9: USG image showing arterial steal syndrome

HEART FAILURE: When a big arteriovenous fistula develops, this is the worst possible outcome. An arteriovenous fistula connects two blood vessels, allowing for faster blood flow than is possible via a normal arteriole or vein. More blood flowing through it means the heart has to work harder to pump that blood around. Heart failure may develop from chronic stress.

Doppler ultrasound imaging demonstrates substantial anterograde flow throughout the entirety of the diastolic phase, as well as a significantly lower peripheral resistance on the inflow side of a normal AVF when compared to the limb on the opposite side of the heart [46]. There is a noticeable broadening of the spectrum that is at its worst close to the anastomosis and extends all the way down to the nadir when the acoustic window closes.

.As one moves further and further from the AVF, the arterial phasicity gradually fades away, the mean flow velocity decreases, and the spectrum takes on the characteristics of normal venous flow.

Anna Muddoni's research emphasises the nephrologist's centrality throughout the entire vascular access process, from the initial stages of planning (which involve preserving vessels for placement) to the later stages (which involve managing the vascular access development and functionality through methods like clinical examination, data, and role of doppler ultrasound in the vascular monitoring). They believed that color doppler ultrasound helps in knowing the vessels anatomy, also detects the blood flow and thus provides an efficient help in early detection of complications like thrombosis and stenosis and in the further management and early intervention. There is a variety of clinical outcome evidence that shows color doppler ultrasound should be incorporated into an integrated access management system.

A study by Pietura and coworkers found no association between the following factors: (1) the age of the patient and the age of the fistula; (2) the age and the number of fistulas in a patient and also its location. There was found some relation between the time of dialysis and the how many fistulas a patient has.

Mean flow rate was “1204.1 ml/min”. The values were much higher for fistulas that had aneurysms, calcifications, and tortuous arteries, whereas the values were lower for fistulas that had stenosis.

64% of the fistulas that were examined showed signs of stenosis. The anastomotic region was responsible for 57% of the stenoses, the vein junction was responsible for 22%, the ends of the aneurysm were responsible for 19%, and the remaining portion of the efferent vein was responsible for 2%. The bulk of the fistulas, which made up 94% of the total, exhibited perivascular colour artefacts despite having stenosis. Only 6% of fistulas had chronic venous obstruction, and it was usually caused by collateral veins. Aneurysms were found in approximately one half of the fistulas that were examined. Aneurysms averaged 12.4 mm in diameter. The majority of puncture sites, 96%, were found to be aneurysms. In ten different patients, a microscopic thrombus was discovered within an aneurysm or at the puncture site. According to the findings of this research, even in adults who have arteriovenous fistulas that are completely functional, there remains a sizeable amount of irregularity. Despite these abnormalities, the dialysis fistula continued to function normally. This was a very unfortunate development.

Researchers from Cansu et al. wanted to find out how well colour Doppler ultrasonography (CDUS) and multidetector computed tomography (MDCT) angiography compared to digital subtraction angiography (DSA) and surgery for determining whether or not hemodialysis arteriovenous fistulas had failed (AVFs) [47]. It was determined using DSA and/or a surgical biopsy that 64 segmental lesions were present. When it came to detecting all of the lesions in the vascular tree, CDUS had an accuracy of 94.5%, a sensitivity of 85.9%, a specificity of 99.2%, a PPV of 96.4%, an NPV of 96.7%, and both a PPV and an NPV of 96.7%. When it came to MDCT angiography, the percentages came in at 96.7 percent, 99.6 percent, 98.5 percent, 99.2 percent, and 98.5 percent respectively. When used in conjunction with one another, MDCT and CDUS are just as effective as the tried-and-true method of DSA in determining whether or not the AVF is dysfunctional.

According to the findings of the study, patients with chronic renal failure are unable to receive successful haemodialysis without first establishing an arteriovenous fistula (AVF) that is in good working order. Evaluating the performance of an artificial ventricular septum using the methods that are already in use is either invasive (such as a clinical examination) or imprecise (eg, angiography).

The purpose of the Nonnast-Daniel study was to investigate the application of colour flow-doppler ultrasonography (CFDU) in the diagnostic workup of clinically suspected AVF malfunction [48]. The CFDU looked at 51 individuals who had issues with their AVF; of those individuals, 28 also had an angiography. The outcomes of the second operation were evaluated alongside the gold standard, and a comparison was made between the two. CFDU was able to detect AVF stenoses in 18 patients, which were later verified on reoperation. In 13 of these 18 patients, the findings of the angiography were completely congruent with those of the CFDU as well as the surgical procedure. The results of the CFDU showing AVF thrombosis were confirmed in all 33 patients who underwent reoperation; 15 patients additionally underwent angiography, and thrombi were not identified in 6 individuals (in 4 because of technical failure). Surgery was able to confirm the presence of aneurysms on the CFDU in all seven of the patients, and angiography was successful in confirming the diagnosis in two of the three patients who were examined. Patients who have been diagnosed with possible AVF anomalies may soon have access to CFDU, which is now the procedure of choice for assessing AVF since it provides a reliable non-invasive assessment of AVF shape and function.

Vascular access for hemodialysis is frequently accomplished through the creation of Brescia-Cimino arteriovenous fistulas or synthetic loop grafts through surgical procedures. Duplex and colour Doppler sonography offer a noninvasive alternative to angiography, which has been the standard method for imaging these circulatory systems [49,50]. Angiography, on the other hand, has been the standard method for imaging these vascular systems. Flow waveforms are monophasic in normally functioning fistulas, with peak systolic velocities of 100–400 cm/sec and end-diastolic velocities of 60–200 cm/sec [51]. Normal end-diastolic velocities range from 60–200 cm/sec to 100–400 cm/sec. Arterial pulsations can be found in the draining veins, and their peak velocities range from 30 to 100 cm/sec. Sonographic evaluation can detect common anomalies that pose a threat to or disrupt graft function, including as arterial and venous stenoses, graft thrombosis (occlusive and nonocclusive), infection, aneurysm and pseudoaneurysm development, and arterial steal. Sonographic assessment at the time of initial dysfunction may identify an underlying correctable anomaly, and particular therapy may be initiated before the condition worsens, even though aberrant hemodynamics in access fistulas are frequently found during hemodialysis. Furthermore, if no substantial hemodynamic abnormality is obvious, sonography may replace an invasive angiographic assessment.

Despite the high rate of problems that are associated with arteriovenous fistulas (AVF), they remain the most prevalent kind of vascular access for continuous hemodialysis (HD). HD stands for "continuous hemodialysis." This study was conducted with the intention of determining whether or not Color Doppler sonography (CDS) is helpful in making a diagnosis of AVF malfunction. In total, 45 patients diagnosed with AVF access dysfunction participated in the trial throughout the course of its 29-month duration, which began in January 2005 and ended in May 2007. The King Fahd University Hospital in Al-Khobar, which is located in the Kingdom of Saudi Arabia, was the location where all CDS procedures were performed. Because of CDS, a total of twenty-three individuals were found to have stenotic segments, and an additional sixteen patients were found to have venous thromboses. It was found that six patients suffered from venous aneurysm. Two individuals with venous hypertension and two patients with steal syndrome were distinguished using Doppler flow rate evaluation. As a consequence of this, the CDS results were accurate 96.4% of the time. CDS was not able to detect two stenoses in the subclavian veins, both of which were confirmed by angiography as reducing the flow of blood and were both responsible for the patient's condition. The surgical procedures were performed on a total of thirty-four patients.

The research conducted by Khaled M. Moghazy demonstrates that CDS can be utilised for minimally invasive techniques in order to analyse the architecture and hemodynamics of the AVF [52].

There are a variety of imaging methods that can be utilised in order to evaluate damaged hemodialysis connections. The most common methods is color doppler ultrasonography. Other methods are digital subtraction angiography (DSA)and contrast-enhanced magnetic resonance angiography (CE-MRA). However, the efficacy of these three methods for detecting stenosis in non-functioning shunts has not been compared in any published research. To investigate if the interventionalist would benefit from CDUS conducted prior to DSA and endovascular intervention, both were compared. DSA found that out of 433 arterial segments, 111 had moderate to severe stenoses, which is a percentage of 50%. When it came to detecting substantially stenosed arterial segments, CDUS exhibited a sensitivity of 91% (95% confidence interval [CI], 84%-95%) and a specificity of 97% (95% confidence interval [CI], 94%-98%]. MRA exhibited a 96% (95% CI, 90%-98%) sensitivity, a 90% (95% CI, 90%-98%) specificity, a 94% (95% CI, 88%-97%) positive predictive value, and a 98% (95% CI, 96%-99%) negative predictive value. Six nondiagnostic DSA segments were shown to have three or more significant stenoses by CDUS and CE-MRA, respectively.

In 2005 by Khaled M. Moghazy[52], discovered that color doppler sonography had a sensitivity of 96.4% in recognising patients who had stenotic segments, while only having a sensitivity of 29.1% in detecting access thrombosis. According to the findings of a study that was conducted by A. Srivastava and colleagues in 2011, it was discovered that the radial artery and cephalic vein diameter and the peak systolic velocity each play an important role in the functional maturation of a wrist radio cephalic arteriovenous fistula. In addition to this, it was discovered that diabetic individuals who had arterial calcification had a more sluggish maturation process and a higher rate of fistula failure.

According to a study that was conducted and published in 2016 by Chong Ren et al, the brachial artery diameter, as well as the time averaged mean velocity, flow volume, and diastolic peak velocity, were all significantly lower in patients who had issues with their AVF. This study provided evidence that utilising these tests and procedures for the early detection of fistula problems is beneficial [53].

In 2017, Mohammed H. Hassan and colleagues carried out a prospective observational study which demonstrated that the maturation process of an AVF often takes place within the first four weeks after it has been established [54].

Additionally, it demonstrated that thrombosis, which is more evident on fistula venous side is the most common shunt problem that was associated with hemodialysis access.

A study that was conducted in 2018 by Omar Abdelaziz and colleagues found that venous thrombosis was the most common complication experienced by study participants, accounting for 48 percent of the total [55].

Additionally, the findings demonstrated that the patient who had a complex fistula required additional treatment, which could take the form of surgical management or radiological interventions.

MATERIALS AND METHODS

Study Design: A hospital based observational study.

Study site: Conducted in the Department of Radio Diagnosis at Jawaharlal Nehru Medical College, Belagavi, Karnataka.

Study population: Information would be gathered from patients with arteriovenous hemodialysis fistula dysfunction referred to the Department of Radiodiagnosis for color Doppler ultrasonography at KLE’s Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi.

Study Duration: January 2021 till December 2021.

Method of data collection:

Patients diagnosed with clinically suspected complications of their arteriovenous hemodialysis fistula who will be referred to the Department of Radio-Diagnosis for color doppler sonography at the KLE's Dr. Prabhakar Kore Hospital & MRC., Belagavi.

Methodology:

Consent to participate in this study will be provided in writing form by all participants.

When collecting clinical data, a standardized and pre-defined format must be adhered to at all times.

Evaluations of the medical history, clinical condition, and any previous invasive procedures of the patient will all take place in depth.

Patients who are a part of the previously mentioned study population will have a full color doppler ultrasonography assessment of their hemodialysis access system performed on them. This assessment will include an analysis of the afferent artery, the anastomosis site, and the vascular anatomy that is present distal to the arteriovenous fistula.

The machine used is GE Voluson 8 color Doppler machine (GE Health Care USA) equipped with a 7.5-12 MHz high frequency linear array transducer.

Sampling and Sample Size:

Sampling technique:

Universal Sampling i.e. when not all people in the population have the same chance of being in the sample and each person's chance of being chosen is unknown.

Sample size calculation:

The following is the formula for determining the minimal sample size required depending on the prevalence rate:

$N= Z_{\alpha}^{2}\ P(1-P)/d^{2}$

where P is the percentage of prevalence and d is the percentage likely difference in the prevalence.

The amount of significance is connected to the value of Z_{α}. The value of Z_{α} for the 5% level of significance is 1.96.

When P = 73.3% and d = 20% of P = 14.66%.

35 is the number that was determined to be the appropriate sample size.

Inclusion Criteria:

Patients on hemodialysis (between age group 20 to 80years) with clinically suspected complications of arteriovenous fistula who will be referred to the department of Radiodiagnosis for Color Doppler sonography at KLE Dr. Prabhakar Kore Hospital and Medical Research Centre's, Belagavi.

Exclusion criteria:

- Patients with chronically occluded vascular access with failed surgical or interventional attempt.
- Patients suffering from arteriovenous fistula who were unable to keep their limbs steady for the duration of the ultrasonography.

Statistical Analysis:

Because this is an observational study, the methods of data analysis that we will apply are as follows:

- We are going to compute the means of the continuous quantitative variables as well as their standard deviations. In the event that the data is divided into two groups according to a certain qualitative criterion, we will utilise appropriate statistical procedures to compare the continuous variables. One example of such a method is the independent t test. The baseline values and the endpoint values will be compared using a test called the dependent t test.
- The symbol for discrete variables will be the value that is located in the middle of their range.
- To provide a better understanding of the categorical data, we will be using rates, ratios, and percentages. To investigate the degree of correlation that exists between the variables of interest (result, clinical, and demographic), we will either apply the Chi-square test, the test of proportion, or Fisher's exact test.

- The use of nonparametric tests has been decided upon because of their superior performance when dealing with discrete data.
- When necessary, we will make use of several other applicable approaches, such as analysis of variance, correlation, and regression, amongst others.
- Suitable graphs will be utilized in order to provide a graphical representation of the comparison.
- In each and every instance, the level of significance that will be assumed is 5%. ($p<0.05$).

RESULTS

Study population:

35 patients on hemodialysis with clinically suspected complications of arteriovenous fistula who were referred for color Doppler ultrasonography were prospectively evaluated in this study.

Table 1: Descriptive analysis of age distribution among the study population (N=35)

Age (Years)	Frequency	Percentage
20-30	4	11.43
31-40	5	14.29
41-50	11	31.43
51-60	8	22.86
61-70	4	11.43
71-80	3	8.57
Total	**35**	**100.0**

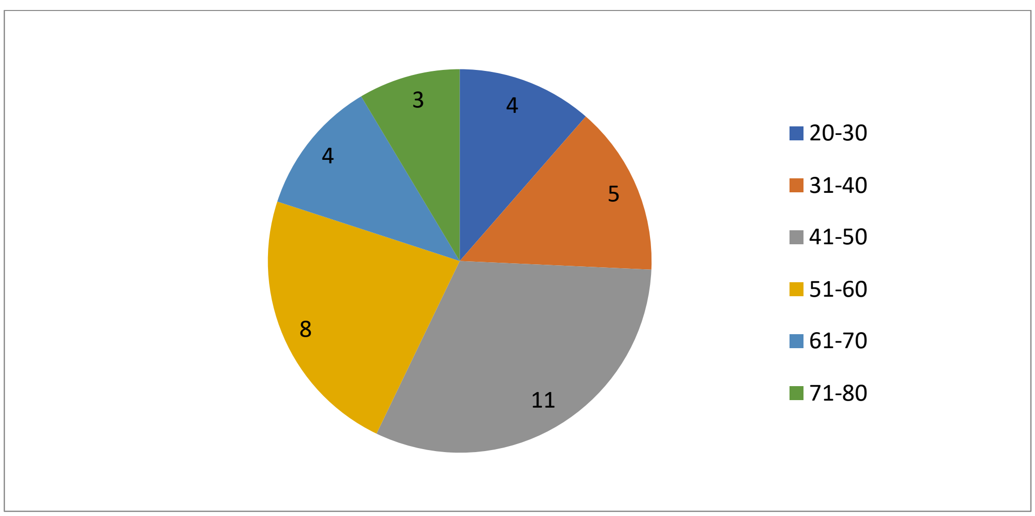

Figure 1: Pie chart of age distribution among study population.

Above table and chart indicate that of total 35 patients, maximum no of patients belong to age group 41-50(31.43%), followed by patients in the age group 51-60 (22.8%).

Table 2: Descriptive analysis of gender among the study population (N =35)

Sex	Frequency	Percentage
Female	15	42.9
Male	20	57.1
Total	35	100.0

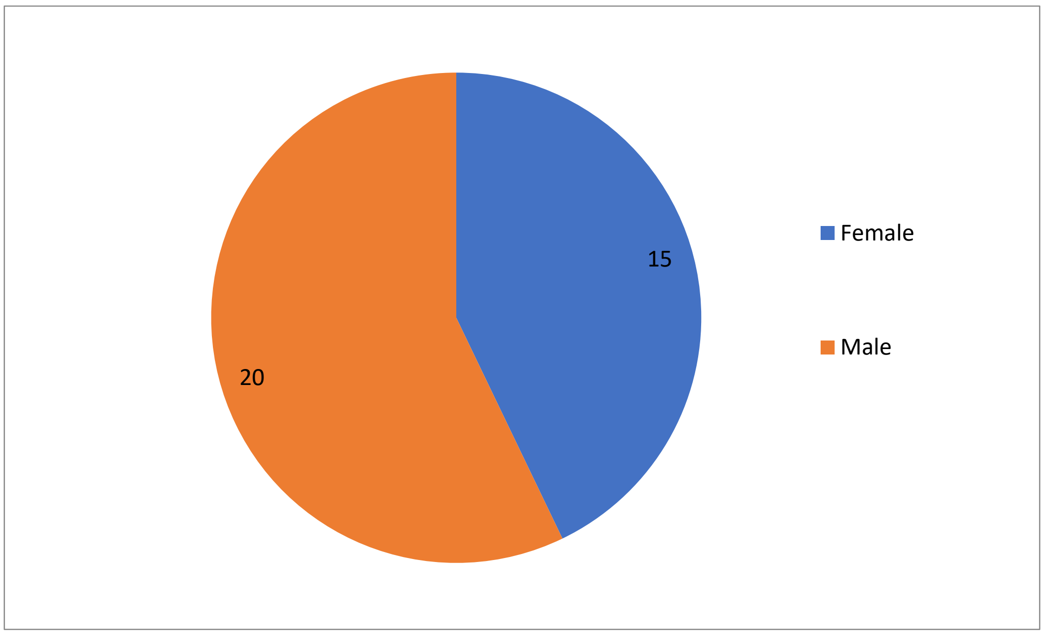

Figure 2: Pie chart of gender distribution among study population.

The table and graph above show that there are 35 patients in total, with 15 (42.9%) of them being female and 20 (57.1) being male.

Table 3: Descriptive analysis of distribution with respect to clinical history in study population (N=35)

Clinical H/O	Absent	Percentage	Present	Percentage	Total
Upper Limb oedema with pain	27	77.1	8	22.9	35
Upper Limb oedema without pain	24	68.6	11	31.4	35
Localised swelling	29	82.9	6	17.1	35
No complaint	25	71.4	10	28.6	35

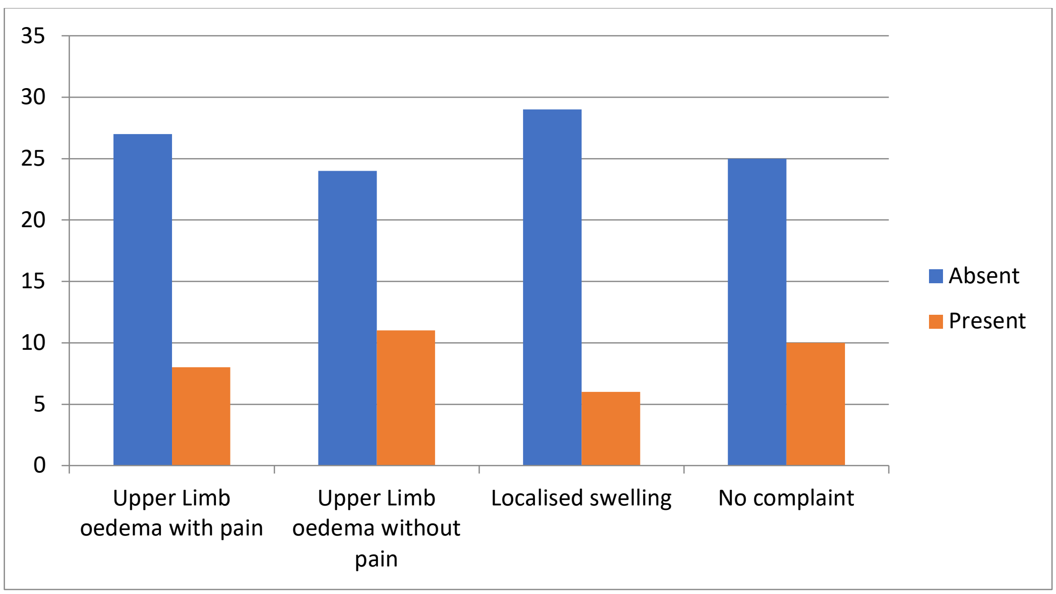

Figure 3: Bar chart of frequency with respect to Clinical H/O among study population

Above table and chart indicate that of total 35 patients, maximum no of patients presented with upper limb oedema without pain (31.4%).

Table 4: Descriptive analysis of type of fistula among the study population(N=35)

Type of fistula	Frequency	Percentage
Brachiobasilic fistula	8	22.9
Brachiocephalic fistula	13	37.1
Radiocephalic fistula	14	40.0
Total	35	100.0

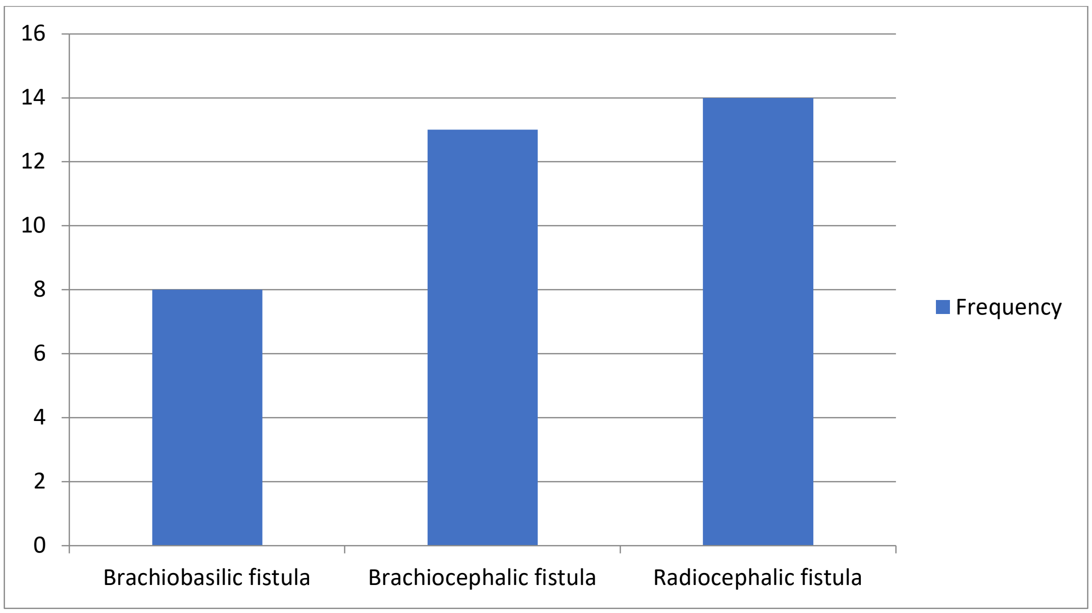

Figure 4: Bar chart of frequency of Type of fistula among study population

The table and graph above show that there were 35 patients in total, of whom 8 patients had fistulas of the Brachiobasilic type, 13 patients had fistulas of the Brachiocephalic type and the remaining 14 patients had fistulas of the Radiocephalic type.

Table 5: Descriptive analysis of Duration of fistula among study population(N=35)

Duration of fistula	Frequency	Percent
1 Years	11	31.5
1.5 Years	9	25.7
2 Years	15	42.9
Total	35	100.0

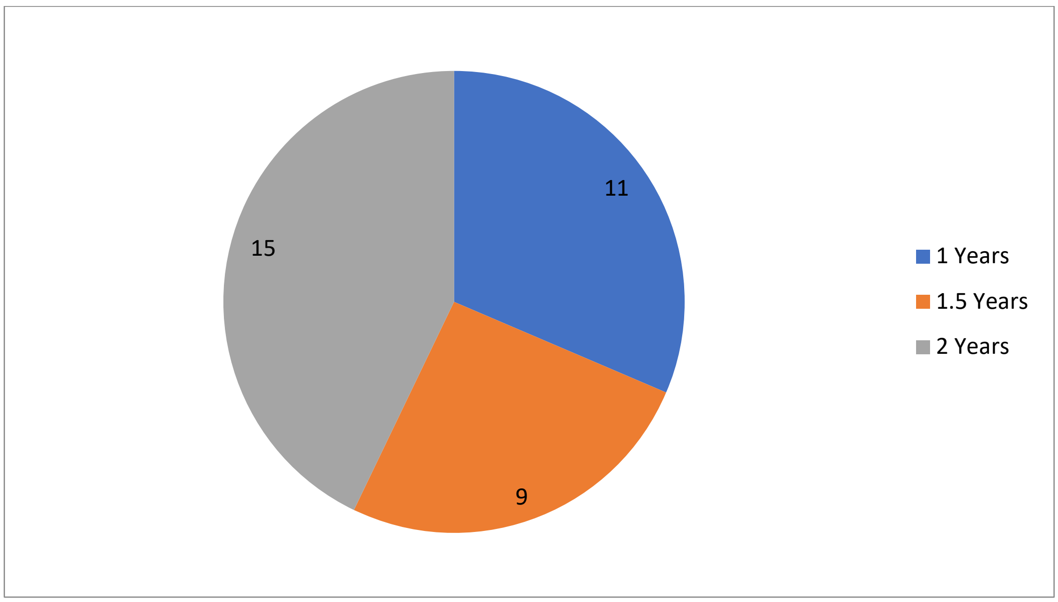

Figure 5: Pie chart of Frequency of Duration of fistula among study population

The table and graph above show that there were 35 patients in all, of which 11 (31.5%) had fistulas of one year duration, 9 (25.7%) had fistulas of 1.5 years duration and the remaining 15 (42.9%) had fistulas of two years duration.

Table 6: Descriptive analysis on Laterality of fistula among study population(N=35)

Laterality	Frequency	Percent
Left	32	91.4
Right	3	8.6
Total	35	100.0

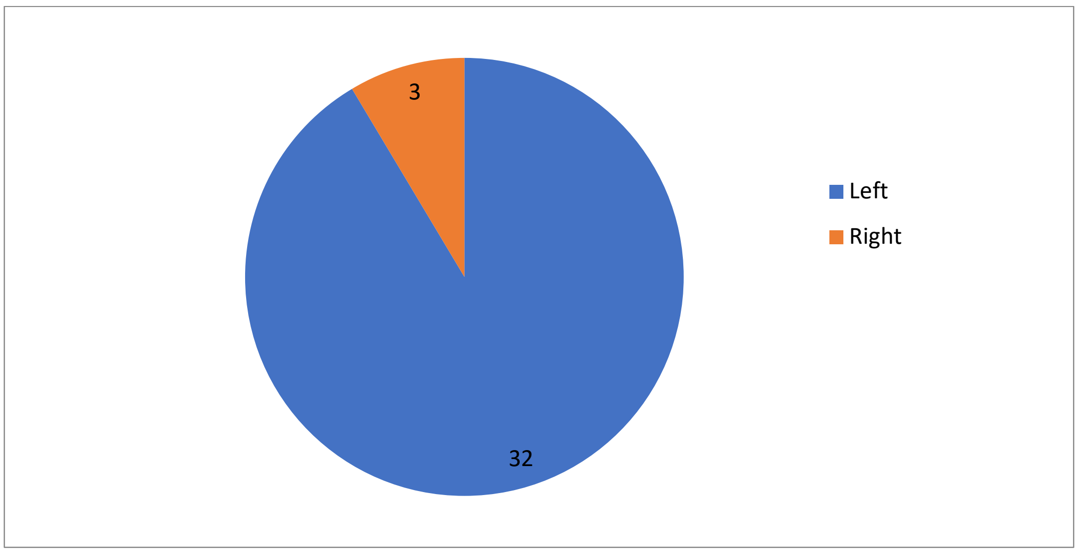

Figure 6: Pie chart on frequency on Laterality of fistula among study population

The table and graph above show that there were 32 (91.4%) patients which had fistula with left laterality and the remaining 3 (8.6%) had right laterality.

Table7: Descriptive analysis of positive cases among the study population (N =35)

Cases	Frequency	Percentage
Positive cases	25	71.4
Normal cases	10	28.6
Total	35	100

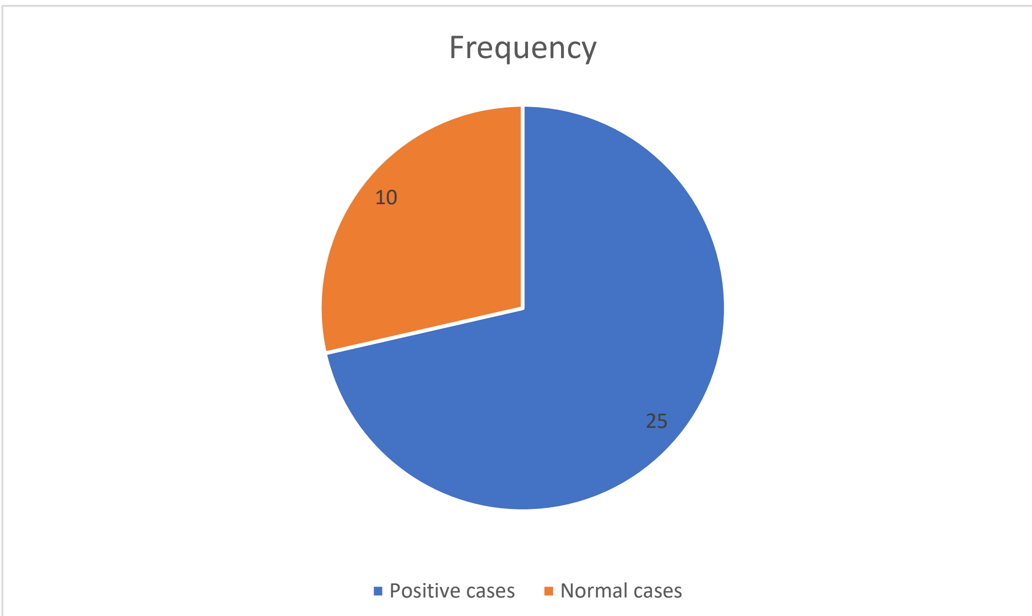

Figure 7: Pie chart on frequency of positive cases among study population

In the current study out of 35 patients on hemodialysis with clinically suspected complications of arteriovenous fistula,25 (71.4%) patients showed complications on color Doppler ultrasonography, and in 10(28.6%) patients normal findings were seen.

Table 8: Descriptive analysis of blood flow rate at AVF among study population(N=35)

Blood flow rate at AVF	Absent	Percentage	Present	Percentage	Total
Adequate (500-1500ml/min)	19	54.3	16	45.7	35
Reduced (<500ml/min)	26	74.3	9	25.7	35
No flow	25	71.4	10	28.6	35

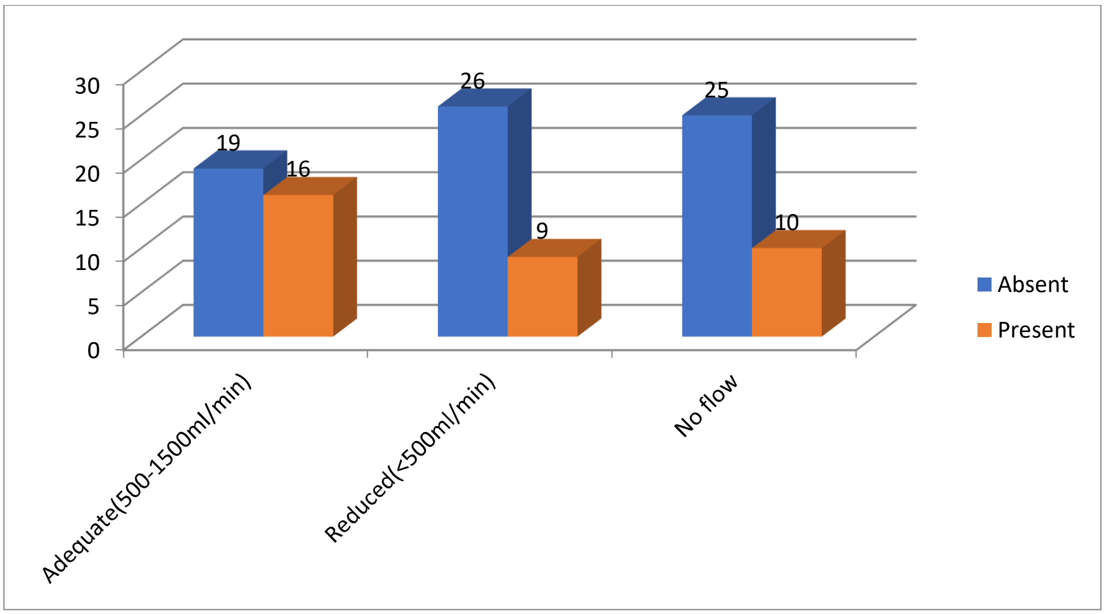

Figure 8: Bar chart on frequency of blood flow rate at AVF among study population.

Above table and chart indicate that of total 35 patients, adequate blood flow rate at AVF (500-1500ml/min) was present in 16 (45.7%) patients, reduced blood flow rate at AVF(<500ml/min) was present in 9 (25.7%) patients and no flow or absent flow was seen in 10 (28.6%) patients.

Table 9: Descriptive analysis of complications at AVF among study population(N=35)

Complications	Absent	Percentage	Present	Percentage	Total
Normal (no complications)	25	71.4	10	28.6	35
Thrombosis	25	71.4	10	28.6	35
Stenosis	26	74.3	9	25.7	35
Pseudo-Aneurysm	31	88.6	4	11.4	35
Hematoma	33	94.3	2	5.7	35

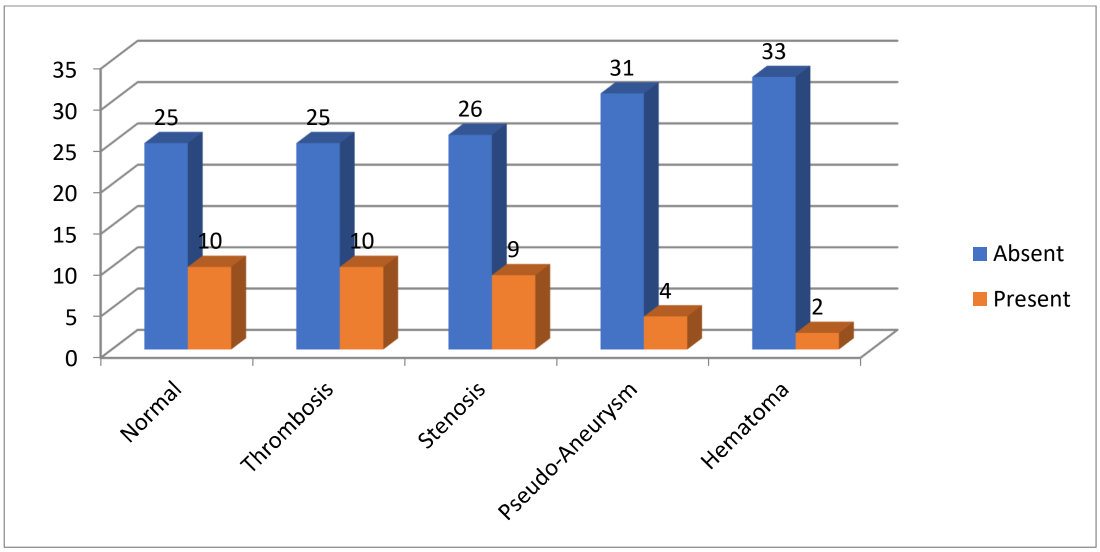

Figure 9: Bar chart of frequency of complications among study population

Above table and chart indicate that 10(28.6%) patients had no complications and remaining 25 (71.4%) patients had complications, among which thrombosis was present in 10(28.6%) patients, stenosis was present in 9(25.7%) patients, pseudo aneurysm was present in 4(11.4%) patients and hematoma in 2 (5.7%) patients.

DISCUSSION

The present study was conducted in Department of Radiodiagnosis at Jawaharlal Nehru Medical College, Belagavi, Karnataka. Patients on hemodialysis with clinically suspected complications of arteriovenous fistula who were referred for color doppler ultrasonography were included in this study, 35 patients were included.

Age wise distribution of cases in study population:

In the present study, maximum number of cases were aged between 41 to 50 years i.e.31.43% followed by 22.8% in the age group of 51 to 60 years. This correlated with the study done by Khaled M. Moghazy et al[52] were the mean age for the study group was 45.2 years.

Sex wise distribution of cases in study population:

In this study, males (57.1%) outnumbered the females (42.9%). This correlated with the study done by Khaled M. Moghazy et al[52] in which the males constituted 69% of the study. Similar findings were reported by Chong Ren et al[53] were male predominance (50.6%) was also seen.

Distribution of cases in relation to clinical history:

This study shows that, majority of patients presented with upper limb oedema without pain (31.4%) followed by no complaint (28.6%), upper limb oedema with pain (22.9%) and localised swelling (17.1%).

In the study conducted by Khaled M. Moghazy et al[52], painless oedema of fistula limb constituted 32.7% followed by no complaint in 27.4% and painful oedema of fistula limb in 23.6%.

Type of fistula among the study population:

In the present study, the most common type of fistula seen was radiocephalic fistula (40%) followed by brachiocephalic fistula (37.1%) and brachiobasilic fistula (22.9%). Similar reports have been made by other workers. In the study conducted by Omar Abdelaziz et al[55], brachiocephalic fistula constituted (40%) followed by radiocephalic fistula (36%) and brachiobasilic fistula (24%).

Study group included most cases that had a duration of fistula of 2 years (42.9%) with majority of fistulas made in left arm (91.4%).

Distribution of positive cases in study population:

This study included a total of 35 patients, in which complications (i.e positive cases) were detected in 71.4% of patients whereas the patients with normal findings were 28.6%. Similar reports have been made by other workers. In the study conducted by Mohammed H. Hassan et al[54], the complications were detected in 73.3% of patients. Other studies done by Khaled M.Moghazy et al[52] and Omar Abdelaziz et al[55], detected complications in 100% of patients.

Blood flow at AVF among study population:

In present study, color doppler ultrasonography detected adequate blood flow rate (500-1500 ml/min) in 45% of patients, reduced blood flow rate (<500 ml/min) in 25.7% of patients and no/absent blood flow in 28.6% of patients. This correlated with the study done by Khaled M. Moghazy et al[52] where adequate blood flow rate was seen in 23.6% patients, reduced blood flow rate in 34.6% and no/absent blood flow in 29.1% patients.

Distribution of cases in relation to complications at AVF:

Color doppler ultrasonography in this study showed no complications (normal findings) among 28.6% of patients.

Among the study group, complications were detected in 71.4% of patients, in which thrombosis was seen in maximum patients constituting about 28.6% of patients followed by stenosis in 25.7%, pseudoaneurysm in 11.4% and hematoma in 5.7% of patients.

In a study conducted by Omar Abdelaziz et al[55], thrombosis was seen in 48% of patients followed by stenosis in 44% and pseudoaneurysm in 4% of patients.

Another study conducted by Mohammed H. Hassan et al[54], showed thrombosis in 16.6%, stenosis in 10%, pseudoaneurysm in 10% and hematoma in 16.6% of patients.

CONCLUSION

- The architecture and hemodynamics of the AVF may be evaluated by minimally invasive color doppler ultrasonography. Being cost-effective, with no radiation exposure and availability at patient's bedside makes color doppler ultrasonography as the safest and the earliest investigation for evaluation of complications of arteriovenous hemodialysis fistula access.
- This study was conducted in Department of Radiodiagnosis at Jawaharlal Nehru Medical College, Belagavi, Karnataka.
- Sample size in present study was 35 which included patients with clinically suspected complications of their arteriovenous hemodialysis fistula.
- This study shows that among the total sample size, complications were detected by color doppler ultrasonography in 71.4%.
- The present study shows male (57.1%) predominance, with the maximum number of cases between the age group of 41 to 50 years (31.4%).
- Radiocephalic fistula (40%) was the most commonly observed fistula among the study population.
- Color doppler ultrasonography done in the present study shows adequate blood flow rate at AVF in maximum no of patients with thrombosis (28.6%) being the most common observed complication.

SUMMARY

- Color doppler ultrasonography is a noninvasive diagnostic test that is used to monitor blood flow through an AVF and detect probable causes of vascular access malfunction.
- This enables early identification of AVF issues and improves patient outcomes. Because it is easily accessible and has a low cost, it ought to be the imaging technique of choice for an AVF that is not operating well.
- Color doppler ultrasound is essential for identifying vascular anatomy that can be used for the formation of AVF, also knowing about the complications that may occur at the fistula site, as a result, it is used routinely by doctors for knowing about the patency and status of the fistula and for its survival on a long run. Color doppler ultrasound is essential for identifying arteries that are ideal for constructing an AVF (surveillance).
- Color doppler ultrasound is the only technology that can monitor the blood flow in the AVF while also studying the possible causes of vascular access dysfunction at the same time. This makes it possible to do early and accurate salvage surgeries, which may decrease the morbidity and mortality.
- The study was a hospital based observational study, conducted among patients referred to radiology department of KLE'S Dr Prabhakar Kore Hospital Belagavi for color Doppler ultrasonography.
- The study had a total of 35 cases, who were diagnosed with clinically suspected complications of their arteriovenous hemodialysis fistula and were referred to the Department of Radio-Diagnosis for color doppler sonography.

- Among the 35 cases, 11 presented with symptoms of upper limb oedema without pain,8 with symptoms of with upper limb oedema with pain and 6 with symptoms of localized swelling,10 patients had no symptoms.
- It was found that males were affected more as compared to females.
- Maximum numbers of cases were in the age group of 41 to 50 yrs.
- It was found that, among the study population, the most common type of fistula observed was radiocephalic fistula (40%) followed by brachiocephalic and brachiobasilic fistula.
- Color doppler ultrasonography in this study also determined the blood flow rate at AVF which showed adequate blood flow rate in 16 patients, reduced flow rate in 9 patients and no/absent flow in10 patients.
- In this study, complications associated with AVF was found among 25 patients whereas 10 patients had normal color doppler findings.
- This study also utilized the color doppler ultrasonography in determining the different types of complications at vascular access, in which thrombosis was present in 10 patients, stenosis in 9 patients, pseudo aneurysm in 4 patients and hematoma in 2 patients.
- Thus this study underlines that for early diagnosis of complications which are associated with the hemodialysis fistula access, color doppler ultrasonography plays a very important role, thus helping in early intervention and prevention of mortality and morbidity.

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ANNEXURE - I –

INFORMED CONSENT

TITLE OF THE STUDY: "ROLE OF COLOR DOPPLER ULTRASOUND IN ASSESSMENT OF COMPLICATIONS OF ARTERIOVENOUS HEMODIALYSIS FISTULA ACCESS:ONE YEAR HOSPITAL BASED OBSERVATIONAL STUDY"

INVESTIGATOR: REGISTRATION NO. BS0120015

GUIDE: DR ________________________________

INTRODUCTION AND PURPOSE:

Hemodialysis has an important role in long term survival of patients with end stage renal disease and to maintain them on long term dialysis, vascular access procedures are required. The arteriovenous fistula provides the best access for longevity and lowest morbidity and mortality, but its adequate functioning is required for a long survival and good quality of life. Color doppler ultrasonography is rapidly emerging as an essential investigation, which helps in assessment of complications of arteriovenous hemodialysis fistula access thus providing early diagnosis of problems and allowing correction before failure of the access thus reducing morbidity and mortality.

PROCEDURE:

The purpose of the study will be explained and written informed consent will be obtained from all participants. The subjects will be selected based on inclusion and exclusion criteria. The study will be conducted over a period of one year. Once the patient signs the informed consent, history and examination will be recorded as per the proforma.

In our study, the patient will be subjected to color doppler ultrasonography on GE Voluson 8 color doppler machine (GE Health Care USA). Patient will be positioned supine and a gel will be applied over the skin surface of interest, the gel is non allergic, can be easily wiped off and allows the transducer probe to move over the region for getting the proper image. Then with the help of 7.5 -12 Mhz high frequency linear array transducer the area of the entire hemodialysis access system will be scanned.

We request you to participate in this study as you are eligible to be included. During the study, you will be asked questions regarding your present and past medical history and you will be required to answer to the best of your knowledge. You will also be clinically examined as per the protocol drawn.

If you agree to participate in the study, please furnish the details pertaining to the study.

BENEFITS:

- Noninvasive modality.

RISKS /COMPLICATIONS:

- No risk to the patient has been documented from color doppler sonography conducted earlier.

ALTERNATIVES:

If patient is not willing to take part in the study, his/her treatment or any other further investigations the patient wants to undergo, in future, in KLE will not be affected by his/her decision.

VOLUNTARY PARTICIPATION/WITHDRAWAL:

Taking part in this study is voluntary. I may choose not to take part in this study, or if I decide to take part, I can later change my mind and withdraw from the study. My decision will not change the present or future health care or other services that I receive. The study doctor or the sponsor may stop my participation in this study. I will tell if any important new findings that may change my willingness to continue to take part. If I choose not to take part in the study, I will receive the standard treatment for patients with my condition.

COSTS:

NIL (The study is to be conducted on the participants who are advised Color doppler ultrasonography as an investigation by the referring consultant and the participants will bear the charges for it.)

Payment for Participation: No incentive will be paid to you for participating in this study.

COMPENSATION:

In the event that I become injured as a result of taking part in this study, treatment whatever available at KLE Ccharitable hospital, Belagavi, will be offered to me. No reimbursement, compensation or free medical care is given.

CONFIDENTIALITY:

All information collected about me during the course of the study will be kept confidential to the extent permitted by the law. The code numbers will identify me in this research record. Information from this study may be published but my identity will be kept confidential in any publication/ presentation.

QUESTION:

If you have any enquiries in the future or in case of research related injury illness, you may contact following persons:

Name: REGISTRATION NO. BS0120015

Mobile No:9431357218

REGISTRATION NO. BS0120015	**DR __________________**	**DR HARSHA HEGDE**
Post-Graduate, Department of Radio-Diagnosis, J.N.Medical College, Belagavi.	Guide, Professor, Department of Radio-Diagnosis, J.N.Medical College, Belagavi.	Chairperson, J.N. Medical College, IEC & Scientist D, ICMR, National Institute of Traditional Medicine, Belagavi.

CONSENT TO PARTICIPATE IN RESEARCH STUDY:

1. I understand that I am participating in the study, which includes color doppler ultrasonography of the entire hemodialysis access.
2. I confirm that I have read and understood the information in the patient information sheet. Procedure is explained to me in detail along with information about the advantages and disadvantages of taking part in the study. I have been given the opportunity to discuss all aspects of the trial, to ask questions and hereby consent to participation in the trial outlined above.
3. I understand that the decision to take part in this study is completely voluntary and I am aware that I can choose to withdraw from the study at any point of time.
4. I consent to the photographing or recording of the procedure to be performed including appropriate portions of my body, for medical, scientific or educational purposes provided my identity is not revealed in the pictures or by the descriptive texts accompanying them.
5. I understand that there is no significant risk involved in the test that would be done in this study.
6. No guarantee or assurance has given by anyone as to the results that may be obtained.
7. My signature on this form signifies that I have willingly decided to participate after understanding the above information.

Participant’s Name/ legally authorized ______________________

representative

Signature ______________________

Name and signature of witness ______________________

Name and signature of interviewer ______________________

Date: ____________

Place_____________

ANNEXURE - II- PROFORMA

PROFORMA FOR DATA COLLECTION

DATE:	
NAME OF THE PATIENT:	
AGE (IN YEARS)/SEX:	
OP/IP NO:	
ADDRESS:	
USG NUMBER:	

CHIEF COMPLAINTS:
DURATION

1.		
2.		

TYPE AND DURATION OF ARTERIOVENOUS FISTULA CREATION:

____

LOCAL EXAMINATION:

	ON EXAMINATION	**PRESENT/ABSENT**
1.	**DIFFUSE UPPER LIMB EDEMA**	
2.	**LOCALISED SWELLING**	
3.	**REDNESS**	
4.	**ISCHEMIC PAIN**	
5.	**DISCOLOURATION**	

USG FINDINGS:

	COMPLICATIONS	PRESENT/ABSENT
1.	THROMBOSIS	
2.	STENOSIS	
3.	HEMATOMA	
4.	PSEUDOANEURYSM	
5.	OTHERS	

COLOR DOPPLER FINDINGS:

Peak systolic velocity at the site of anastomosis is	_ cm/s
Peak systolic velocity at 2.0 cms cephalad from the anastomosis site is	_ cm/s
Blood flow rate at arteriovenous fistula site is	_ ml/min

FINAL DIAGNOSIS:

ANNEXURE III: CLINICAL IMAGES

Fig 10: GE VOLUSON USG machine used for the study

Fig 11: High frequency linear array transducer used for the study

Fig 12: Diagram showing waveform in a normal AVF.

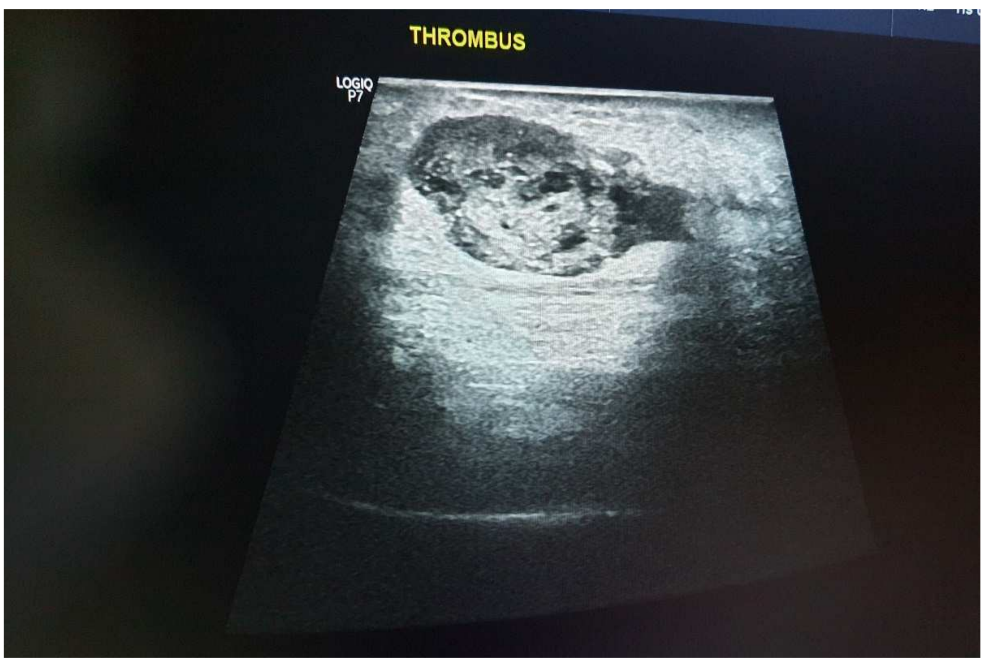

Fig 13: USG image showing the presence of thrombus located at the site of arteriovenous anastomosis of the AVF.

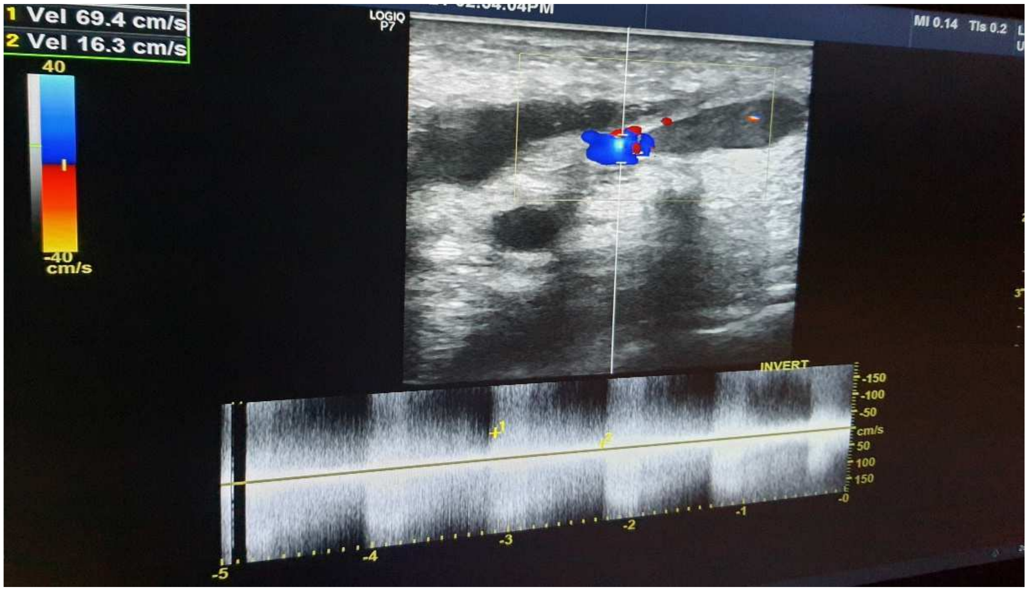

Fig 14: USG image showing the presence of stenosis, at the juxta-anastomotic site of AVF.

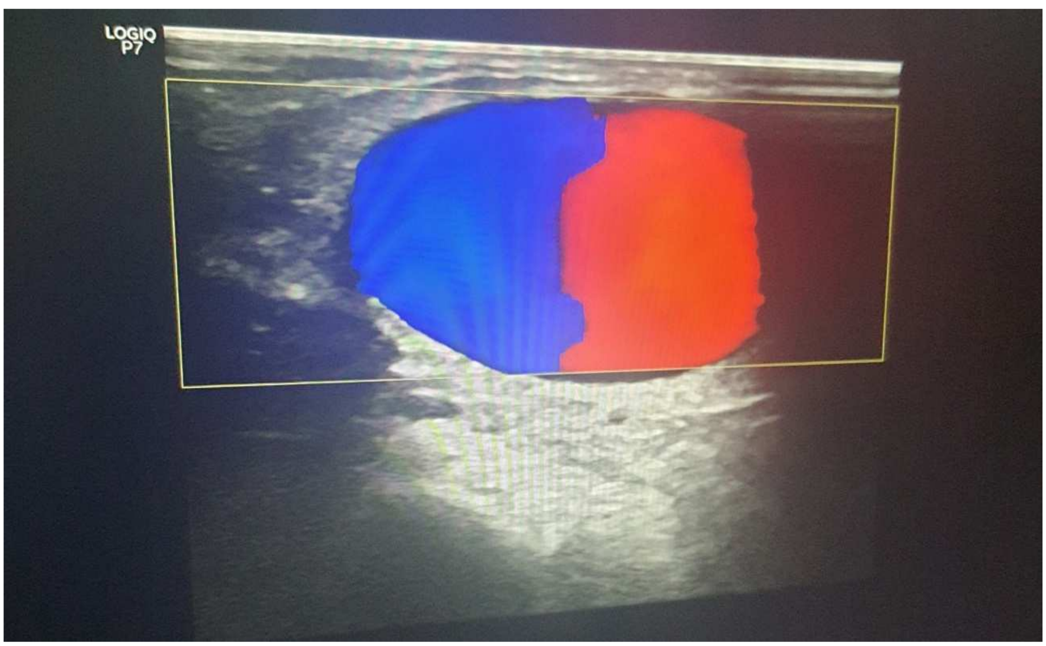

Fig 15: USG image showing the typical ying yang sign present in pseudoaneurysm seen at the site of the anastomosis.

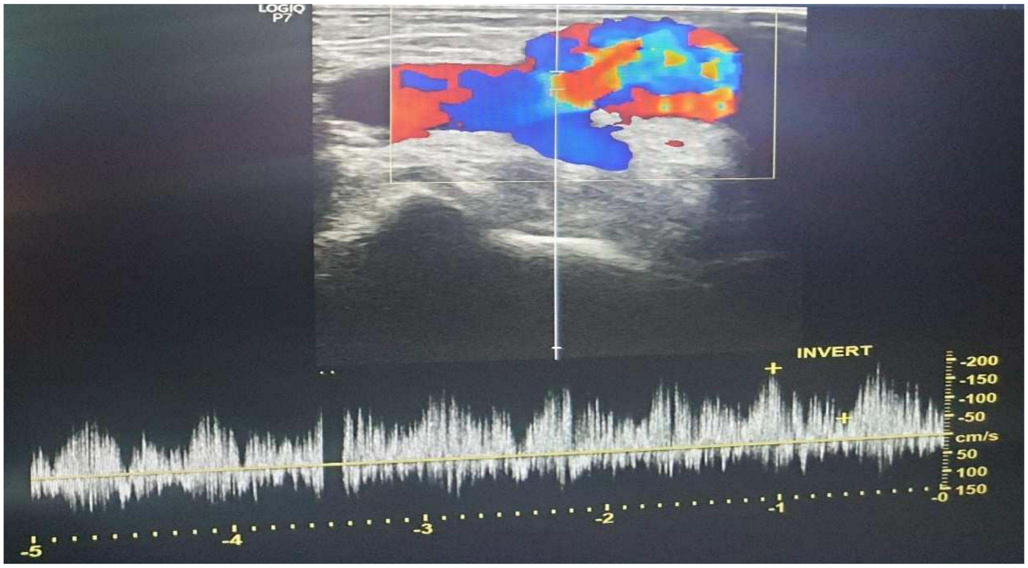

Fig 16: USG image showing the presence of pseudoaneurysm seen at the site of the anastomosis.

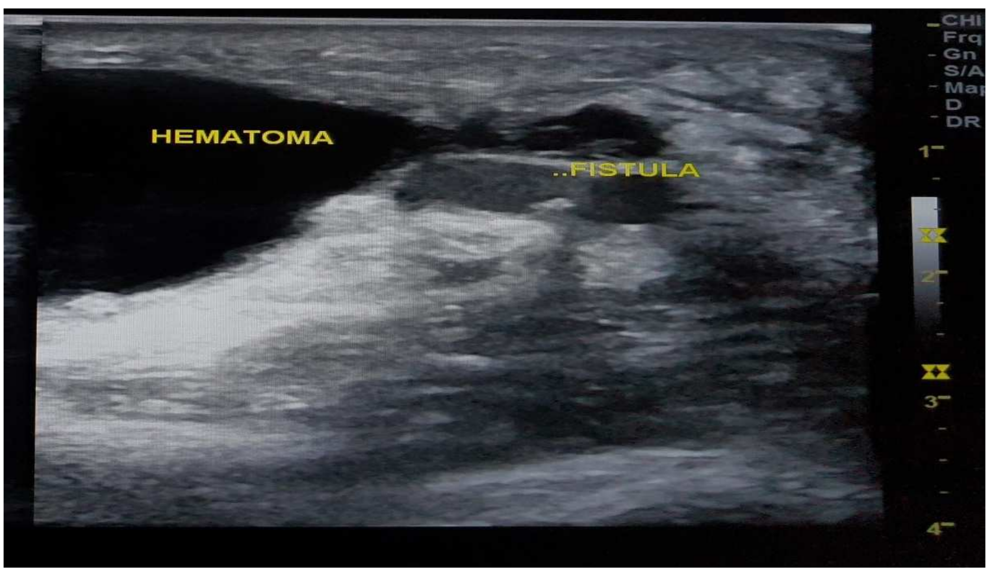

Fig 17: USG image showing the presence of hematoma seen as a localised hypoechoic collection around the site of fistula.

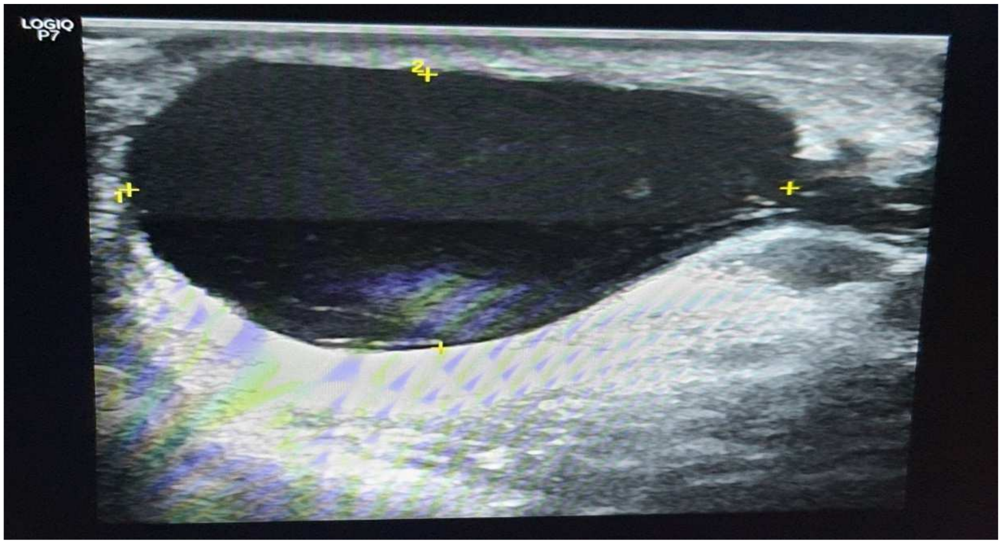

Fig 18: USG image showing the presence of hematoma around the site of fistula.

ANNEXURE IV: KEY TO MASTERCHART

Rt	Right
Lt	Left
N	Normal
P	Present
RC	Radiocephalic fistula
BC	Brachiocephalic fistula
BB	Brachiobasilic fistula
YR	Years
AVF	Arteriovenous fistula
PSV	Peak systolic velocity

Serial No.	USG No.	Age(yrs)	Sex	Duration of fistula	Type of fistula	Laterality	Clinical H/O				Color doppler findings					USG findings				
													Blood flow rate at AVF				Complications			
							Upper Limb oedema with pain	Upper Limb oedema without pain	Localised swelling	No complaint	PSV at anastomosis(cm/sec)	PSV at 2cm cephalad (cm/sec)	Adequate (500-1500ml/min)	Reduced (<500ml/min)	No flow	Normal	Thrombosis	Stenosis	Pseudo-Aneurysm	Hematoma
1	22803	41	M	2 YR	RC	LT		P			ABSENT	120			P		P			
2	27527	48	F	1 YR	BB	LT		P			468	130		P				P		
3	28566	41	F	1 YR	BC	LT				P	380	120	P			N				
4	28573	41	M	1 YR	RC	LT			P		230	120	P							P
5	28947	27	M	2 YR	BB	LT	P				ABSENT	100			P		P			
6	29028	50	F	2 YR	RC	LT		P			570	120		P				P		
7	29232	70	F	1.5 YR	RC	LT				P	350	100	P			N				
8	29990	37	F	1.5 YR	BC	LT			P		300	130	P							P
9	30090	62	M	2 YR	RC	LT	P				ABSENT	120			P		P			
10	39462	29	M	2 YR	BB	LT	P				510	122		P				P		
11	40409	27	F	1 YR	RC	LT		P			ABSENT	110			P		P			
12	41514	47	F	1 YR	BC	LT				P	350	150	P			N				
13	42078	31	M	1.5 YR	BC	LT		P			500	128		P				P		
14	42621	27	M	2 YR	RC	LT				P	ABSENT	100			P		P			
15	44482	47	F	2 YR	BC	LT	P				489	126		P				P		
16	48702	56	F	1.5 YR	BC	LT			P		220	150	P						P	
17	50492	72	M	1 YR	BC	RT	P				327	200	P			N				
18	50542	74	M	1 YR	BC	LT				P	555	130		P				P		
19	50716	36	F	2 YR	RC	LT		P			ABSENT	100			P		P			
20	51267	34	F	1.5 YR	BC	LT		P			590	122		P				P		
21	51836	62	M	1.5 YR	RC	LT			P		184	150	P						P	

22	52095	50	F	1YR	BB	LT	P				350	200	P			N				
23	52869	51	M	2 YR	RC	LT	P				572	130		P				P		
24	54362	60	F	2 YR	RC	RT		P			ABSENT	130			P		P			
25	55171	42	M	1 YR	RC	LT	P				300	150	P			N				
26	56121	44	M	2 YR	BC	LT				P	584	136		P				P		
27	56223	66	F	1 YR	BB	LT				P	360	170	P			N				
28	56299	60	M	1 YR	BC	LT			P		170	120	P						P	
29	56350	59	M	2 YR	RC	LT		P			ABSENT	120			P		P			
30	57000	45	F	2 YR	BB	RT				P	300	130	P			N				
31	57011	72	M	1.5 YR	BC	LT				P	ABSENT	110			P		P			
32	57085	40	M	1.5 YR	RC	LT			P		200	170	P						P	
33	57101	50	M	2 YR	BC	LT		P			ABSENT	120			P		P			
34	57121	52	M	1.5 YR	BB	LT		P			355	130	P			N				
35	57140	55	M	2 YR	BB	LT				P	360	110	P			N				