

A DISSERTATION ON
“ASSESSMENT OF CENTRAL VEINS IN HEMODIALYSIS
PATIENTS USING DOPPLER , MAGNETIC RESONANCE
VENOGRAPHY AND DIGITAL SUBTRACTION VENOGRAPHY –
A COMPARATIVE STUDY TO DETERMINE THE USEFULNESS
OF BEDSIDE DOPPLER IN EXPERT HANDS.”

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RADIODIAGNOSIS



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CHENNAI .

MAY - 2020

CERTIFICATE

This is to certify that the dissertation titled “**ASSESSMENT OF CENTRAL VEINS IN HEMODIALYSIS PATIENTS USING DOPPLER , MAGNETIC RESONANCE VENOGRAPHY AND DIGITAL SUBTRACTION VENOGRAPHY – A COMPARATIVE STUDY TO DETERMINE THE USEFULNESS OF BEDSIDE DOPPLER IN EXPERT HANDS**” submitted by Dr. PON SHANKAR.A , appearing for M.D.RADIODIAGNOSIS degree examination in May 2020, is a bonafide record of work done by him, in partial fulfilment of requirements of The Tamilnadu Dr. M.G.R Medical University, Chennai. I forward this to The Tamilnadu Dr. M.G.R Medical University, Chennai.

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DECLARATION

I, **Dr.PON SHANKAR.A**, (Reg no : **201718205**) certainly declare that this dissertation titled, **“ASSESSMENT OF CENTRAL VEINS IN HEMODIALYSIS PATIENTS USING DOPPLER , MAGNETIC RESONANCE VENOGRAPHY AND DIGITAL SUBTRACTION VENOGRAPHY – A COMPARATIVE STUDY TO DETERMINE THE USEFULNESS OF BEDSIDE DOPPLER IN EXPERT HANDS”**, represent a genuine work of mine done at the Department of Radio Diagnosis, Stanley Medical College, under the supervision of the **PROF.DR.C.NELLAIAPPAN, MDRD, Professor, Department of Radio Diagnosis, Stanley Medical College, Chennai – 600 001.**

I, also affirm that this bonafide work or part of this work was not submitted by me or any others for any award, degree or diploma to any other university board, neither in India or abroad. This is submitted to The Tamil Nadu Dr.MGR Medical University, Chennai in partial fulfilment of the rules and regulation for the award of Master of Radiodiagnosis Branch VIII.

Date : 17/10/2019,

Place: Chennai.

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INTRODUCTION

Chronic kidney disease (CKD) is one of the most important causes of death and disability⁽¹⁾. The prevalence of CKD in different regions of India ranges from 1% to 13%. Recently, according to the International Society of Nephrology's Kidney Disease Data Center Study the prevalence of Chronic kidney disease is 17%⁽²⁾.

The etiology of CKD varies considerably throughout India with high levels of CKD of unknown etiology (CKDu) in parts of the states of Andhra Pradesh, Odisha and Goa. CKDu is a chronic interstitial nephropathy with insidious onset and slow progression⁽³⁾.

Hemodialysis is performed for patients with CKD through temporary catheterization of the subclavian and jugular veins before creating Arterio Venous fistula(AVF) or implanting an ArterioVenous graft(AVG). Adequate blood flow is a determining factor for appropriate function of the vascular access for most patients on chronic hemodialysis. Access to the proper vein is also vital for adequacy of hemodialysis⁽⁴⁾.

Catheterization of central veins is associated with severe complications such as hemothorax, pneumothorax and long-term-use complications, such as occlusion of these veins⁽⁵⁾. Central venous steno-occlusive disease (CVSD) is a common and significant problem in the management of hemodialysis patients, the incidence of which reported in the literature was to be in the range of 25-40%⁽⁶⁾.

Naroe Nejad et al (2010) studied the prevalence of stenosis of the central vein and concluded that stenosis can happen following their long-term catheterization for hemodialysis in patients with CKD ⁽⁷⁾.

Central venous steno-occlusive disease can result in the loss of the access site, increased venous pressure on the dialysis machine leading to its stoppage, and arm swelling due to venous hypertension. Prompt treatment of Central venous steno-occlusive disease is required ⁽⁸⁾.

The cause of central vein stenosis is usually iatrogenic. It may be due to repeated insertion of dialysis catheters in the same vein over long period and also the repeated infection that occurs at the tip of the catheter ⁽⁹⁾. The diagnosis of central venous stenosis is made based on both clinical and imaging findings.

Ultrasonography has been widely used for the detection of CVSD. It can diagnose easily the thrombosis or stenosis in internal jugular veins and subclavian veins. The stenotic or thrombotic lesions in other central veins such as brachiocephalic veins and superior vena cava (SVC) are difficult to be diagnosed ⁽¹⁰⁾.

Magnetic resonance venography (MRV) shows to be more accurate and reliable than ultrasonography in diagnosis of CVSD. The images obtained from MRV show better morphological findings detecting the length and degree of the lesions ⁽¹¹⁾. MRV indicate whether interventional procedures are necessary and can identify the length of the lesion that requires crossing with the catheter and guide wire ⁽¹²⁾.

MRV can be done by contrast and non-contrast techniques. Non-contrast MRV using Time of Flight (TOF) and phase contrast (PC) techniques allowing noninvasive visualization of the venous structures ⁽¹³⁾. Contrast enhanced MRV can also be done safely with using small dose of contrast such as Gadoterate meglumine (Dotarem) instead of Gadopentetate dimeglumine (Magnevist). This contrast proved to be more safe in patients with renal impairment and less likely to induce nephrogenic systemic fibrosis (NSF) ⁽¹⁴⁾.

Digital subtraction contrast venography is the gold standard for the diagnosis of Central venous steno-occlusive disease ⁽¹⁵⁾. This is an invasive method and has several adverse effects, including sensitivity to contrast substance, thrombosis and undesirable effects on kidney function. Thus alternative methods to detect Central venous steno-occlusive disease, with minimum adverse effects and maximum detectability, is very important.

The sensitivity and specificity of Duplex ultrasound for diagnosing central vein stenosis, however, are limited and venography remains the gold standard for evaluation of central vein patency.

AIM AND OBJECTIVES

AIM:

- The current study is aimed at investigating the diagnostic accuracy of Doppler ultrasonography in the assessment of the Internal Jugular, Subclavian, Brachiocephalic Veins and Superior Vena Cava as a non-invasive screening test at the bed-side.

OBJECTIVES:

- To determine the Sensitivity, Specificity, Positive predictive value(PPV), Negative predictive value(NPV) of Doppler and Magnetic resonance venography (MRV) and compare with Digital subtraction venography(DSV) in the assessment of the patency and steno-occlusive disease of intra-thoracic central veins in hemodialysis patients.
- The individual outcomes are compared between Doppler, MRV and DSV and the degree of agreement is evaluated by calculating the Kappa value(K-value).

REVIEW OF LITERATURE

CKD is an important public health problem because of its high prevalence, morbidity and mortality. Over 50% of patients with advanced CKD are first seen when the eGFR is 15 ml/min per 1.73 m² because of challenges in access to care ⁽¹⁶⁾.

Patients with acute renal failure or end stage renal disease require renal replacement therapy, which includes peritoneal dialysis (PD), haemodialysis (HD) or kidney transplantation (Fig:1) Hemodialysis (HD) was first introduced in India in 1962. Transplantation was introduced in 1971, followed by peritoneal dialysis (PD) in 1991. HD is the most common modality followed by transplantation, and PD is the last option.

Treatment options for patients with ESRD

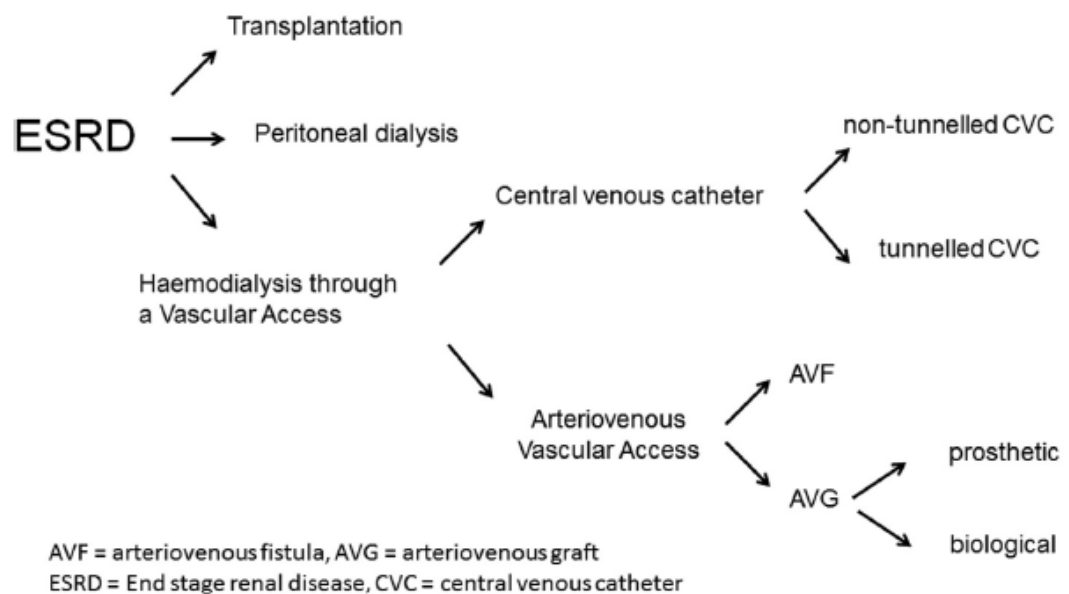


Figure: 1

A Vascular Access (VA) is essential for patients on HD and can be accomplished with central venous catheters (CVC), but also with arterialisation of a vein or by interposition of a graft between an artery and a vein for the insertion of HD needles. The blood flow available for HD should reach at least 300 ml/min and preferably 500 ml/min depending on the VA modality to allow a sufficient HD.

Successful HD treatment is only possible with a well functioning VA. The ideal VA should allow cannulation using two needles, deliver a minimum blood flow of at least 300 ml/min through the artificial kidney, resistant to infection and thrombosis, and should have minimum adverse events. The first option for the construction of a VA is the creation of an autogenous Arterio Venous Fistula (AVF). Secondary and tertiary options are prosthetic Arterio Venous Graft (AVG) and CVCs. The reason for creating autogenous AVFs is that observational studies show a lower incidence of postoperative complications and fewer endovascular and surgical revisions for AVF failure in comparison to AVGs⁽¹⁷⁾.

In addition, the use of CVCs results in a significantly higher morbidity and mortality rate. The risk of hospitalisation for VA related reasons and particularly for infection is highest for patients on HD with a catheter at initiation and throughout follow-up⁽¹⁸⁾. The principle of venous preservation dictates that the most distal AVF possible should usually be performed⁽¹⁹⁾.

THE NORMAL THORACIC CENTRAL VEINS:

Thoracic veins can be categorized as central (systemic veins), somatic (azygos/hemiazygos, superficial, body wall veins), or visceral (pulmonary veins, coronary sinus). The obstruction of the thoracic central veins, can be broadly considered as a continuation of the deep veins of the head, neck, and upper extremities. However, before addressing the thoracic central veins, it is worth noting that somatic veins (including the azygos/hemiazygos system and the superficial, paraspinal, epidural, and body wall veins) often provide collateral circulation as Central venous steno-occlusive disease (CVSD) develops. These collateral pathways play a role in mitigating the clinical effects of CVSD.

The thoracic central veins (Fig:2) include intrathoracic segments of the internal jugular veins (IJVs), subclavian veins (SCVs), brachiocephalic vein(BCVs), superior vena cava(SVC), and the suprahepatic portion of the inferior vena cava (IVC). These veins are located central to the superior thoracic aperture (C7–T1 intervertebral disc level), central to the lateral margin of the first rib margin, and superior to the diaphragmatic caval opening ⁽²⁰⁾.

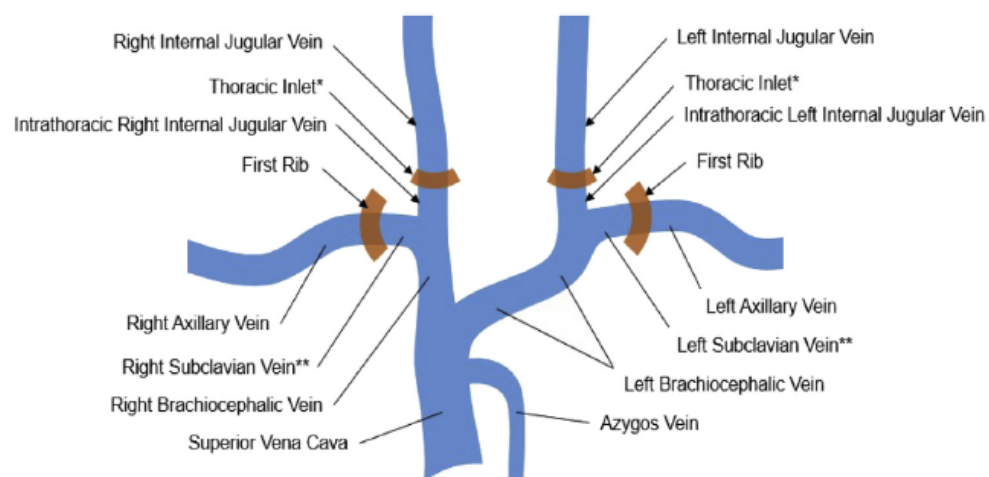


Figure:2

The SVC serves as the final pathway for thoracic central venous return to the right atrium. The azygos vein drains into the SVC between the confluence of the BCVs and the right atrium and serves as an important collateral pathway in the setting of many cases of CVSD. Obstruction of the central SVC (ie, between the azygos vein and heart) prevents antegrade azygous venous drainage to the right atrium and therefore defines the most central type of CVSD.

The suprahepatic IVC is a thoracic central vein because it lies above the diaphragm (and is therefore in the thorax). However, obstruction of this venous segment has a markedly different clinical presentation than obstruction of the thoracic central veins above the right atrium. It will not be further considered in the study.

Anomalies of the thoracic central veins have also been described. The most common, found in 0.3% of people, is persistence of the left SVC, typically seen along with a right-sided SVC⁽²¹⁾. The left SVC is almost always an incidental finding, and carries venous flow from the left BCV to the coronary sinus. Given its infrequent occurrence, the role of a left sided SVC in CVSD remains unknown. Other thoracic central vein anomalies are much less common and therefore are not included in the study.

CENTRAL VENOUS STENO-OCCLUSIVE DISEASE (CVSD):

Venous obstruction is defined as a pathophysiologic venous luminal narrowing that impedes blood flow. Obstruction may be partial (ie, stenosis) or complete (ie, occlusion). In this study, obstructions are considered to be central (ie, closer to the right atrium; BCVs and SVC) or peripheral (ie, further from the right atrium, eg, IJV and SCV obstructions).

MECHANISMS OF OBSTRUCTION:

Although many conditions cause CVSD, there are 3 predominant mechanisms of obstruction. Extrinsic compression is caused by arterial compression, musculoskeletal compression, postoperative scarring, fibrosis, or compression as a result of tumor. Venous wall thickening may be caused by de novo smooth muscle hyperplasia, organized mural thrombus, or fibrosis or secondary to stent, stent graft, catheter, or implanted cardiac rhythm device leads. Tumor infiltration, infection, inflammation, intramural dissection, or hematoma can cause wall thickening.

Endoluminal obstruction is commonly caused by thrombus, but may be caused by endoluminal device implants such as stents or stent grafts, catheters, or cardiac rhythm device leads that occupy luminal space or by secondary formation of adherent tissue (ie, “fibrin”) sheath or neointimal tissue. Rarely, it is the result of tumor (eg, angiosarcoma) or congenital or acquired webs or membranes.

Thoracic malignancy, particularly lung cancer and lymphoma, and other neoplastic, infectious, and inflammatory mediastinal processes may obstruct the thoracic central veins ⁽²²⁾. Paget–Schroetter syndrome and subclavian venous thrombosis may cause CVSD ⁽²³⁾.

CVSD is frequently associated with the use of indwelling venous devices such as infusion ports, peripherally inserted central catheters, and transvenous cardiac rhythm device leads ⁽²⁴⁾. Chronic central venous catheters in children and adults have been associated with CVSD ⁽²⁵⁾. Patients receiving hemodialysis who have had previous venous catheter access or cardiac rhythm

device leads are known to have a high prevalence of symptomatic CVSD ⁽²⁶⁾. Some cases of CVSD cannot be attributed to any particular cause ⁽²⁷⁾.

The use of tunneled hemodialysis catheters has become essential in the care of patients undergoing hemodialysis. The safety and effectiveness of ultrasonographically (US) guided venous access in the placement of hemodialysis catheters has been well established ⁽²⁸⁾. Documented long-term complications of subclavian access, including stenosis and thrombosis, have led to the current treatment strategy of using the internal jugular vein for primary access ⁽²⁹⁾.

In addition to guidance, preprocedural US of the internal jugular vein also provides a baseline evaluation of venous integrity and patency. Few studies have addressed the long-term complications, specifically thrombosis and stenosis, associated with internal jugular access ⁽³⁰⁾.

Recent experience suggests that these complications are more common than previously suspected ⁽³¹⁾, which could be due to an increased use of this access site, larger catheter sizes, or possibly the type of biomaterials (polyurethane and silicone) that compose the majority of catheters currently in use.

The association of central venous catheterization with subsequent thrombosis has been well documented. Allen et al ⁽³²⁾ found an overall thrombosis rate of 38% among patients with peripherally inserted central catheters. Many publications have illustrated the association between hemodialysis catheter placement through the subclavian vein and the subsequent development of stenosis and/or thrombosis ⁽³³⁾.

It is not uncommon for patients with subclavian venous stenosis and/or thrombosis to have clinical signs, such as upper extremity edema. This is exacerbated in the setting of an ipsilateral arteriovenous fistula or graft, which often leads to painful upper extremity swelling, venous collateral formation, and problems with access, including prolonged bleeding and increased recirculation ⁽³⁴⁾. The awareness of late complications of subclavian access prompted the use of alternate access sites, such as the internal jugular vein.

Thrombosis of the SVC is another important clinical problem that requires prompt diagnosis. Confirmation of suspected SVC syndrome requires the use of an imaging study to document the obstruction and presence of collateral venous channels ⁽³⁵⁾. In a study by Hammerli and Meyer, flow in the SVC could be recorded by using color-flow Doppler examinations in the setting of central venous catheters ⁽³⁶⁾. The SVC flow in the subjects before catheter placement was characterized by two distinct peaks, respiratory variability, and maximal velocities between 0.5 and 1.5 m/s which were unchanged by the catheters.

Patients with thrombus or obstruction had turbulent flow, loss of a distinct biphasic profile, and increased velocity downstream to the thrombus and decreased velocity upstream. It appears that Doppler study is a worthwhile adjunct to 2-D echocardiography in the evaluation of catheter-related thrombus, and that an altered SVC flow profile with increased velocity suggests thrombus formation with obstruction ⁽³⁷⁾.

Similarly, thrombosis of upper extremity veins and the SVC can occur in patients with indwelling central venous catheters ⁽³⁸⁾. Contrary to earlier reports, pulmonary embolism (PE) can result from these thrombi, especially

when they are attached to catheters (sleeve thrombi) rather than to the venous wall (mural thrombi). Removal of catheters may be required when sepsis occurs or to reduce risk of sepsis when lines have been left in for several days.

Transesophageal echocardiography may have a role in showing thrombus dislodgment and embolization during removal of venous catheters complicated by SVC thrombi⁽³⁹⁾. Direct visualization of thrombus dislodgment may aid in early diagnosis of PE because signs and symptoms of PE are often missed or mistaken for underlying cardiopulmonary disease.

Transesophageal echocardiography may also play a role in implementing appropriate treatment in patients with PE who show right ventricular strain⁽⁴⁰⁾. Thrombosis of the innominate vein and SVC is also a serious complication in patients with pacemakers, inducing pulmonary embolism or SVC syndrome. Venography is the definitive method for its diagnosis; however, in a study on patients with pacemakers, sensitivity and specificity for detecting severe innominate vein stenosis due to thrombosis using combined color-flow and pulse Doppler were 94 and 100%, respectively⁽⁴¹⁾.

Superior vena caval syndrome may be caused by extravascular compression or intravascular obstruction. Knowing the mechanism of SVC syndrome allows the physician to choose appropriate treatment. The valuable role of TEE in demonstrating the mechanism of SVC syndrome has been reported by Ayala *et al*⁽⁴²⁾.

A randomized trial by Mugge *et al.* concluded that TEE was superior to TTE for diagnosing right heart and SVC lesions such as thrombi, vegetations, and tumors.⁽⁴³⁾ TEE was the only reliable non-invasive method for imaging the SVC to evaluate these lesions⁽⁴⁴⁾.

IMAGING MODALITIES:

The imaging modalities included in this study are, Doppler, Magnetic Resonance Venography and Digital Subtraction Venography.

I] Doppler :

When sound is reflected from a moving object, such as blood cells, the returned echoes are at a different frequency to that of the original sound source and the amount of change in the frequency is proportional to the velocity of the interface(Fig:3).

- If the object is moving away from the source, the frequency decreases.
- If the object is moving towards the source, the frequency increases.

As the angle between the transmitter and the interface (Insonation angle) nears 90° the accuracy of the estimation of the velocity of the interface decreases. In general use, **an insonation angle of less than 60°** is used to give accurate estimates of velocity.

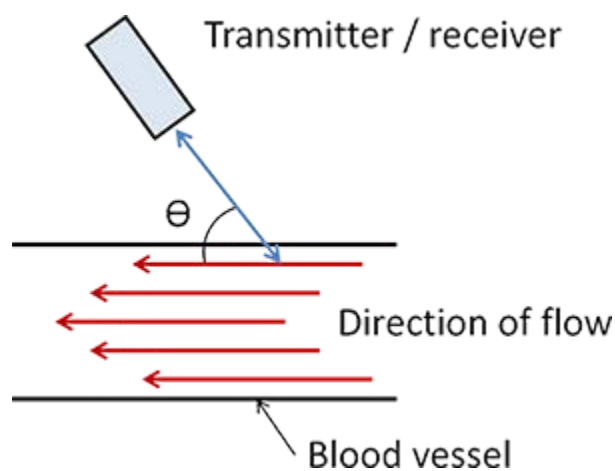


Figure:3

a) Continuous wave Doppler:

These are usually dedicated handheld devices (e.g. ABPIs, cardiopograms for fetal heartwave). The Doppler effect is emitted as an audible sound as the Doppler shift is in the audible sound frequency range: the higher the pitch the greater the velocity; the harsher the sound the more turbulent the flow (Fig:4). As they transmit (and receive) continuously, they have to contain two separate transmit and receive elements.

Advantages:

- Cheap and Easy to use
- Sensitive to flow

Disadvantages:

- Can't measure velocity
- Insonate all vessels in the beam path until the beam is attenuated. This means that as arteries and veins usually lie close together the output often combines arterial and venous signals.
- Can't determine depth

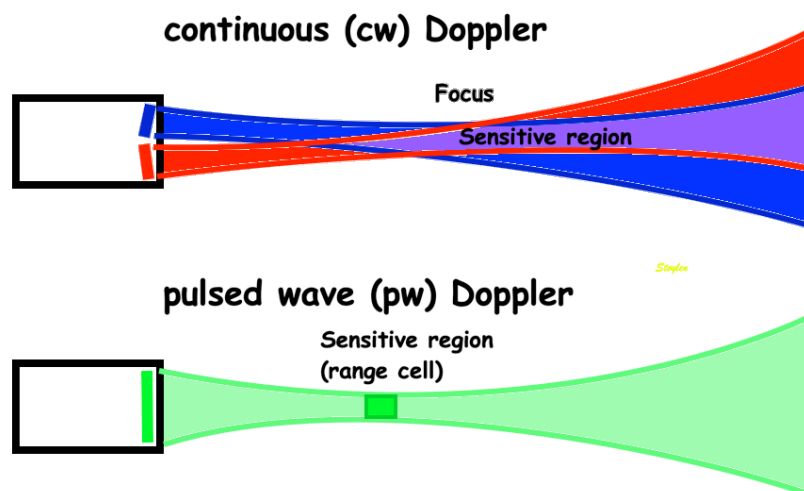


Figure:4

b) Pulsed wave Doppler:

In pulsed wave Doppler, the same elements are used for transmitting and receiving and brief pulses of ultrasound energy are emitted. Range gating is used to only accept echoes returning from a specific depth (Fig:4). Duplex involves Doppler imaging overlaid over B-mode imaging.

There are three types of pulsed wave Doppler used in ultrasound machines:

- Colour
- Power
- Spectral.

i) Colour Doppler:

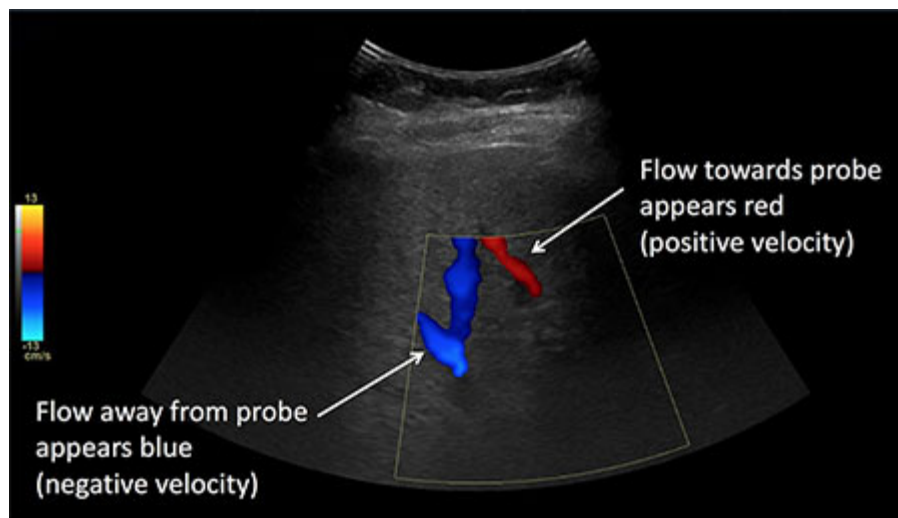


Figure:5

In colour Doppler the **sampling volume** is set and the mean and variance of the velocity of the moving structures calculated (Fig:5). This velocity is then represented by a scale of arbitrary colours ranging from minus (moving away from the transducer) to zero (no calculated velocity) to plus (moving towards transducer). The pulse frame rate affects the real-time colour Doppler measurement. A lower frame rate results in a stuttering colour Doppler (e.g)

using a larger Doppler sampling box which requires more Doppler pulses and, therefore, lowers the frame rate.

ii) Power Doppler:

Power Doppler images map the **amplitude only** of the Doppler signal without any indication of the velocity. All movement, regardless of phase, contributes to the amplitude. This means that power Doppler emphasises the quantity of blood flow.

Advantages:

- Less dependent on insonation angle
- Can show very low flow rates
- Not subject to aliasing

Disadvantages:

- No indication of flow direction
- Tissue motion creates artefacts

iii) Spectral Doppler:

Spectral Doppler shows the range of Doppler frequencies returned over time and displayed in a **sonogram (Fig:6)**. Differences in vessel wall resistance produce different spectral traces. The characteristics of the vessel walls can be represented numerically as **Resistive Index (RI)** and **Pulsatility Index (PI)**.

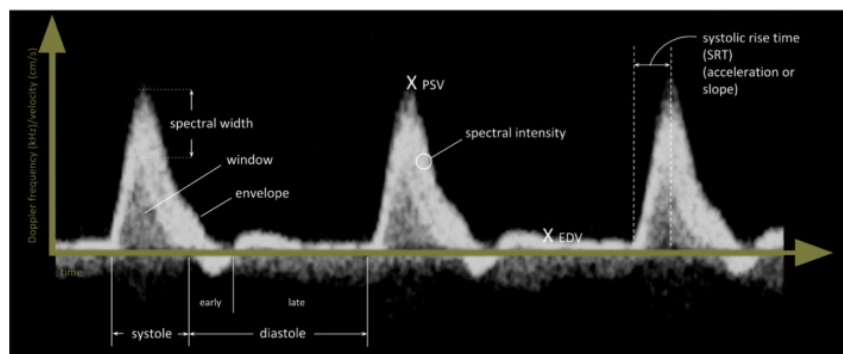


Figure:6

II] MR angiogram techniques:

The types of MR angiograms can be broadly separated out into two types: dark blood and bright blood. The bright blood techniques are then further subdivided according to whether they use gadolinium or not (Fig:7).

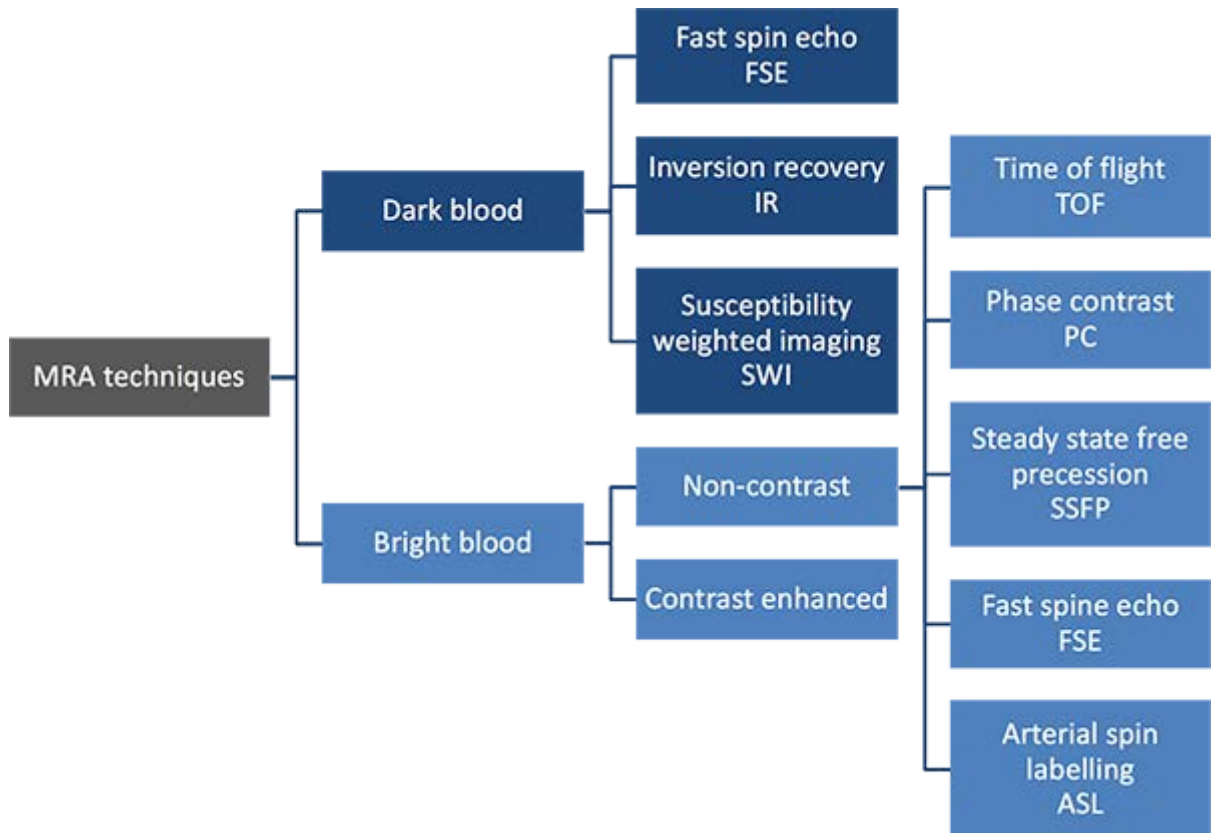


Figure:7

The main techniques used are time-of-flight, phase contrast and contrast-enhanced techniques.

a) Time of flight (TOF):

This is a **gradient echo** sequence that uses **flow-related enhancement**. It has a short repetition time (TR) to ensure that all stationary spins will have their signal saturated out. Only spins that then move into the imaging field, that have not experienced the saturating Radio Frequency(RF) pulses, will yield a high signal. It can either be a 2D or 3D study(Fig:8).

Pre-saturating bands are used to reduce the signal from blood flowing into the imaging field from a certain direction e.g. apply it distal to the imaging field to saturate out returning venous flow but ensure high signal from outgoing arterial flow.

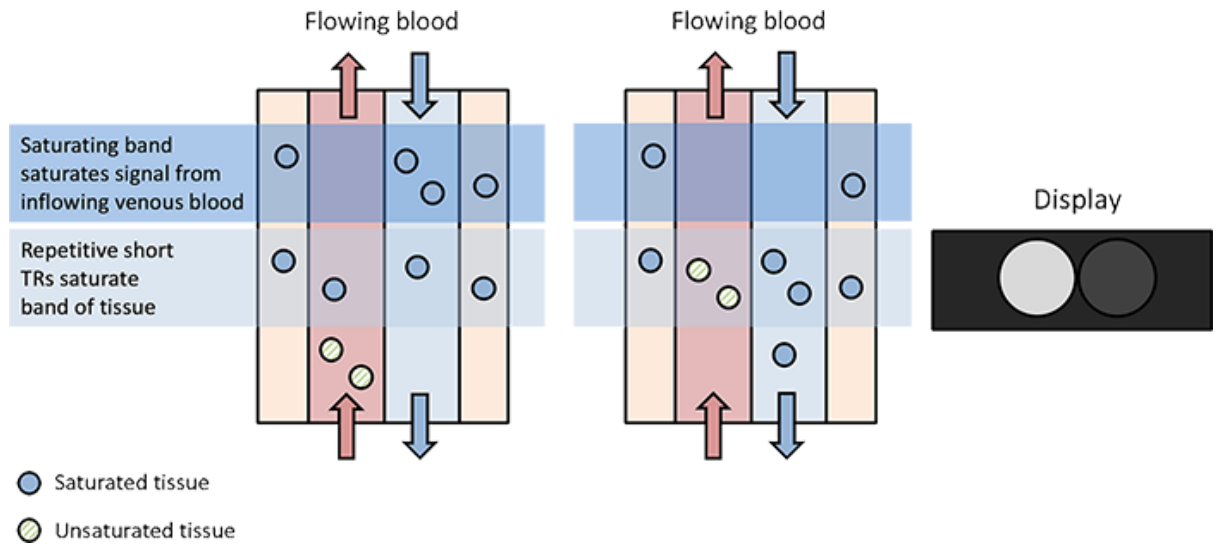


Figure:8

Advantages:

- Contrast agent not required
- Can be used for venous (2D, good for low velocities) or arterial imaging (3D, good for high velocities)
- Very sensitive to flow
- Saturates out all background signal
- 3D TOF has very high resolution (1mm)

Disadvantages:

- Flow voids due to:
 - In-plane saturation
 - Post-stenotic turbulence distal to the stenosis
 - Slow flow

- Can exaggerate the length of occlusion and stenosis
- Long imaging time
- Sensitive to metal artefact
- Stationary objects with very high T1 signal will be visible (e.g. haemorrhage)
- Retrograde arterial flow may be obscured if venous saturation bands have been applied

b) Phase contrast (PC):

Exploits differences in transverse magnetisation i.e. spin phase.

Advantages:

- Contrast agent not used
- Can reconstruct the data in any plane as usually acquired using 3D method
- Good background suppression
- Insensitive to T1 effects
- Can control the velocity dependent phase shift to alter sensitivity to different flow velocities
- Velocity can be quantified as well as the direction unlike TOF Magnetic Resonance Angiography(MRA) which is just bright or not

Disadvantages:

- Takes 4x as long as TOF as image required in three orthogonal directions to create image
- No in-plane flow voids
- More sensitivity to turbulence

c) Contrast enhanced (CE):

Uses Gadolinium Chelate agents which cause shortening of the T1 relaxation of blood compared with background tissue leading to a high signal

intensity of blood on T1-weighted sequences. The area of interest is imaged in the first pass of the contrast to ensure the best signal.

Advantages:

- More accurate
- Reproducible
- Faster scan so can image at different phases e.g. pre-contrast, arterial, venous
- Fewer flow-related artefacts

Disadvantages:

- Not flow-sensitive

III] Digital subtraction angiography (DSA):

It is a fluoroscopic technique used extensively in interventional radiology for visualizing blood vessels. Radiopaque structures such as bones are eliminated ("subtracted") digitally from the image, thus allowing for accurate depiction of the blood vessels.

History:

Angiography is largely possible because of the Seldinger technique (first described in 1952) for intravascular access.

Digital subtraction angiography, whereby a pre-contrast image is acquired, then subtracted from subsequent post-contrast images, was made possible in the 1970's, thanks to real-time refreshing of the resulting images.

The fluoroscopy unit consists of a C-arm unit that can be rotated axially and sagittally around the floating-top table. The distance between the X ray tube and the image intensifier can be adjusted, as can collimation and several

other parameters. In dedicated angiography units, there is a second set of controls for the angiographer (radiographer).

A modern angiography unit has all of the following features :

- Collimators (including oblique) and filters for dose reduction
- Pulsed fluoroscopy with a variety of frame rates for dose reduction
- Ability to change and display collimator position without fluoroscopy
- Roadmapping and Landmarking(Fig:10)
- Last image hold and Frame-grab
- Display of images side-by-side
- Masks
- Image enhancement
- Different image manipulations
- Cine
- Measurements and quantification (e.g. of degree of arterial stenosis)

The image is at least a 1024 x 1024 pixel matrix. Most modern medical displays are flat screens; some of the detectors are flat panel.

DSA technique:

Digital subtraction angiography is used to produce images of the blood vessels without interfering shadows from overlapping tissues. This provides a clear view of the vessels and allows for a lower dose of contrast medium.

- The non-contrast image (mask image) of the region is taken before injecting contrast material and therefore shows only anatomy, as well as any radiopaque foreign bodies (surgical clips, stents, etc.) as would a regular x-ray image.

- Contrast images are taken in succession while contrast material is being injected. These images show the opacified vessels superimposed on the anatomy and are stored on the computer.
- The mask image is then subtracted from the contrast images pixel by pixel. The resulting subtraction images show the filled vessels only.
- Recording can continue to provide a sequence of subtracted images based on the initial mask.

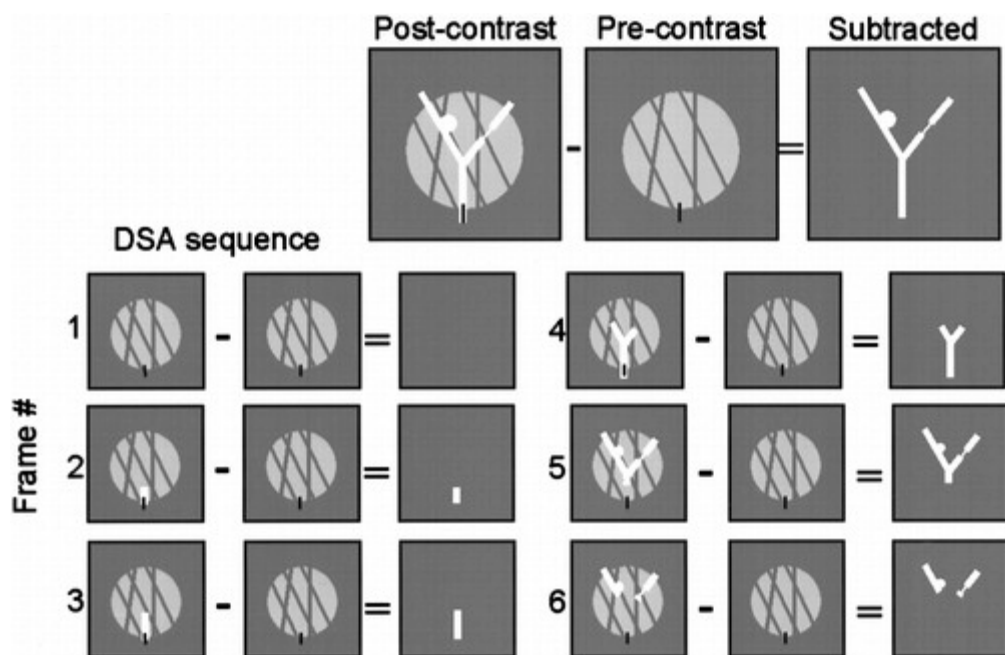


Figure:9

- The subtraction images can be viewed in real time(Fig:9). Even if the patient lies still, there is bound to be some degree of misregistration of images due to movement between the acquisition of the mask image and the subsequent contrast images. The effect is prominent at high-contrast interfaces, such as bone-soft tissue, metal staples and coils, and bowel air. Pixel shifting (either manual or automatic), i.e. moving the mask retrospectively, can minimize misregistration, but focal movement such as bowel peristalsis, will not be corrected.

It should be noted that since image subtraction causes a decrease in signal-to-noise ratio, the subtraction images appear noisier than the source images. The inevitable solution to this is to increase mA. There are also algorithms in place for reducing scatter.

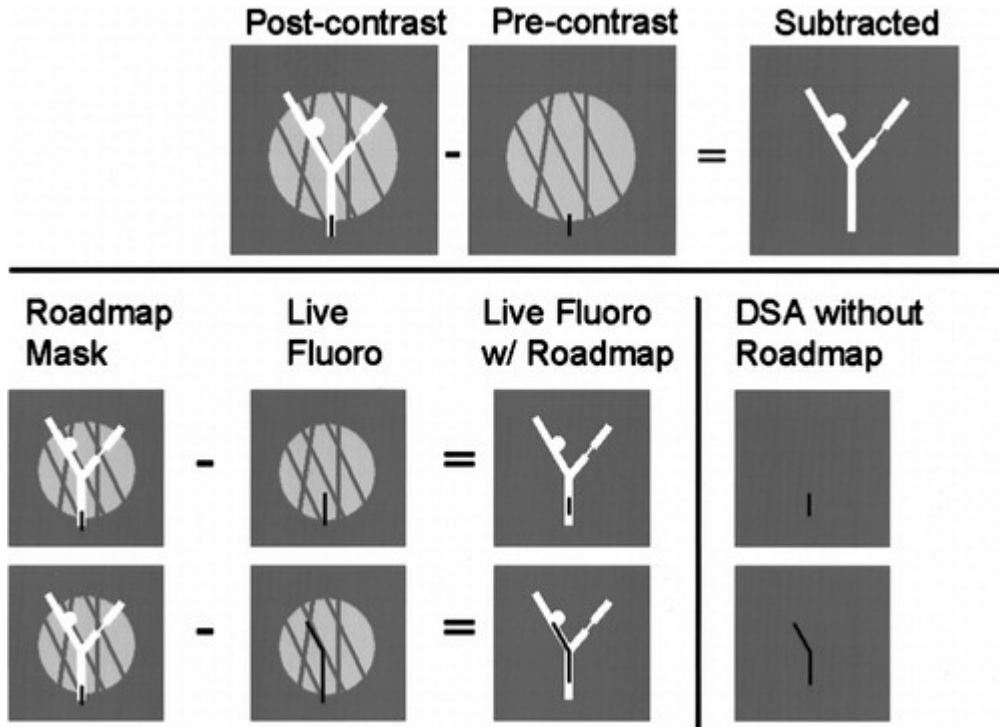


Figure:10

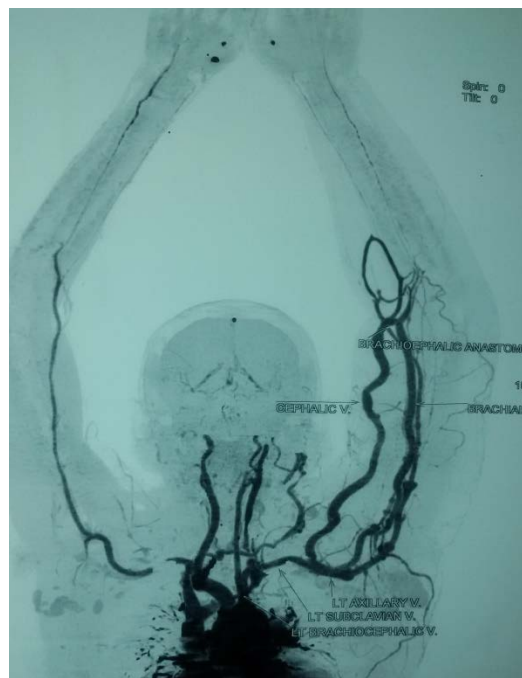


Figure:11

MATERIALS AND METHODS

- **Study design:**

The study is a Prospective observational study.

- **Study population:**

Patients in Govt Stanley hospital, undergoing hemodialysis between January 2018 & June 2019.

- **Study duration:**

1 year and 6 months.

- **Sample size : 82**

- **Inclusion criteria:**

All End Stage Renal Disease patients who require hemodialysis with Central Venous Catheter (CVC).

- **Exclusion criteria:** Patients who are contraindicated for MRI such as,

- Implanted electric and electronic devices,
- Heart pacemakers
- Implanted hearing aids,
- Intracranial metal chips,
- Metallic bodies in the eye, etc, are excluded.

Imaging Techniques:

Between January 2018 and June 2019, hemodialysis patients were examined by Doppler, MRV, Digital subtraction venography (DSV). First, the demographic data, including clinical complaints and signs, were collected. At first, patients were assessed using Doppler ultrasonography and then by venography for any probable stenosis or occlusion, resulting from catheterization of these veins.

- Doppler is to be done in all the hemodialysis patients, to look for any stenocclusive disease.
- Phase contrast MRV is then done in patients for diagnosis of patency and stenocclusive disease of intrathoracic central veins in hemodialysis patients.
- Digital subtraction venography is done in the patients diagnosed with Central venous stenocclusive disease and used as the gold standard reference.

- **Duplex Ultrasound Scanning Technique:**

A high frequency linear phased array probe and a probe with small footprint (endocavitary) should be used with the arm dependent to the possible extent of anatomy. The arm is scanned proximal to distal. Essential parameters which are measured include vessel depth, internal diameter, continuity with the deep system and the presence of any stenosis or thrombosis.

- Sonographic examination was performed using the Samsung Accuvix (XG) ultrasound system. Patients were examined in the supine position with their arms slightly abducted. Using a 10 MHz linear probe, the proximal part of the

subclavian vein was examined, with middle supraclavicular, and distal infraclavicular windows. The BCV and SVC were examined by the suprasternal notch window. In overweight patients or those with severe edema in the upper limb, a convex 5 MHz probe was used. The veins were assessed for stenosis, occlusion, venous flow, cardiac pulsatility and respiratory phasicity. Venous blood flow was assessed during inspiration and expiration and presence or absence of large collateral blood vessels around the subclavian vein were also investigated. Internal jugular vein ultrasonography was performed, first in the transverse axis, to assess compressibility and presence of thrombosis and then in the longitudinal axis, to assess venous flow, cardiac pulsatility and respiratory phasicity and probable stenosis or occlusion. Ultrasonography was performed in both directions to compare venous flow and determine the possibility of proximal or slight stenosis.

- **MRI examination:**

Magnetic resonance venography is performed on a 1.5 T SIEMENS MAGNETOM AMIRA MR unit using a torso phased-array coil centered over the thoracic inlet. The field of view (FOV) covered the region from above the clavicle to the diaphragm in craniocaudal extension and the whole chest in axial diameter. MRV was done by 3D phase contrast (PC) technique. 3D Phase contrast technique is a gradient echo technique with TR 74.65 ms; TE 9.56 ms; flip angle 15°; FOV 270 mm; Venc 10 cm/s; total scan time 2 min and 43 s. Reconstruction of images was done by maximum intensity projections (MIPs) and multi-planar reformations (MPRs) using the standard software of the

magnetic resonance unit. Resulted images describe examined veins whether they are patent, stenotic or occluded.

- **Digital subtraction venography (DSV):**

Digital subtraction venography (DSV) was conducted on all the patients as the standard reference. An intravenous cannula was inserted at the veins of hand or forearm, 50 ml iodinated contrast was injected manually as rapid as possible (10 ml bolus at each run) and image acquisition was done through the DSA unit (Siemens, Artis Zee Biplane).

There was difficult cannulation in 5 patients, so they were cannulated through the arteriovenous fistula to be examined on the affected side. The same procedure was repeated at the other side. The aim was to assess the patency of subclavian veins, brachiocephalic veins and superior vena cava, interpreted as patent, stenotic or totally occluded.

Immediately after examination, a hemodialysis session was arranged to each case, observed for 24 hours for signs of anaphylaxis, and discharged on follow-up in the outpatient clinic for three months for any delayed complications.

Interpretation of the results was done separately by 2 independent radiologists both had experience of 15 and 10 years respectively in MRV and DSV. They were blinded to the results of the other modality. Then the findings of the three modalities were correlated together as regards the ability to assess each vein. Interpretations of Doppler and MRV were compared to interpretations of DSV.

STATISTICAL ANALYSIS

The statistical analysis was done using the SPSS software version 23. The results were analysed with tables and bar charts.

The distribution of outcomes of individual veins Right Internal Jugular Vein(IJV), Right Subclavian Vein(SCV), Right Brachiocephalic Vein(BCV), Left Internal Jugular Vein(IJV), Left Subclavian Vein(SCV), Left Brachiocephalic Vein(BCV) and Superior Vena Cava(SVC) using various modalities Doppler , MRV, and Digital subtraction venography (DSV) were tabulated based on their frequency, and percentage was calculated.

The individual outcomes are compared between Doppler, MRV and DSV and the degree of agreement was evaluated .The Kappa value was calculated and the 95% Confidence Interval(CI) were arrived.

The diagnostic test characteristics like Sensitivity, Specificity, Positive Predictive Value (PPV), Negative Predictive Value(NPV) and Diagnostic accuracy were calculated and compared with the gold standard DSV. The results were statistically significant if the P-value is less than 0.05.

OBSERVATION AND RESULTS

Right Internal Jugular Vein:

Table 1: Distribution of outcomes of Right Internal Jugular Vein using Doppler.

Doppler	Frequency	Percent
Patent	51	62.2
Stenosis	11	13.4
Occlusion	20	24.4
Total	82	100.0

Table 2 : Distribution of outcome of Right Internal Jugular Vein using MRV.

MRV	Frequency	Percent
Patent	48	58.5
Stenosis	11	13.4
Occlusion	20	24.4
Not done	3	3.7
Total	82	100.0

Table 3: Distribution of outcomes of Right Internal Jugular Vein using DSV.

DSV	Frequency	Percent
Patent	48	58.5
Stenosis	11	13.4
Occlusion	20	24.4
Not done	3	3.7
Total	82	100.0

Figure: 12 - Bar chart showing distribution of outcomes of Right Internal Jugular Vein using Doppler, MRV, DSV.

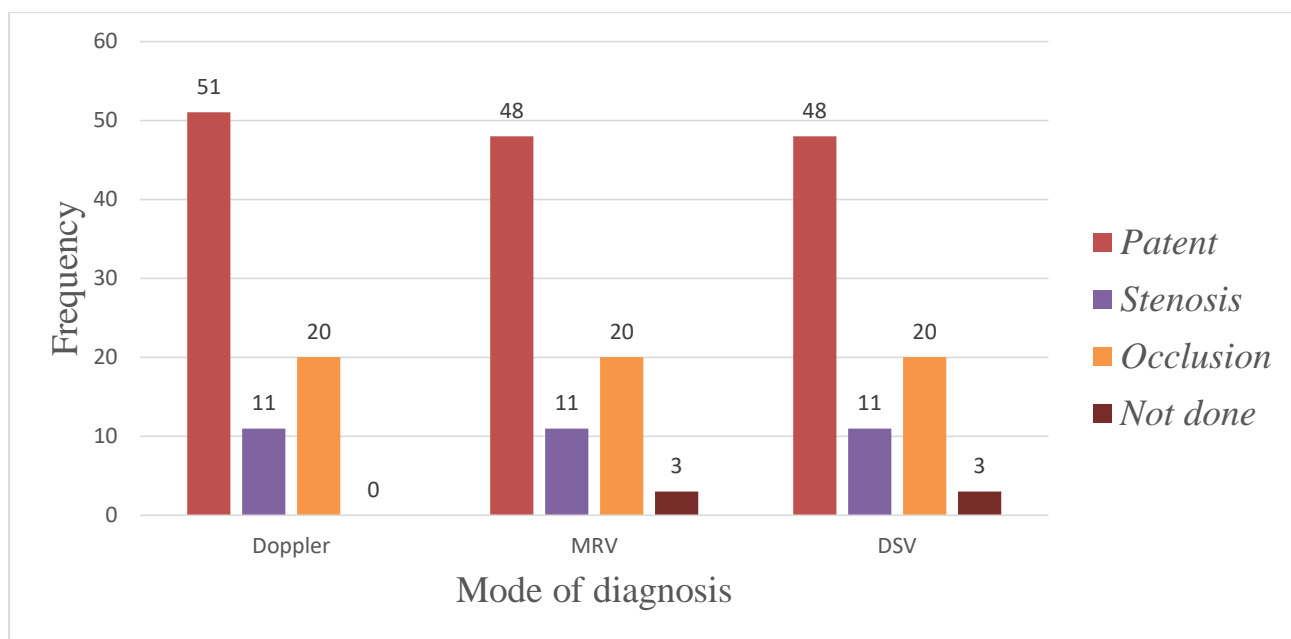


Table 4: Distribution of outcomes between Doppler and DSV for Right Internal Jugular Vein.

Doppler	DSV				Total	
	Stenoocclusive disease		Patent		N	%
	N	%	N	%		
Stenoocclusive disease	28	90.3	3	6.4	31	39.7
Patent	3	9.7	44	93.6	47	60.3
Total	31	39.7	47	60.3	78	100

Figure: 13 - Compound bar chart showing the comparison of outcome between Doppler and DSV for Right Internal Jugular Vein.

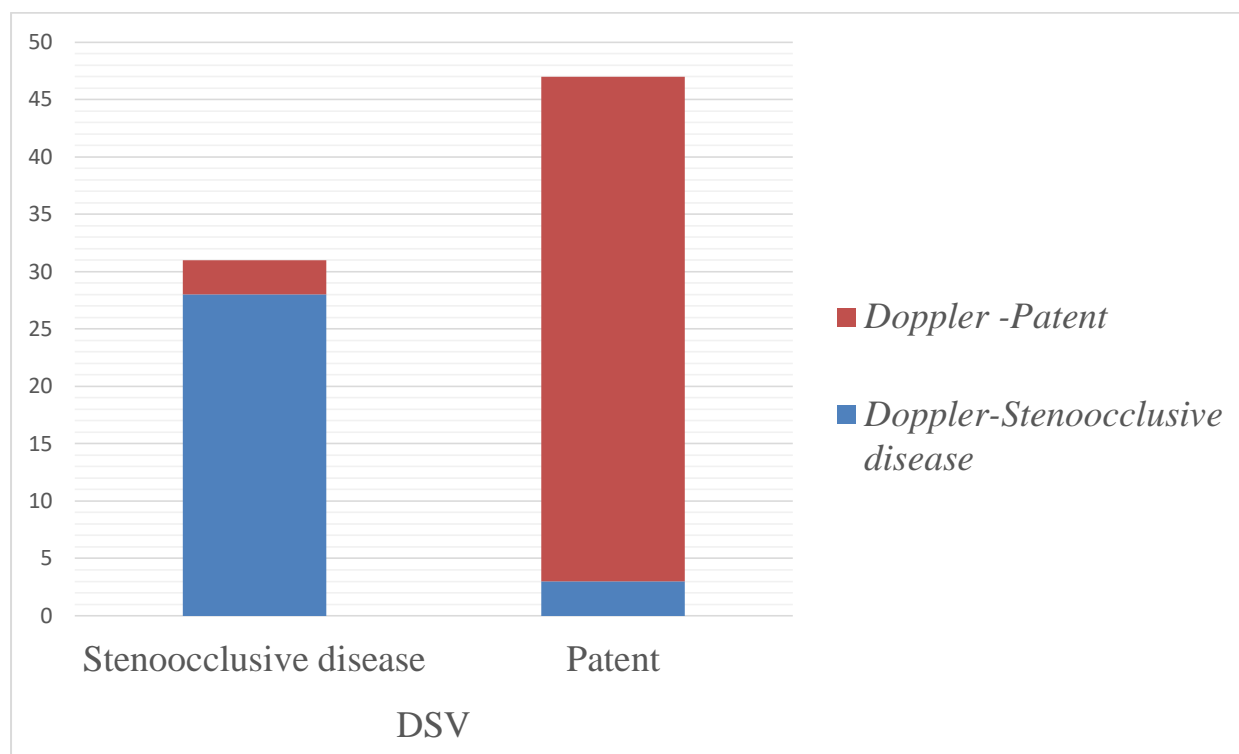


Table 5: Distribution of outcomes between MRV and DSV for Right Internal Jugular Vein.

MRV	DSV				Total	
	Stenoocclusive disease		Patent		N	%
	N	%	N	%		
Stenoocclusive disease	30	96.8	1	2.1	31	39.7
Patent	1	3.2	46	97.9	47	60.3
Total	31	39.7	47	60.3	78	100

Figure: 14 - Compound bar chart showing the comparison of outcome between MRV and DSV for Right Internal Jugular Vein.

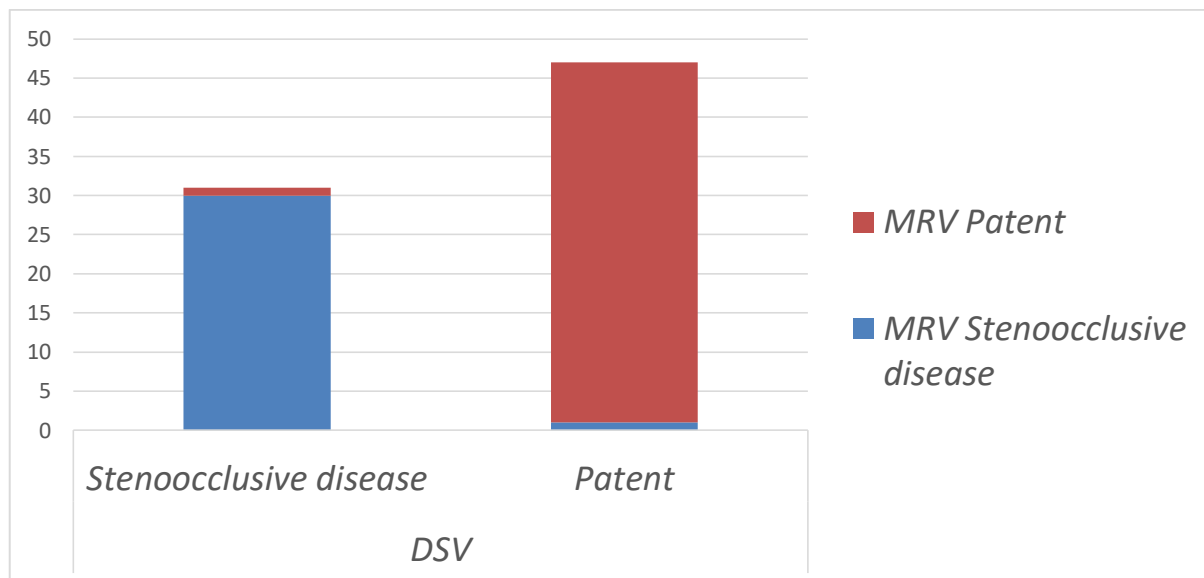


Table 6: Degree of agreement between Doppler, MRV and DSV for Right Internal Jugular vein.

Comparison	K value	95% CI	P-value
Doppler VS DSV	0.839	0.716-0.962	<0.05
MRV vs DSV	0.946	0.873-1.018	<0.05

Table 7: Diagnostic test characteristics comparing Doppler and MRV to DSV outcomes.

Characteristics	Doppler VS DSV		MRV vs DSV	
	Value	95% CI	Value	95% CI
Sensitivity	90.32	74.25-97.96	96.77	83.30-99.92
Specificity	97.87	88.71-99.95	97.87	88.71-99.95
PPV	96.67	80.63-99.51	96.77	81.17-99.52
NPV	95.83	85.75-98.88	97.87	86.99-99.69
Accuracy	96.15	89.17-99.20	97.44	91.04-99.69

Right Subclavian Vein:

Table 8: Distribution of outcomes of Right Subclavian Vein using Doppler.

Doppler	Frequency	Percent
Patent	66	81.7
Stenosis	7	7.3
Occlusion	9	11.0
Total	82	100.0

Table 9: Distribution of outcomes of Right Subclavian Vein using MRV.

MRV	Frequency	Percent
Patent	64	78.0
Stenosis	6	7.3
Occlusion	9	11.0
Not done	3	3.7
Total	82	100.0

Table 10: Distribution of outcomes of Right Subclavian Vein using DSV.

DSV	Frequency	Percent
Patent	64	78.0
Stenosis	6	7.3
Occlusion	9	11.0
Not done	3	3.7
Total	82	100.0

Figure: 15 - Bar chart showing distribution of outcomes of Right Subclavian Vein using Doppler, MRV, DSV.

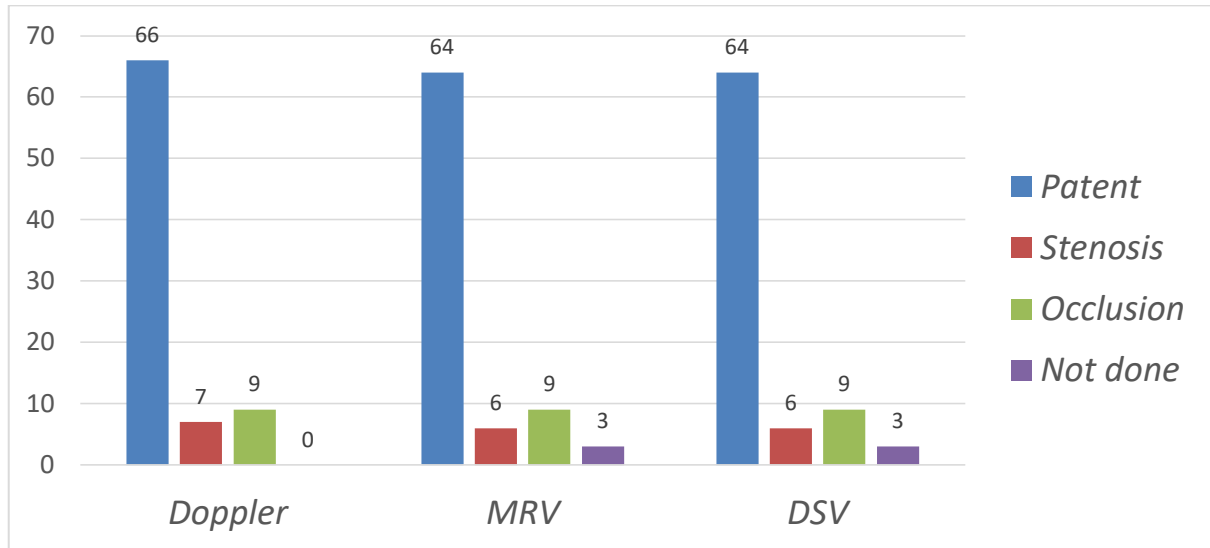


Table 11: Comparison of outcomes for Right Subclavian Vein between Doppler and DSV.

Doppler	DSV				Total	
	Stenoocclusive disease		Patent			
	N	%	N	%	N	%
Stenoocclusive disease	13	86.7	3	4.8	16	20.5
Patent	2	13.3	60	95.2	62	79.5
Total	15	19.2	63	80.8	78	100

Figure: 16 - Compound bar chart comparing the outcomes of Doppler and DSV for Right Subclavian Vein.

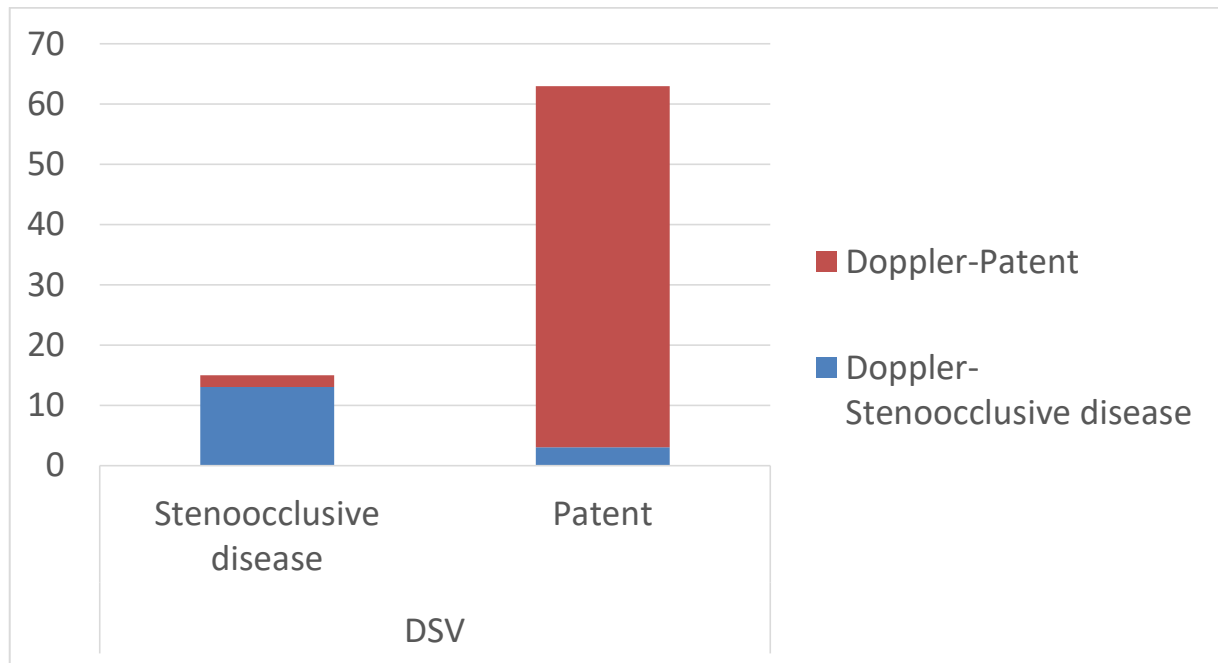


Table 12: Comparison of outcomes for Right Subclavian Vein between MRV and DSV.

MRV	DSV				Total	
	Stenoocclusive disease		Patent		N	%
	N	%	N	%		
Stenoocclusive disease	14	93.3	1	1.6	15	19.2
Patent	1	6.7	62	98.4	63	80.8
Total	15	19.2	63	80.8	78	100

Figure: 17 - Compound bar chart for comparing the outcomes of MRV and DSV for Right Subclavian Vein.

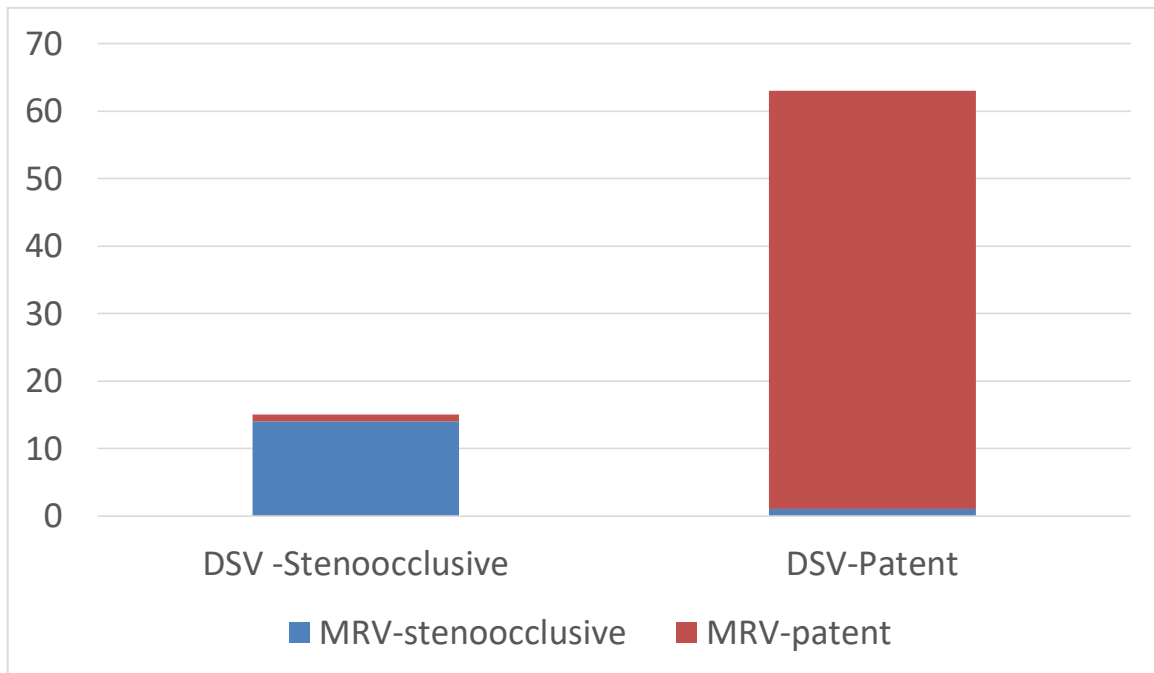


Table 13: Degree of agreement between Doppler, MRV and DSV for Right Subclavian Vein.

Comparison	K value	95% CI	P-value
Doppler VS DSV	0.799	0.630-0.967	<0.05
MRV vs DSV	0.917	0.803-1.03	<0.05

Table 14: Diagnostic test characteristics comparing Doppler and MRV to DSV outcomes for Right Subclavian Vein.

Characteristics	Doppler VS DSV		MRV vs DSV	
	Value	95% CI	Value	95% CI
Sensitivity	86.67	59.54-98.34	93.33	68.05-99.83
Specificity	95.24	86.71-99.01	98.41	91.47-99.96
PPV	81.25	58.52-93.01	93.33	66.60-98.99
NPV	96.77	89.19-99.09	98.41	90.32-99.76
Accuracy	93.59	85.67-97.89	97.44	91.04-99.69

Right Brachiocephalic Vein:

Table 15: Distribution of outcomes of Right Brachiocephalic Vein using Doppler.

Doppler	Frequency	Percent
Patent	62	75.6
Stenosis	11	13.4
Occlusion	9	11.0
Total	82	100.0

Table 16: Distribution of outcomes of Right Brachiocephalic Vein using MRV.

MRV	Frequency	Percent
Patent	59	72.0
Stenosis	11	13.4
Occlusion	9	11.0
Not done	3	3.7
Total	82	100.0

Table 17: Distribution of outcomes of Right Brachiocephalic Vein using DSV.

DSV	Frequency	Percent
Patent	59	72.0
Stenosis	11	13.4
Occlusion	9	11.0
Not done	3	3.7
Total	82	100.0

Figure: 18 - Bar chart showing distribution of outcomes of Right Brachiocephalic Vein using Doppler, MRV, DSV.

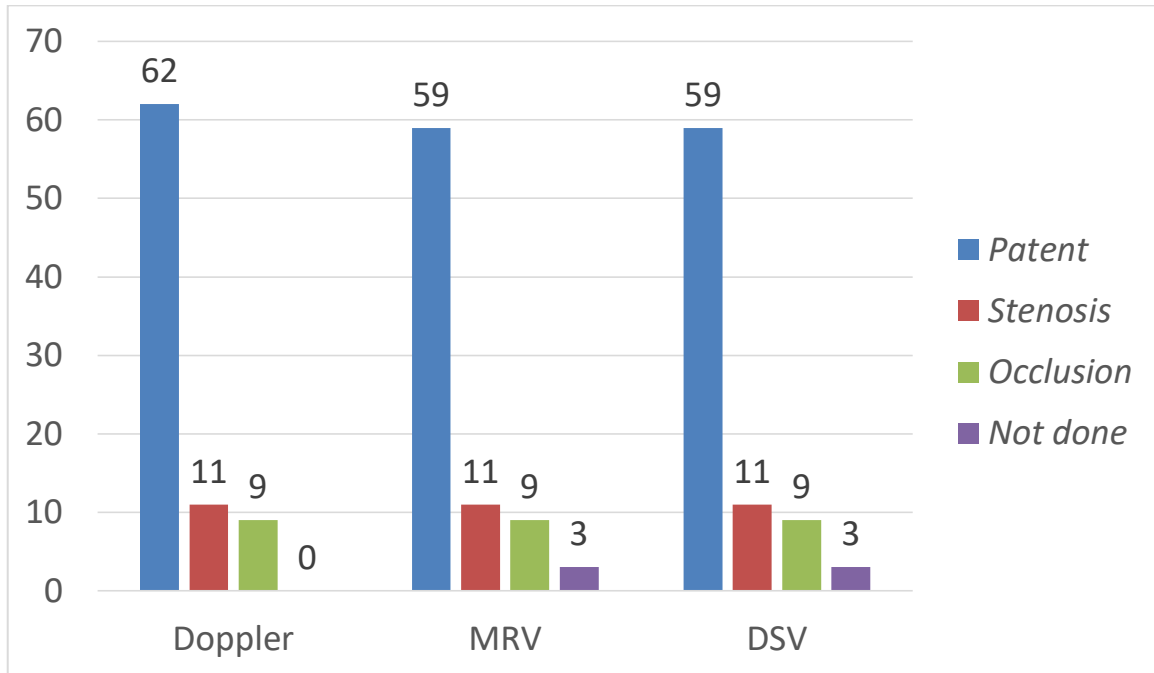


Table 18: Comparison of outcomes for Right Brachiocephalic Vein between Doppler and DSV.

Doppler	DSV				Total	
	Stenoocclusive disease		Patent			
	N	%	N	%	N	%
Stenoocclusive disease	18	90.0	2	3.4	20	25.6
Patent	2	10.0	56	96.6	58	74.4
Total	20	25.6	58	74.4	78	100

Figure: 19 - Compound bar chart showing the comparison of outcome between Doppler and DSV for Right Brachiocephalic Vein.

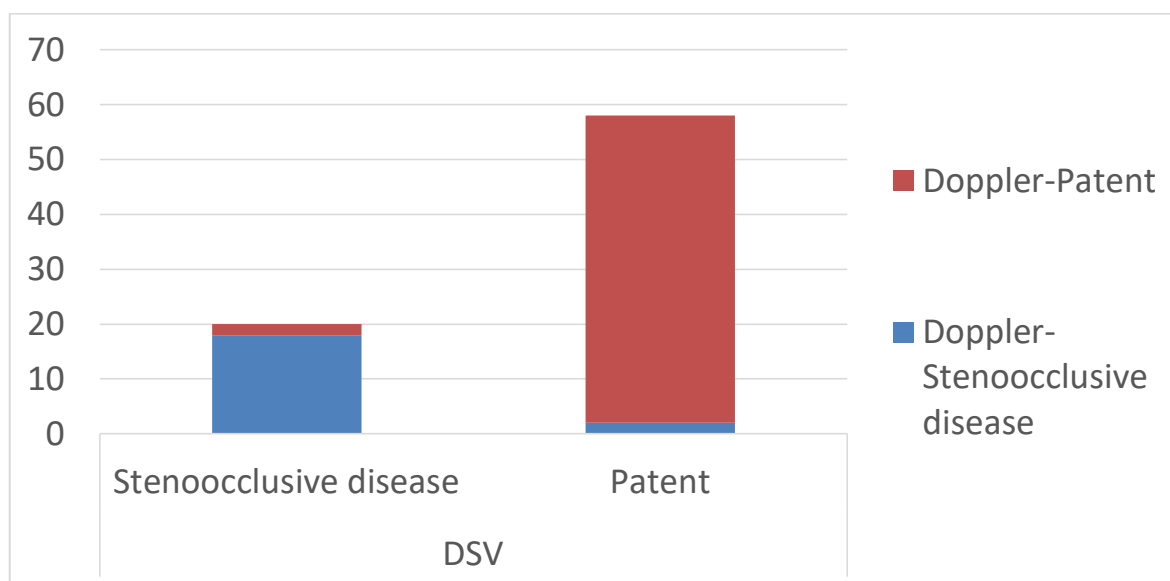


Table 19: Comparison of outcomes for Right Brachiocephalic Vein between MRV and DSV.

MRV	DSV				Total	
	Stenoocclusive disease		Patent		N	%
	N	%	N	%		
Stenoocclusive disease	19	95.0	1	1.7	20	25.6
Patent	1	5.0	57	98.3	58	74.4
Total	20	25.6	58	74.4	78	100

Figure: 20 - Compound bar chart showing the comparison of outcome between MRV and DSV for Right Brachiocephalic Vein.

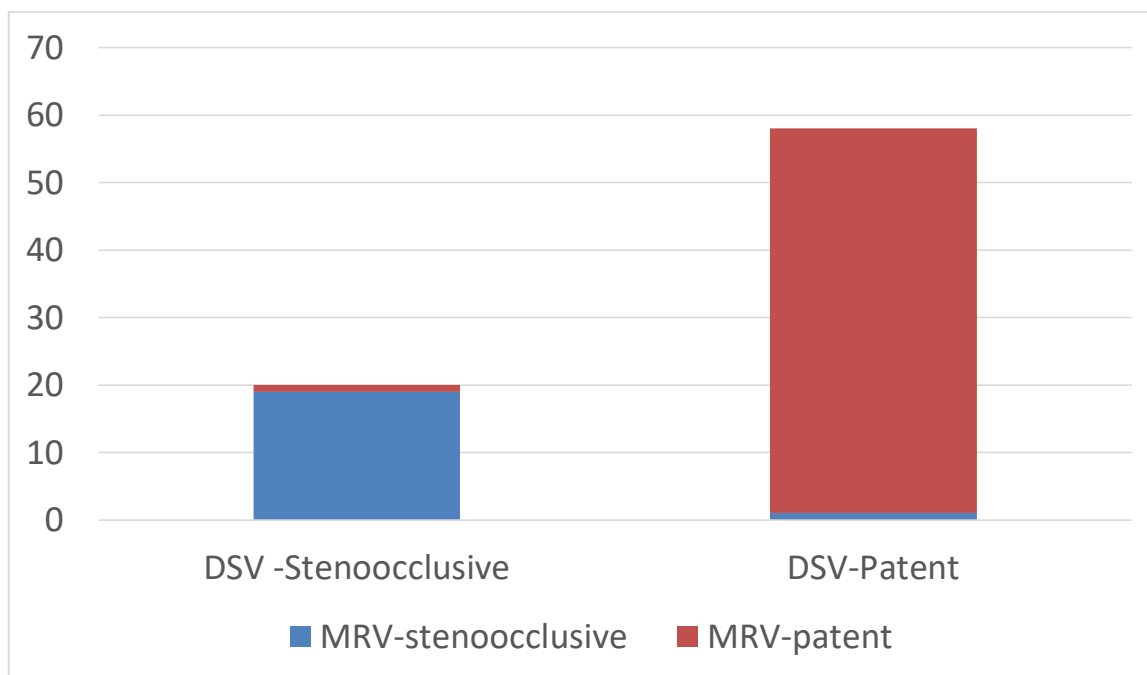


Table 20: Degree of agreement between Doppler, MRV and DSV for Right Brachiocephalic Vein.

Comparison	K value	95% CI	P-value
Doppler VS DSV	0.866	0.738-0.993	<0.05
MRV vs DSV	0.933	0.840-1.025	<0.05

Table 21: Diagnostic test characteristics comparing Doppler and MRV to DSV outcomes for Right Brachiocephalic Vein.

Characteristics	Doppler VS DSV		MRV vs DSV	
	Value	95% CI	Value	95% CI
Sensitivity	90.0	68.30-98.77	95	75.13-99.87
Specificity	96.55	88.09-99.58	98.28	90.76-99.96
PPV	90.0	69.58-97.25	95.0	73.08-99.25
NPV	96.55	88.25-99.05	98.28	89.40-99.74
Accuracy	94.87	87.39-98.59	97.44	91.04-99.69

Left Internal Jugular Vein:

Table 22: Distribution of outcomes of Left Internal Jugular Vein using Doppler.

Doppler	Frequency	Percent
Patent	51	63.4
Stenosis	21	25.6
Occlusion	10	11.0
Total	82	100.0

Table 23: Distribution of outcomes of Left Internal Jugular Vein using MRV.

MRV	Frequency	Percent
Patent	49	59.8
Stenosis	21	25.6
Occlusion	9	11.0
Not done	3	3.7
Total	82	100.0

Table 24: Distribution of outcomes of Left internal Jugular Vein using DSV.

DSV	Frequency	Percent
Patent	49	59.8
Stenosis	21	25.6
Occlusion	9	11.0
Not done	3	3.7
Total	82	100.0

Figure: 21 - Bar chart showing distribution of outcomes of Left Internal Jugular Vein using Doppler, MRV, DSV.

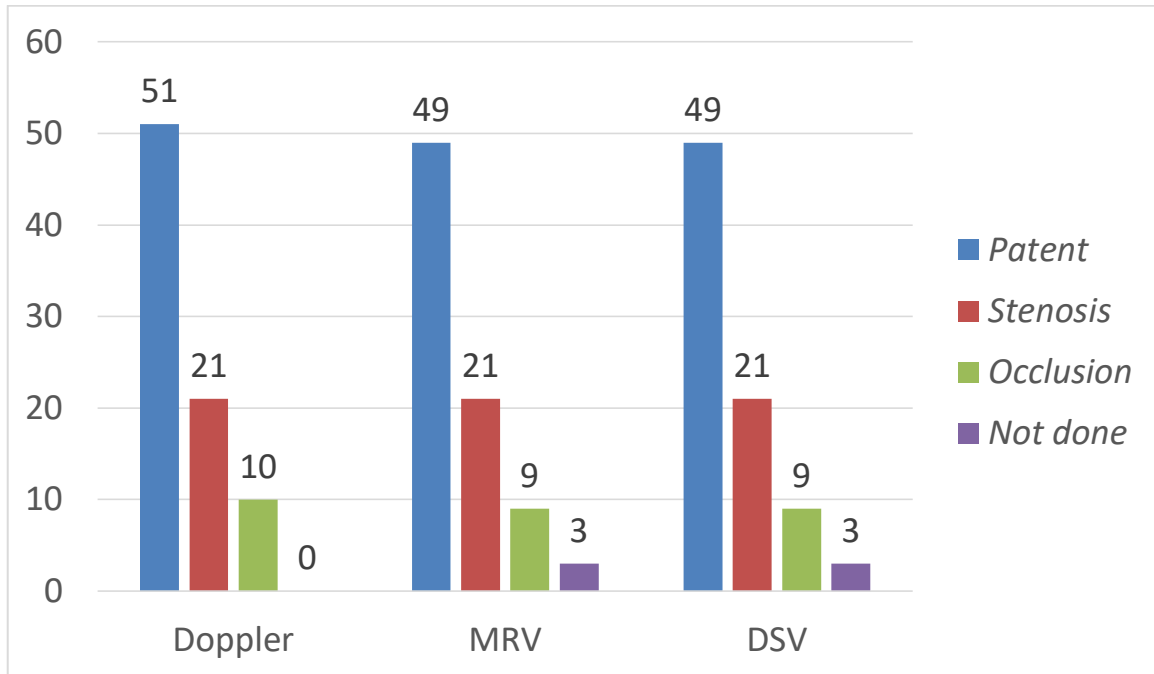


Table 25: Comparison of outcomes for Left Internal Jugular Vein between Doppler and DSV.

Doppler	DSV				Total	
	Stenoocclusive disease		Patent		N	%
	N	%	N	%		
Stenoocclusive disease	28	93.3	3	6.3	31	39.7
Patent	2	6.7	45	93.8	47	60.3
Total	30	38.5	48	61.5	78	100

Figure: 22 - Compound bar chart showing the comparison of outcome between Doppler and DSV for Left Internal Jugular Vein.

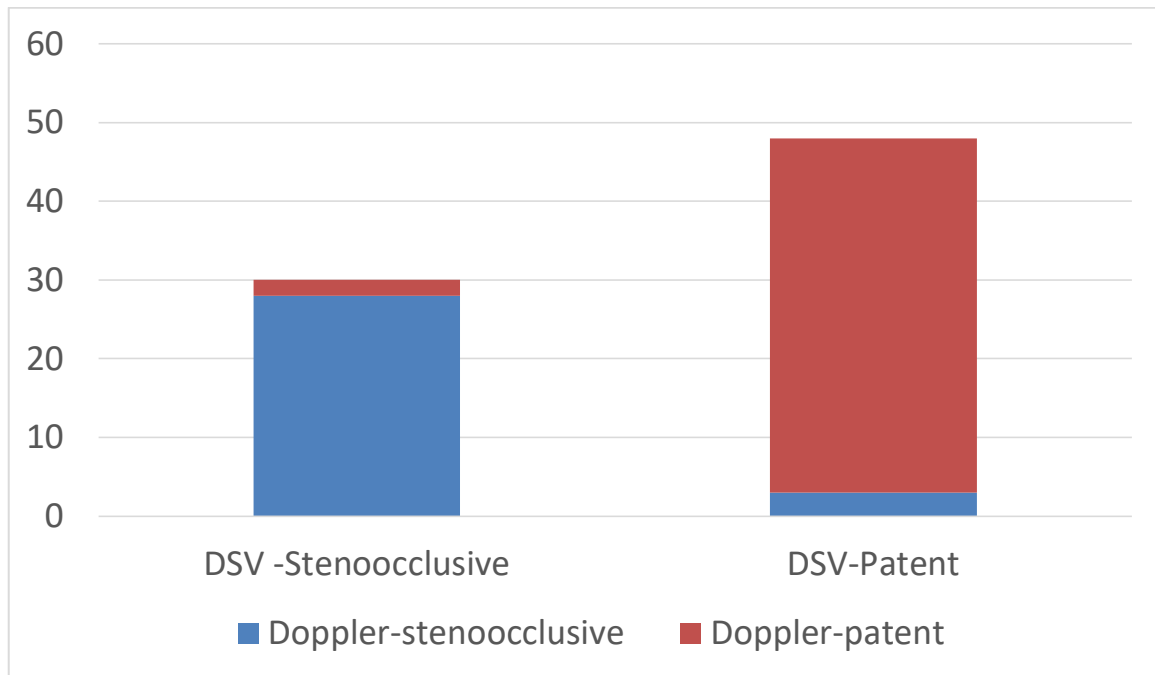


Table 26: Comparison of outcomes for Left Internal Jugular vein between MRV and DSV.

MRV	DSV				Total	
	Stenoocclusive disease		Patent		N	%
	N	%	N	%		
Stenoocclusive disease	30	100	1	2.1	31	39.7
Patent	0	0	47	97.9	47	60.3
Total	30	38.5	48	61.5	78	100

Figure: 23 - Compound bar chart showing the comparison of outcome between MRV and DSV for Left Internal Jugular Vein.

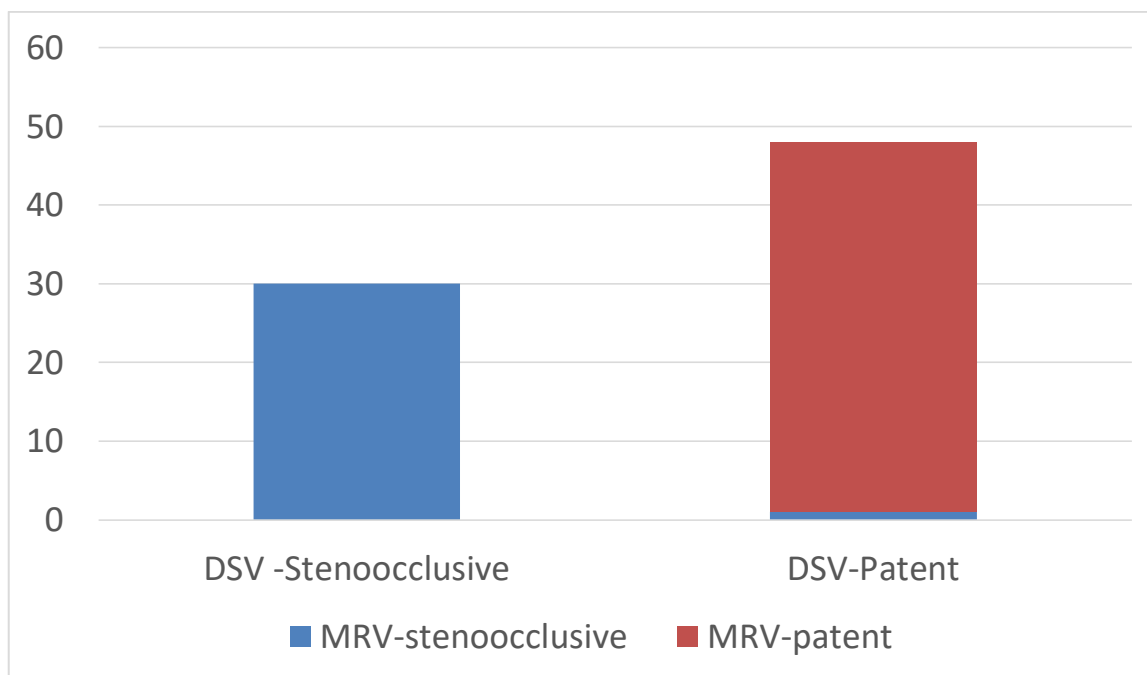


Table 27: Degree of agreement between Doppler, MRV and DSV for Left Internal Jugular Vein.

Comparison	K value	95% CI	P-value
Doppler VS DSV	0.865	0.751-0.978	<0.05
MRV vs DSV	0.973	0.920-1.02	<0.05

Table 28: Diagnostic test characteristics comparing Doppler and MRV to DSV outcomes for Left Internal Jugular Vein.

Characteristics	Doppler VS DSV		MRV vs DSV	
	Value	95% CI	Value	95% CI
Sensitivity	93.33	77.93-99.18	100	88.43-100.
Specificity	93.75	82.80-98.69	97.92	88.93-99.95
PPV	90.32	75.65-96.56	96.77	81.18-99.52
NPV	95.74	85.48-98.85	100	-
Accuracy	93.59	85.67-97.89	98.72	93.06-99.97

Left Subclavian Vein:

Table 29: Distribution of outcomes of Left Subclavian Vein using Doppler.

Doppler	Frequency	Percent
Patent	61	74.4
Stenosis	15	18.3
Occlusion	6	7.3
Total	82	100.0

Table 30: Distribution of outcomes of Left Subclavian Vein using MRV.

MRV	Frequency	Percent
Patent	58	70.7
Stenosis	15	18.3
Occlusion	6	7.3
Not done	3	3.7
Total	82	100.0

Table 31: Distribution of outcomes of Left Subclavian Vein using DSV

DSV	Frequency	Percent
Patent	58	70.7
Stenosis	15	18.3
Occlusion	6	7.3
Not done	3	3.7
Total	82	100.0

Figure: 24 - Bar chart showing distribution of outcomes of Left Subclavian Vein using Doppler, MRV, DSV.

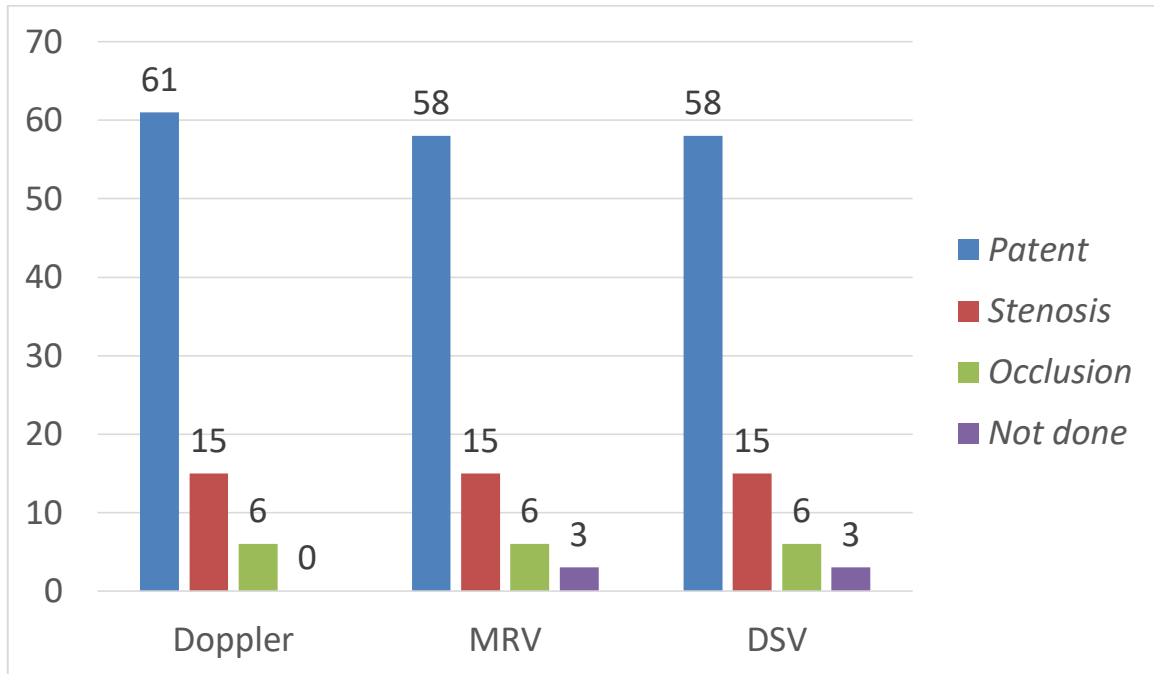


Table 32: Comparison of outcomes for Left Subclavian Vein between Doppler and DSV.

Doppler	DSV				Total			
	Stenoocclusive disease		Patent		N		%	
	N	%	N	%				
Stenoocclusive disease	17	81.0	3	5.3	20	25.6		
Patent	4	19.0	54	94.7	58	74.4		
Total	21	26.9	57	73.1	78	100		

Figure: 25 - Compound bar chart showing the comparison of outcome between Doppler and DSV for Left Subclavian Vein.

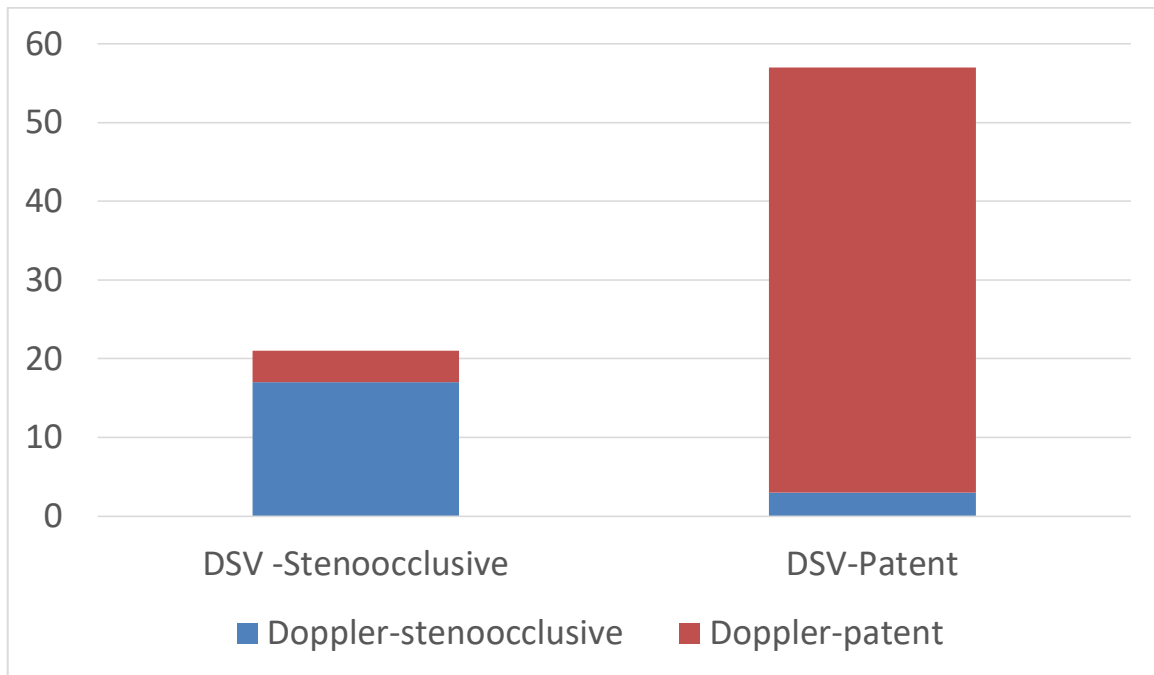


Table 15: Comparison of outcomes for Left Subclavian Vein between MRV and DSV.

MRV	DSV				Total	
	Stenoocclusive disease		Patent			
	N	%	N	%	N	%
Stenoocclusive disease	19	90.5	1	1.8	20	25.6
Patent	2	9.5	56	98.2	58	74.4
Total	21	26.9	57	73.1	78	100

Figure: 26 - Compound bar chart showing the comparison of outcome between MRV and DSV for Left Subclavian Vein.

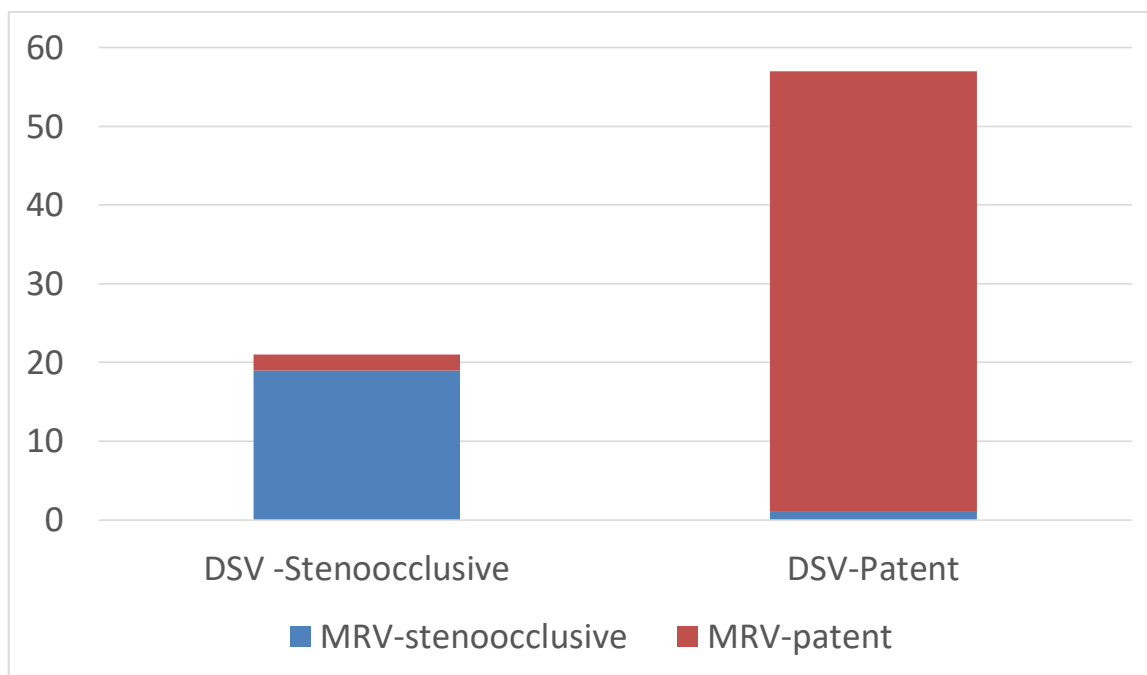


Table 34: Degree of agreement between Doppler, MRV and DSV for Left Subclavian Vein.

Comparison	K value	95% CI	P-value
Doppler VS DSV	0.768	0.605-0.930	<0.05
MRV vs DSV	0.901	0.791-1.01	<0.05

Table 35: Diagnostic test characteristics comparing Doppler and MRV to DSV outcomes for Left Subclavian Vein.

Characteristics	Doppler VS DSV		MRV vs DSV	
	Value	95% CI	Value	95% CI
Sensitivity	80.95	58.09-94.55	90.48	69.62-98.83
Specificity	94.74	85.38-98.90	98.25	90.61-99.96
PPV	85.0	64.88-94.56	95.0	73.04-99.26
NPV	93.10	84.80-97.03	96.55	88.22-99.05
Accuracy	91.03	82.88-96.32	96.15	89.17-99.20

Left Brachiocephalic Vein:

Table 36: Distribution of outcomes of Left Brachiocephalic Vein using Doppler.

Doppler	Frequency	Percent
Patent	62	75.6
Stenosis	14	17.1
Occlusion	6	7.3
Total	82	100.0

Table 37: Distribution of outcomes of Left Brachiocephalic Vein using MRV.

MRV	Frequency	Percent
Patent	59	72.0
Stenosis	14	17.1
Occlusion	6	7.3
Not done	3	3.7
Total	82	100.0

Table 38: Distribution of outcomes of Left Brachiocephalic Vein using DSV

DSV	Frequency	Percent
Patent	58	72.0
Stenosis	14	17.1
Occlusion	7	7.3
Not done	3	3.7
Total	82	100.0

Figure: 27 - Bar chart showing distribution of outcomes of Left Brachiocephalic Vein using Doppler, MRV, DSV.

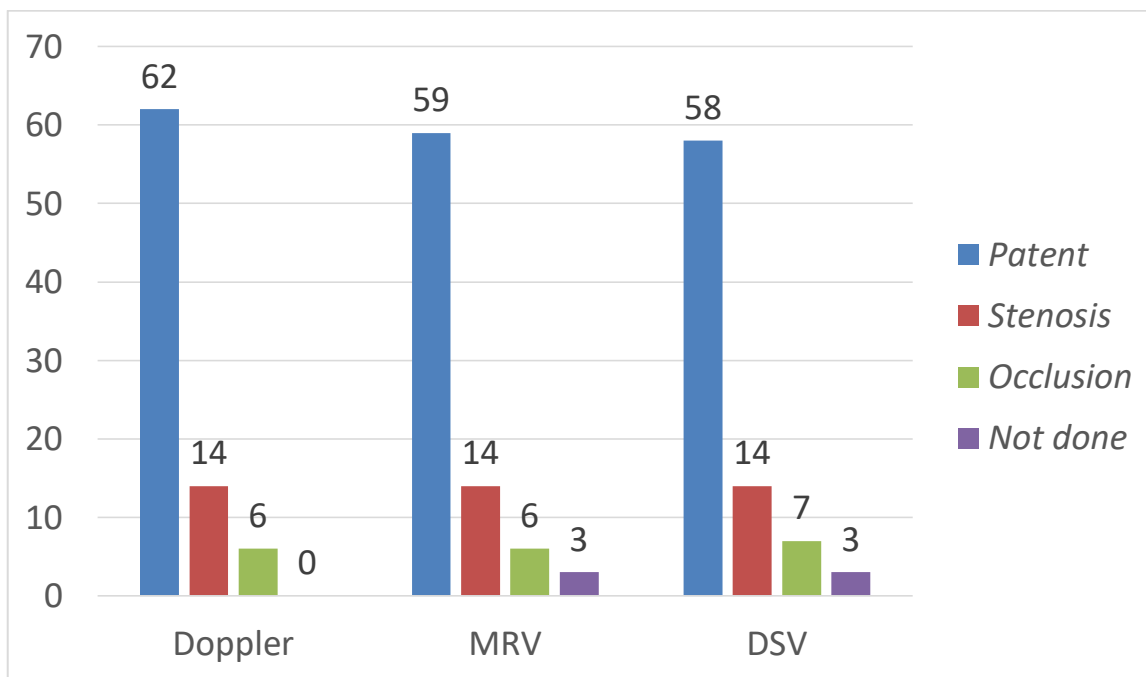


Table 39: Comparison of outcomes for Left Brachiocephalic Vein between Doppler and DSV.

Doppler	DSV				Total	
	Stenoocclusive disease		Patent		N	%
	N	%	N	%		
Stenoocclusive disease	18	90.0	2	3.4	20	25.6
Patent	2	10.0	56	96.6	58	74.4
Total	20	25.6	58	74.4	78	100

Figure: 28 - Compound bar chart showing the comparison of outcome between Doppler and DSV for Left Brachiocephalic Vein.

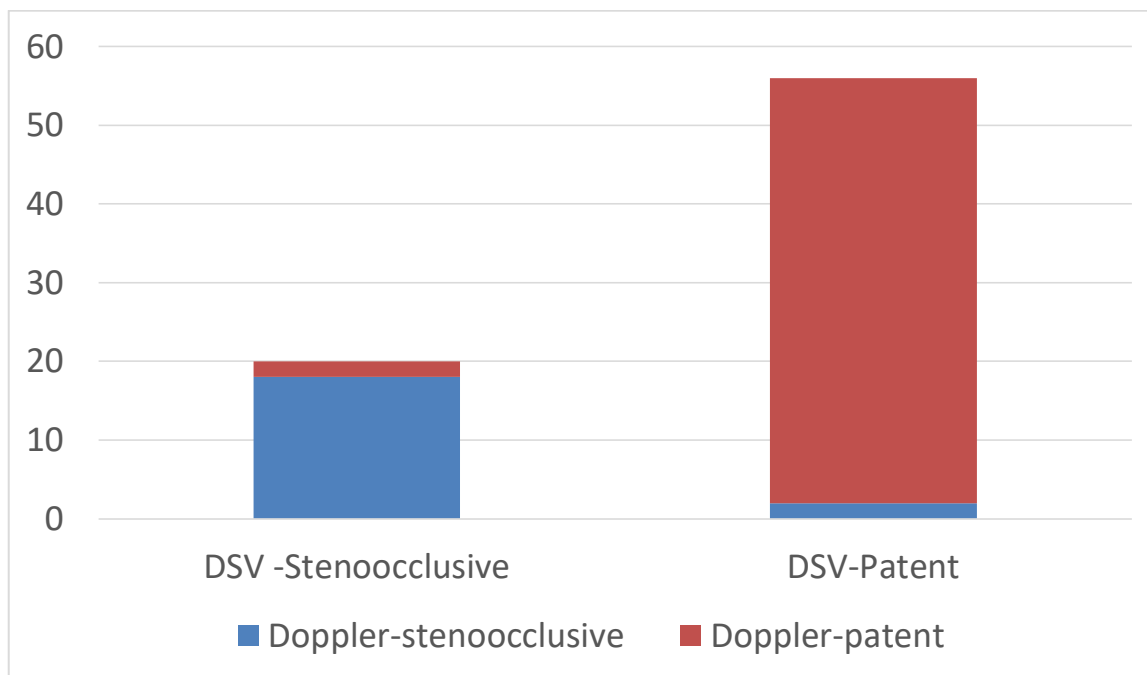


Table 40: Comparison of outcomes for Left Brachiocephalic Vein between MRV and DSV.

MRV	DSV				Total	
	Stenoocclusive disease		Patent			
	N	%	N	%	N	%
Stenoocclusive disease	19	95.0	1	1.7	20	25.6
Patent	1	5.0	57	98.3	58	74.4
Total	20	25.6	58	74.4	78	100

Figure: 29 - Compound bar chart showing the comparison of outcome between MRV and DSV for Left Brachiocephalic Vein.

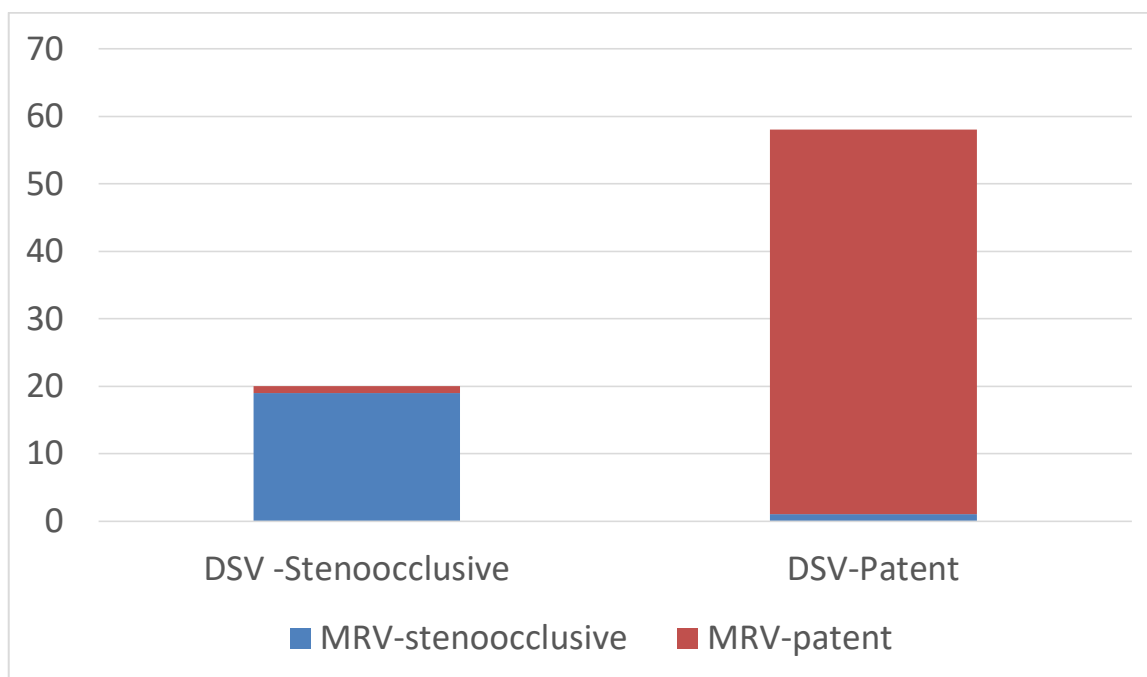


Table 41: Degree of agreement between Doppler, MRV and DSV for Left Brachiocephalic Vein.

Comparison	K value	95% CI	P-value
Doppler VS DSV	0.866	0.739-0.993	<0.05
MRV vs DSV	0.933	0.841-1.025	<0.05

Table 42: Diagnostic test characteristics comparing Doppler and MRV to DSV outcomes for Left Brachiocephalic Vein.

Characteristics	Doppler VS DSV		MRV vs DSV	
	Value	95% CI	Value	95% CI
Sensitivity	90.0	68.3-98.77	95.0	75.13-99.87
Specificity	96.55	88.09-99.58	98.28	90.76-99.96
PPV	90.00	69.58-97.25	95.0	73.08-99.25
NPV	96.55	88.25-99.05	98.28	89.4-99.74
Accuracy	94.87	87.39-98.59	97.44	91.04-99.69

Superior Vena Cava:

Table 43: Distribution of outcomes of Superior Vena Cava using Doppler.

Doppler	Frequency	Percent
Patent	35	42.7
Stenosis	1	1.2
Occlusion	3	3.7
Could not be visualized	43	52.4
Total	82	100.0

Table 44: Distribution of outcomes of Superior Vena Cava using MRV.

MRV	Frequency	Percent
Patent	73	89.0
Stenosis	3	3.7
Occlusion	3	3.7
Not done	3	3.7
Total	82	100.0

Table 45: Distribution of outcomes of Superior Vena Cava using DSV

DSV	Frequency	Percent
Patent	73	89.0
Stenosis	3	3.7
Occlusion	3	3.7
Not done	3	3.7
Total	82	100.0

Figure: 30 - Bar chart showing distribution of outcomes of Superior Vena Cava using Doppler, MRV, DSV.

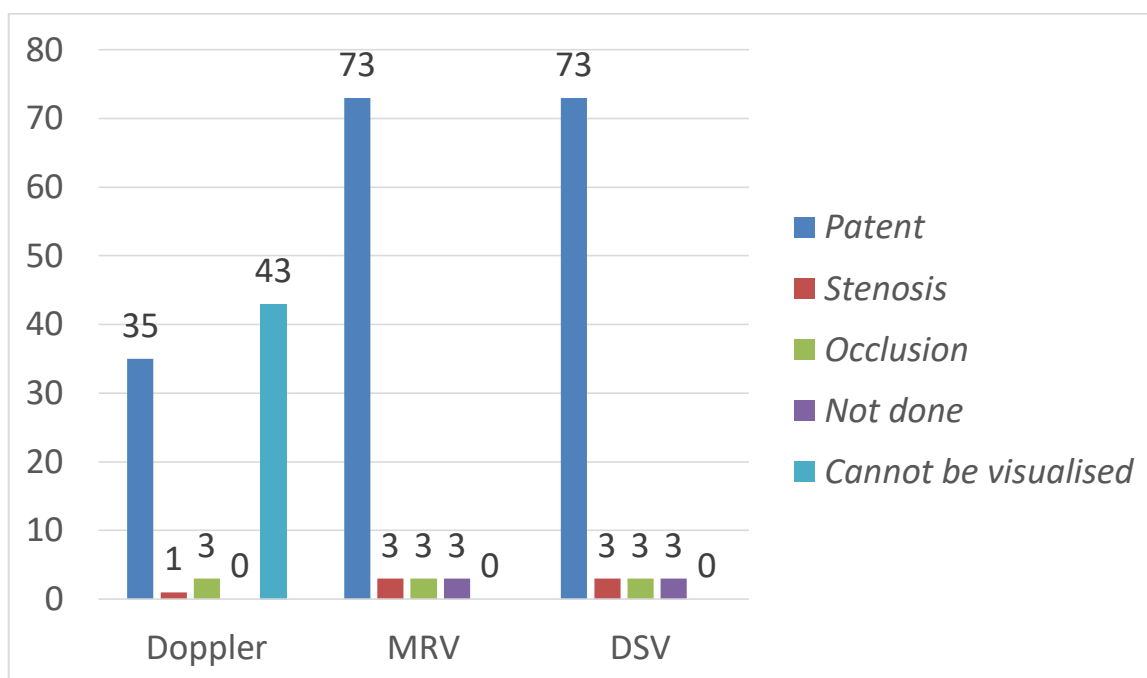


Table 46: Comparison of outcomes for Superior Vena Cava between Doppler and DSV.

Doppler	DSV				Total	
	Stenoocclusive disease		Patent			
	N	%	N	%	N	%
Stenoocclusive disease	3	75.0	1	3.0	4	10.8
Patent	1	25.0	32	97.0	33	89.2
Total	4	10.8	33	89.2	37	100

Figure: 31 - Compound bar chart showing the comparison of outcome between Doppler and DSV for Superior Vena Cava.

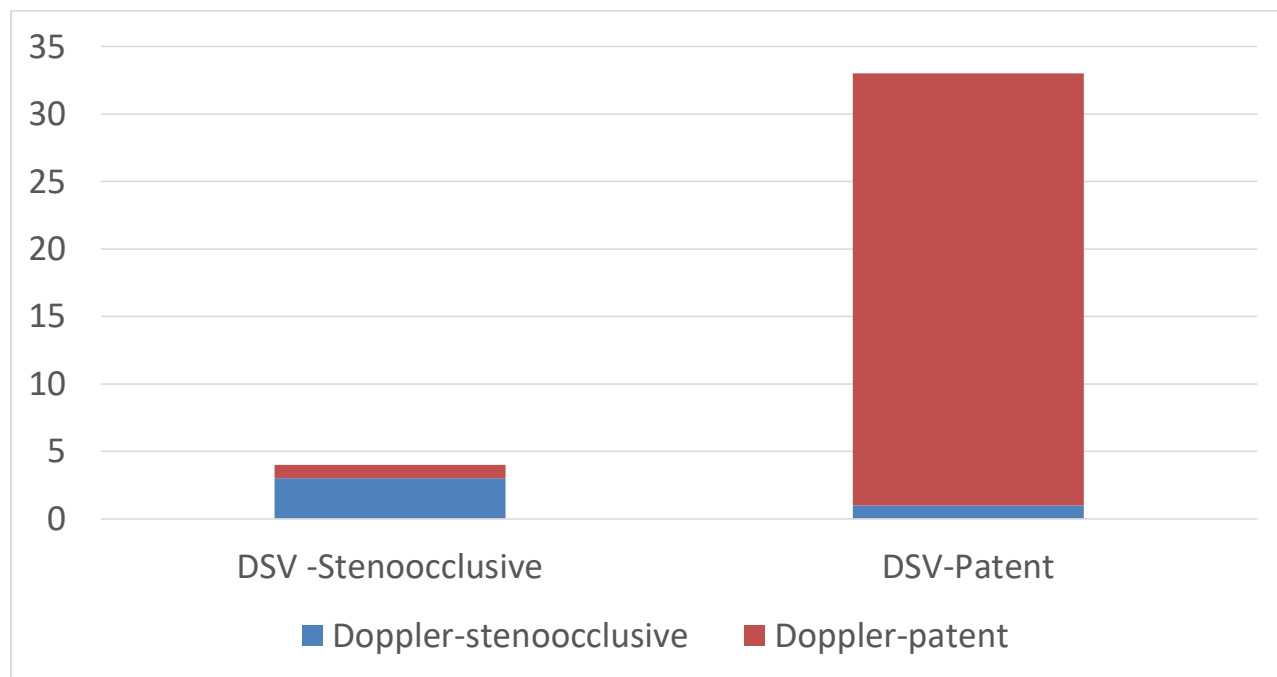


Table 47: Comparison of outcomes for Superior Vena Cava between MRV and DSV.

MRV	DSV				Total	
	Stenoocclusive disease		Patent		N	%
	N	%	N	%		
Stenoocclusive disease	4	100	0	0	4	10.8
Patent	0	0	33	100	33	89.2
Total	4	10.8	33	89.2	37	100

Figure: 32 - Compound bar chart showing the comparison of outcome between MRV and DSV for Superior Vena Cava.

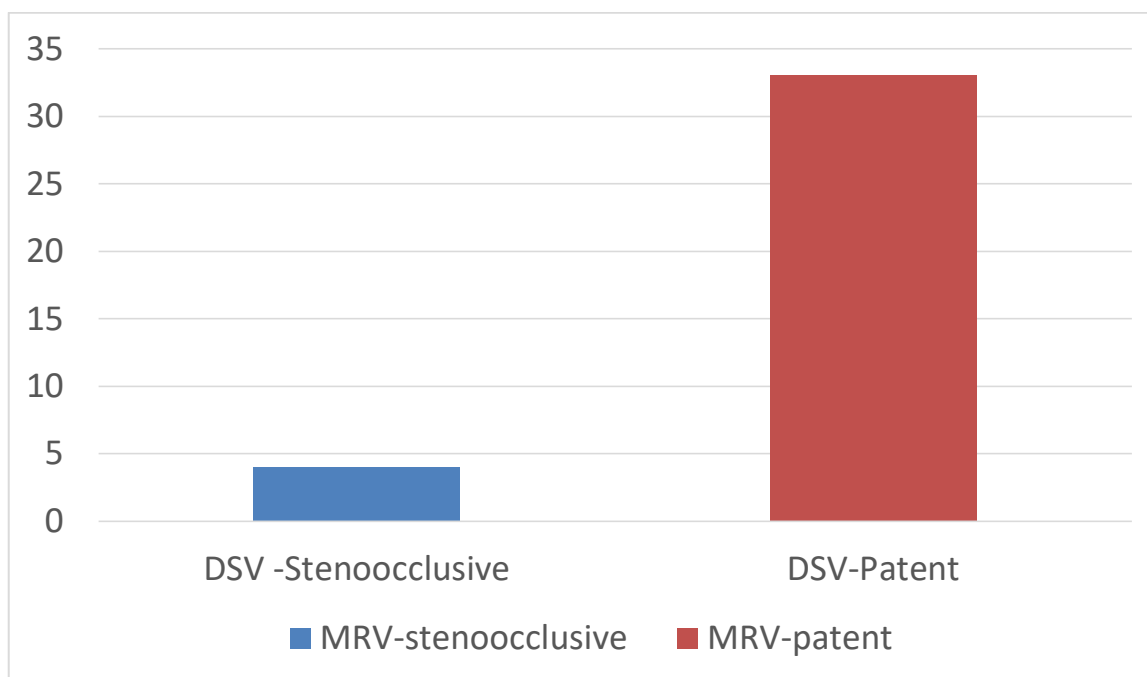


Table 48: Degree of agreement between Doppler, MRV and DSV for Superior Vena Cava.

Comparison	K value	95% CI	P-value
Doppler VS DSV	0.720	0.352-1.088	<0.05
MRV vs DSV	1	-	<0.05

Table 49: Diagnostic test characteristics comparing Doppler and MRV to DSV outcomes for Superior Vena Cava.

Characteristics	Doppler VS DSV		MRV vs DSV	
	Value	95% CI	Value	95% CI
Sensitivity	75	19.41-99.37	100	39.76-100
Specificity	96.97	84.24-99.92	100	89.42-100
PPV	75.00	28.65-95.73	100	-
NPV	96.97	85.41-99.43	100	-
Accuracy	94.59	81.81-99.34	100	90.51-100

All Veins:

Table 50: Distribution of outcomes for all the veins studied using Doppler.

Doppler	Frequency	Percent
Patent	388	67.5
Stenosis	80	13.9
Occlusion	63	10.9
Could not be visualized	43	7.2
Total	574	100.0

Table 51: Distribution of outcomes for all the veins studied using MRV.

MRV	Frequency	Percent
Patent	410	71.4
Stenosis	81	14.1
Occlusion	62	10.8
Not done	21	3.6
Total	574	100.0

Table 52: Distribution of outcomes for all the veins studied using DSV

DSV	Frequency	Percent
Patent	409	71.2
Stenosis	81	14.1
Occlusion	63	10.9
Not done	21	3.6
Total	574	100.0

Figure: 33 - Bar chart showing distribution of outcomes for all the veins studied using Doppler, MRV, DSV.

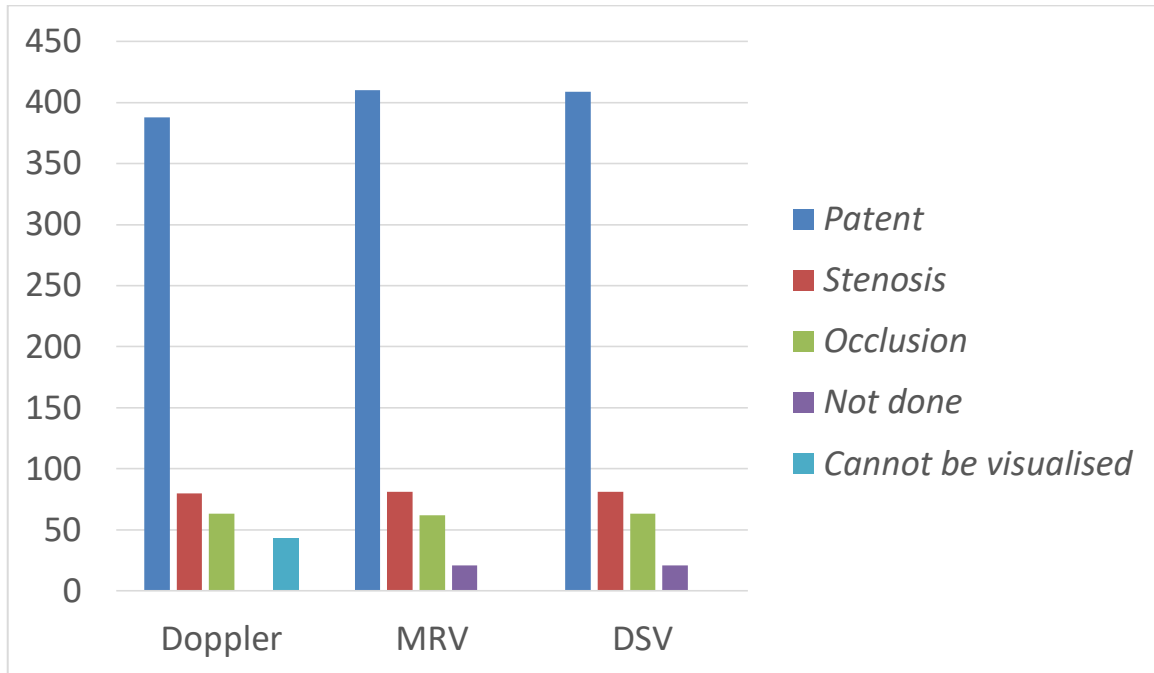


Table 53: Comparison of outcomes between Doppler and DSV.

Doppler	DSV				Total	
	Stenoocclusive disease		Patent			
	N	%	N	%	N	%
Stenoocclusive disease	125	88.7	17	4.7	142	28.1
Patent	16	11.3	347	95.3	363	71.9
Total	141	27.9	364	72.1	505	100

Figure: 34 - Compound bar chart comparing the outcomes of Doppler and DSV.

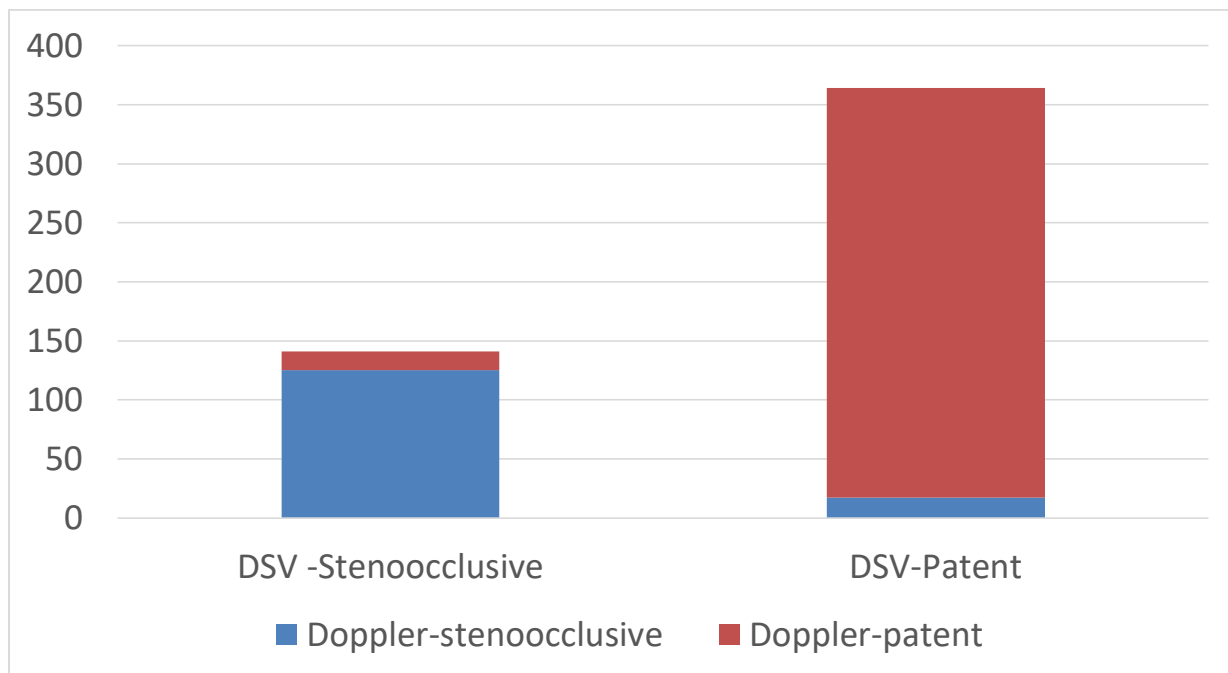


Table 54: Comparison of outcomes for between MRV and DSV.

MRV	DSV				Total	
	Stenoocclusive disease		Patent		N	%
	N	%	N	%		
Stenoocclusive disease	135	95.7	6	1.6	141	27.9
Patent	6	4.3	358	98.4	364	72.1
Total	141	27.9	364	72.1	505	100

Figure: 35 - Compound bar chart comparing the outcomes of MRV and DSV.

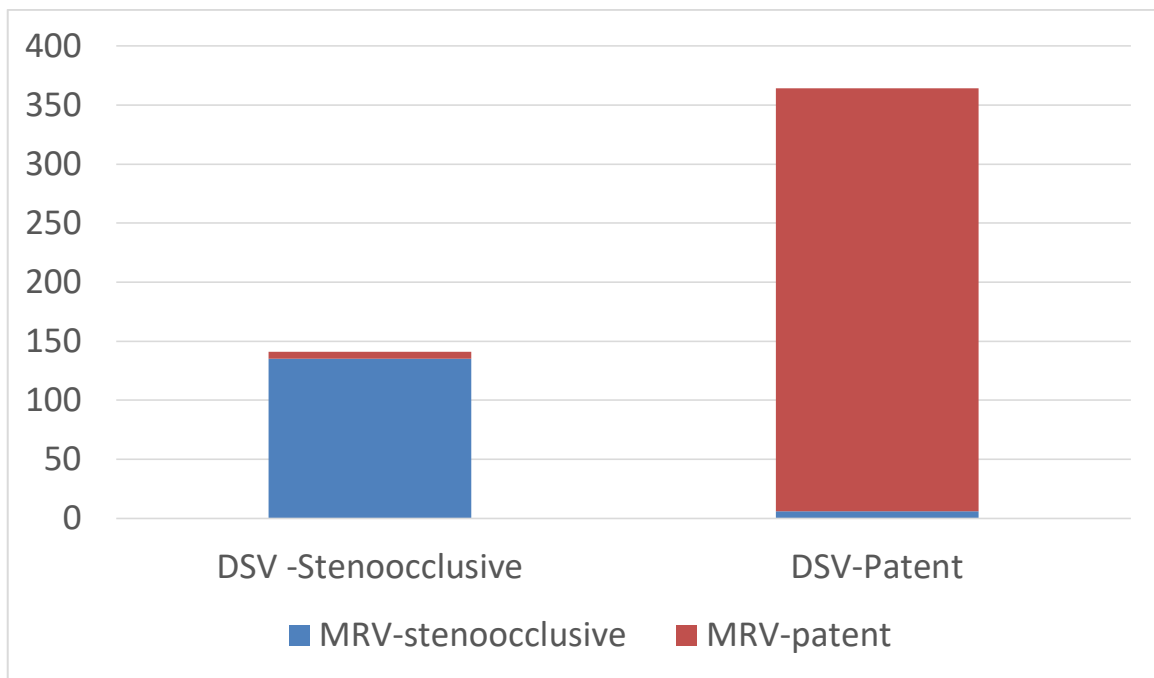


Table 55: Degree of agreement between Doppler, MRV and DSV.

Comparison	K value	95% CI	P-value
Doppler VS DSV	0.838	0.786-0.89	<0.05
MRV vs DSV	0.941	0.908-0.974	<0.05

Table 56: Diagnostic test characteristics comparing Doppler and MRV to DSV outcomes.

Characteristics	Doppler VS DSV		MRV vs DSV	
	Value	95% CI	Value	95% CI
Sensitivity	88.65	82.23-93.37	95.74	90.97-98.42
Specificity	95.33	92.63-97.26	98.35	96.45-99.39
PPV	88.03	82.16-92.15	95.74	91.05-98.03
NPV	95.59	93.18-97.18	98.35	96.46-99.24
Accuracy	93.47	90.95-95.46	97.62	95.89-98.77

DISCUSSION

Right Internal Jugular Vein:

Using Doppler, 11(13.4%) of the right internal jugular vein were stenosed and 20 (24.4%) had occlusion.

Using MRV, 11 (13.4%) were found to be stenosed and 20 (24.4%) had occlusive disease. In 3 patients MRV was not done.

Using DSV, 11 (13.4%) were found to be stenosed and 20 (24.4%) had occlusive disease. In 3 patients MRV was not done.

Out of 31 patients diagnosed as having steno-occlusive disease by DSV, Doppler identified 28 (90.3%) correctly. Among the 47 diagnosed to have patent vein by DSV, 44 (93.6%) were identified by doppler correctly.

Out of 31 patients diagnosed as having steno-occlusive disease by DSV, MRV identified 30 (96.8%) correctly. Among the 47 diagnosed to have patent vein by DSV, 46 (97.9%) were identified by doppler correctly.

When outcome of Doppler and MRV were compared with DSV, respectively for agreement. Both were found to have almost perfect agreement. The magnitude of agreement was more with MRV than Doppler.

MRV was found to have more sensitivity, PPV, NPV and accuracy than Doppler when compared with DSV. Both the tests were found to have almost equal specificity. MRV was found to be superior to doppler in the diagnosis of stenoocclusive disease of Right Internal Jugular Vein.

Right Subclavian Vein:

Out of 82 study participants, 7 (7.3%) participants were diagnosed to have stenosis and 9 (11%) participants were diagnosed to have occlusion in the Right Subclavian Vein using Doppler.

Out of 82 study participants, 6 (7.3%) participants were diagnosed to have stenosis and 9 (11%) participants were diagnosed to have occlusion in the Right Subclavian Vein using MRV. The procedure was not done in 3 participants.

Out of 82 study participants, 6 (7.3%) participants were diagnosed to have stenosis and 9 (11%) participants were diagnosed to have occlusion in the Right Subclavian Vein using DSV. The procedure was not done in 3 participants.

DSV diagnosed 15 (19.2%) study participants to have stenoocclusive disease. Doppler diagnosed 16 (20.5%) study participants to have stenoocclusive disease. 13 (16.6%) study participants were diagnosed by both DSV and doppler to have stenoocclusive disease. 60(76.9%) study participants were diagnosed to have patent vein by both DSV and Doppler.

When outcome of doppler and MRV were compared with DSV, respectively for agreement. Both were found to have almost perfect agreement. The magnitude of agreement was more with MRV than Doppler.

DSV diagnosed 15 (19.2%) study participants to have stenoocclusive disease. MRV diagnosed 15 (19.2%) study participants to have stenoocclusive disease. 14 (17.9%) study participants were diagnosed by both DSV and MRV

to have stenocclusive disease.62 (79.4%) study participants were diagnosed to have patent vein by both DSV and MRV.

MRV was found to have more sensitivity, specificity, PPV, NPV and accuracy than Doppler when compared with DSV. MRV was found to be superior to Doppler in the diagnosis of steno-occlusive disease of Right Subclavian Vein.

Right Brachiocephalic Vein:

Out of 82 Right brachiocephalic veins studied with the help of Doppler, 11(13.4%) and 9 (11%) were found to have stenosis and occlusion, respectively.

Out of 82 Right brachiocephalic veins studied with the help of MRV, 11(13.4%) and 9 (11%) were found to have stenosis and occlusion, respectively. In 3 participants the procedure was not done.

Out of 82 Right brachiocephalic veins studied with the help of DSV, 11(13.4%) and 9 (11%) were found to have stenosis and occlusion, respectively. In 3 participants the procedure was not done.

DSV diagnosed 20 (25.6%) study participants to have stenocclusive disease. Doppler diagnosed 20 (25.6%) study participants to have stenocclusive disease. 18 (23.1%) study participants were diagnosed by both DSV and doppler to have stenocclusive disease. 56(71.7%) study participants were diagnosed to have patent vein by both DSV and Doppler.

DSV diagnosed 20 (25.6%) study participants to have stenocclusive disease. MRV diagnosed 20 (25.6%) study participants to have stenocclusive disease. 19 (24.3%) study participants were diagnosed by both DSV and MRV

to have steno-occlusive disease. 57 (73.1%) study participants were diagnosed to have patent vein by both DSV and MRV.

When outcome of Doppler and MRV were compared with DSV, respectively for agreement. Both were found to have almost perfect agreement. The magnitude of agreement was more with MRV than Doppler.

MRV was found to have more sensitivity, specificity, PPV, NPV and accuracy than Doppler when compared with DSV. MRV was found to be superior to Doppler in the diagnosis of steno-occlusive disease of right brachiocephalic vein.

Left Internal Jugular Vein:

Out of 82 Left internal Jugular veins studied with the help of MRV, 21(25.6%) and 9 (11%) were found to have stenosis and occlusion, respectively. In 3 participants the procedure was not done.

Out of 82 Left internal Jugular veins studied with the help of Doppler, 21(25.6%) and 10 (11%) were found to have stenosis and occlusion, respectively.

Out of 82 Left internal Jugular veins studied with the help of DSV, 21(25.6%) and 9 (11%) were found to have stenosis and occlusion, respectively. In 3 participants the procedure was not done.

DSV diagnosed 30 (38.5%) study participants to have stenoocclusive disease. Doppler diagnosed 31 (39.7%) study participants to have stenoocclusive disease. 28 (35.8%) study participants were diagnosed by both DSV and doppler to have stenoocclusive disease. 45(57.7%) study participants were diagnosed to have patent vein by both DSV and Doppler.

DSV diagnosed 30 (38.5%) study participants to have stenocclusive disease. MRV diagnosed 31 (39.7%) study participants to have stenocclusive disease. 30 (38.5%) study participants were diagnosed by both DSV and MRV to have stenocclusive disease. 47 (60.3%) study participants were diagnosed to have patent vein by both DSV and MRV.

When outcome of Doppler and MRV were compared with DSV, respectively for agreement. Both were found to have almost perfect agreement. The magnitude of agreement was more with MRV than Doppler.

MRV was found to have more sensitivity, specificity, PPV, NPV and accuracy than Doppler when compared with DSV. MRV was found to be superior to Doppler in the diagnosis of Left Internal Jugular Vein.

Left Subclavian Vein:

Out of 82 Left Subclavian veins studied with the help of Doppler, 15(18.3%) and 6 (7.3%) were found to have stenosis and occlusion, respectively.

Out of 82 Left Subclavian veins studied with the help of MRV, 15 (18.3%) and 6 (7.3%) were found to have stenosis and occlusion, respectively. In 3 participants the procedure was not done.

Out of 82 Left Subclavian veins studied with the help of DSV, 15 (18.3%) and 6 (7.3%) were found to have stenosis and occlusion, respectively. In 3 participants the procedure was not done.

DSV diagnosed 21 (26.9%) study participants to have stenocclusive disease. Doppler diagnosed 20 (25.6%) study participants to have stenocclusive disease. 17 (21.7%) study participants were diagnosed by both

DSV and doppler to have stenoocclusive disease. 54(69.2%) study participants were diagnosed to have patent vein by both DSV and Doppler.

DSV diagnosed 21 (26.9%) study participants to have stenoocclusive disease. MRV diagnosed 20 (25.6%) study participants to have stenoocclusive disease. 19 (24.3%) study participants were diagnosed by both DSV and MRV to have stenoocclusive disease. 56 (71.8%) study participants were diagnosed to have patent vein by both DSV and MRV.

When outcome of Doppler and MRV were compared with DSV, respectively for agreement. MRV had a perfect agreement while Doppler had substantial agreement with DSV. The magnitude of agreement was more with MRV than Doppler.

MRV was found to have more sensitivity, specificity, PPV, NPV and accuracy than Doppler when compared with DSV. MRV was found to be superior to Doppler in the diagnosis of Left subclavian Vein.

Left Brachiocephalic Vein:

Out of 82 Left brachiocephalic veins studied with the help of Doppler, 14 (17.1%) and 6 (7.3%) were found to have stenosis and occlusion, respectively.

Out of 82 Left brachiocephalic veins studied with the help of MRV, 14 (17.1%) and 6 (7.3%) were found to have stenosis and occlusion, respectively. In 3 participants the procedure was not done.

Out of 82 Left brachiocephalic veins studied with the help of DSV, 14 (17.1%) and 7 (7.3%) were found to have stenosis and occlusion, respectively. In 3 participants the procedure was not done.

DSV diagnosed 20 (25.6%) study participants to have stenoocclusive disease. Doppler diagnosed 20 (25.6%) study participants to have stenoocclusive disease. 18 (23.1%) study participants were diagnosed by both DSV and Doppler to have stenoocclusive disease. 56 (71.8%) study participants were diagnosed to have patent vein by both DSV and Doppler.

DSV diagnosed 20 (25.6%) study participants to have stenoocclusive disease. MRV diagnosed 20 (25.6%) study participants to have stenoocclusive disease. 19 (24.4%) study participants were diagnosed by both DSV and MRV to have stenoocclusive disease. 57 (73.1%) study participants were diagnosed to have patent vein by both DSV and MRV.

When outcome of Doppler and MRV were compared with DSV, respectively for agreement. Both were found to have almost perfect agreement. The magnitude of agreement was more with MRV than Doppler.

MRV was found to have more sensitivity, specificity, PPV, NPV and accuracy than Doppler when compared with DSV. MRV was found to be superior to Doppler in the diagnosis of Left brachiocephalic vein.

Superior

Superior Vena Cava:

Out of 82 Superior Vena cava studied with the help of Doppler, 1(1.2%) and 3 (3.7%) were found to have stenosis and occlusion, respectively. In about 43 study participants superior vena cava was not visualized.

Out of 82 Superior Vena cava studied with the help of MRV, 3(3.7%) and 3 (3.7%) were found to have stenosis and occlusion, respectively. In 3 participants the procedure was not done.

Out of 82 Superior Vena cava studied with the help of DSV, 3 (3.7%) and 3 (3.7%) were found to have stenosis and occlusion, respectively. In 3 participants the procedure was not done

DSV diagnosed 4 (10.8%) study participants to have stenoocclusive disease. Doppler diagnosed 4 (10.8%) study participants to have stenoocclusive disease. 3 (8.1%) study participants were diagnosed by both DSV and doppler to have stenoocclusive disease. 32 (86.4%) study participants were diagnosed to have patent vein by both DSV and Doppler.

DSV diagnosed 4 (10.8%) study participants to have stenoocclusive disease. MRV diagnosed 4(10.8%) study participants to have stenoocclusive disease. 4 (10.8%) study participants were diagnosed by both DSV and MRV to have stenoocclusive disease. 33 (89.1%) study participants were diagnosed to have patent vein by both DSV and MRV.

When outcome of Doppler and MRV were compared with DSV, respectively for agreement. MRV was found to have almost perfect agreement with DSV. The magnitude of agreement was more with MRV than Doppler.

MRV was found to have more sensitivity, specificity, PPV, NPV and accuracy than Doppler when compared with DSV. MRV was found to be superior to Doppler in the diagnosis of Superior Vena cava.

All Veins:

Out of 574 veins studied, 80 (13.9%) were found to be stenosed and 63 (10.9%) were found to be occluded by Doppler.

Out of 574 veins studied, 81 (14.1%) were found to be stenosed and 62 (10.8%) were found to be occluded by MRV.

Out of 574 veins studied using DSV, 81 (14.1%) were found to be stenosed and 63 (10.9%) were found to be occluded.

DSV diagnosed 141(27.9%) veins to have stenoocclusive disease while doppler diagnosed stenoocclusive disease in 142 (28.1%) veins. In about 125 (24.8%) veins both the diagnostic modalities had positive result while in about 347 (68.7%) veins both modalities gave negative results.

DSV diagnosed 141 (27.9%) veins to have stenoocclusive disease and MRV diagnosed 141(27.9%) too. In case of 135 (26.7%) veins, both MRV and DSV had given positive results and in 364 (72.1%) veins negative results.

When outcome of Doppler and MRV were compared with DSV, respectively for agreement. Both were found to have almost perfect agreement. The magnitude of agreement was more with MRV than Doppler.

MRV was found to have more sensitivity, specificity, PPV, NPV and accuracy than Doppler when compared with DSV. MRV was found to be superior to Doppler in the diagnosis of stenoocclusive veins.

Noncontrast techniques such as phase contrast MRV provided another safe, noninvasive option in patients with renal impairment because no contrast is needed. However, Elkins and Alley ⁽⁴⁵⁾ said that the difficulty faced in phase contrast MRV was low image quality of the 3D reformats in partially occluded segments.

Elkins and Alley found another difficulty was the long time of examination of phase contrast MRV that reached more than 6 min and the patient should be immobile all this period. This technique needs highly oriented, cooperative patients and the procedure should be fully explained to them. This is in agreement with Layer et al.⁽⁴⁶⁾ who confirmed that contrast

enhanced MRV has the advantage of high image quality as compared with phase contrast, as it has high signal to noise ratio. Also it has the advantage of increasing vascular signal and reducing background signal without risk of saturating slowly flowing blood. But in our study the duration of 3D PC MRV was 2 min 43 sec.

The main difficulty we faced while performing DSV was dilution of the dye inside the veins as was reported by Kroencke et al. ⁽⁴⁷⁾ who also concluded that MRV showed superiority in the assessment of internal jugular vein over the gold standard DSV; it was difficult in DSV to cannulate this. The reasons for venography were assessment of veins before creating an access for hemodialysis, determining occlusion or stenosis, and both.

All patients had the history of one- or two-side catheterization in the jugular or subclavian veins. Venography results were abnormal in 27.9% of the cases. In comparison, in the Passman study ⁽⁴⁸⁾, 82% and 38% of patients had a history of one-side vein catheterization and stenosis in venography, respectively. In this study, in patients with abnormal venography, catheterization of the same-side jugular vein and the other-side subclavian vein had the highest and the lowest prevalence rates, respectively. This finding can be due to the higher prevalence of jugular vein catheterization in the studied patients.

In the current study, sensitivity, specificity and PPV and NPV of duplex ultrasonography, compared with venography, in the assessment of proximal veins of hemodialysis patients were 88.65%, 95.33%, 88.03% and 95.59% respectively. The results were similar to the Passman study, which were 81%, 97%, 94% and 89%, respectively.

In the Baxter study ⁽⁴⁹⁾, sensitivity was 89%. Nack's study ⁽⁵⁰⁾ reported vein stenosis detection in ultrasonography with 81% sensitivity, 90% specificity, 91% PPV and 78% NPV. In a study by Aywak ⁽⁵¹⁾, sensitivity, specificity and accuracy of ultrasonography in the diagnosis of deep vein thrombosis were 88.9%, 91.8% and 90.9%, respectively. These results are in consistence with the results of the current study.

Some studies have shown that difference in accuracy of duplex ultrasonography in assessment of proximal veins can be due to variations in factors, including operator, patient, ultrasonography instrument, the vein under study and the rate of stenosis. In this study, for example, sensitivity of diagnosis of stenosis and occlusion rate in the subclavian and brachiocephalic veins were 80.95% and 90%, respectively. These results are comparable to Marc's study, which reported stenosis and occlusion of these veins with 94% and 36% sensitivity, respectively. In Patel's study ⁽⁵²⁾, the sensitivity and specificity of ultrasonography in the assessment of the distal subclavian vein were higher than those of its central part and brachiocephalic vein. However, this difference can be related to the higher rate of subclavian vein involvement compared with the brachiocephalic vein in patients with a history of catheterization.

Thus, Doppler ultrasonography has the highest reliability when it is technically possible and the involvement is in the Internal Jugular Vein, Subclavian Vein and BrachioCephalic Vein with stenosis or occlusion.

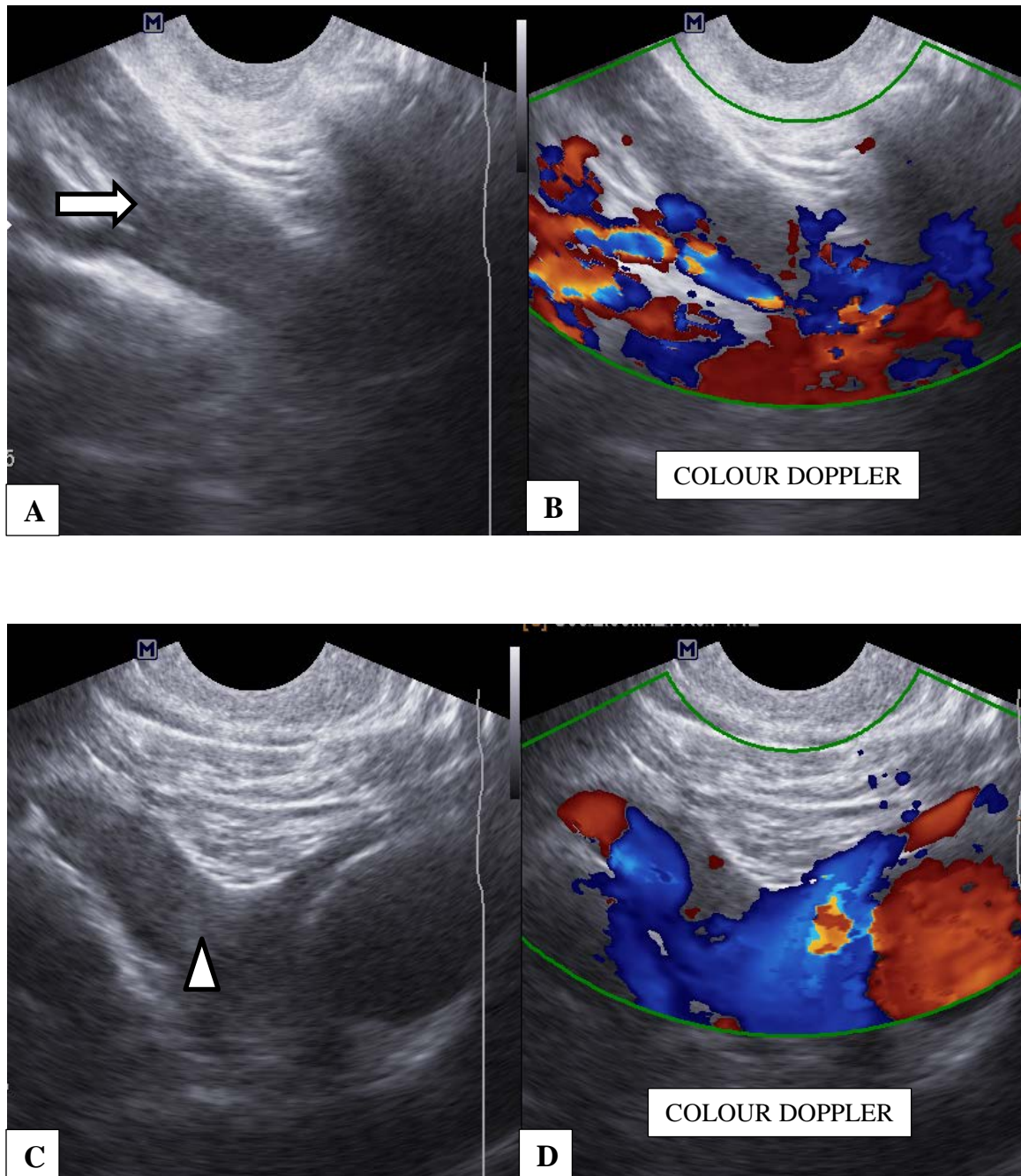
LIMITATIONS

Central vein stenosis could occur in the absence of central vein instrumentation due to extrinsic compression by narrow thoracic inlet, dilated arteries, or benign or malignant growths in adjacent structures ⁽⁵³⁾.

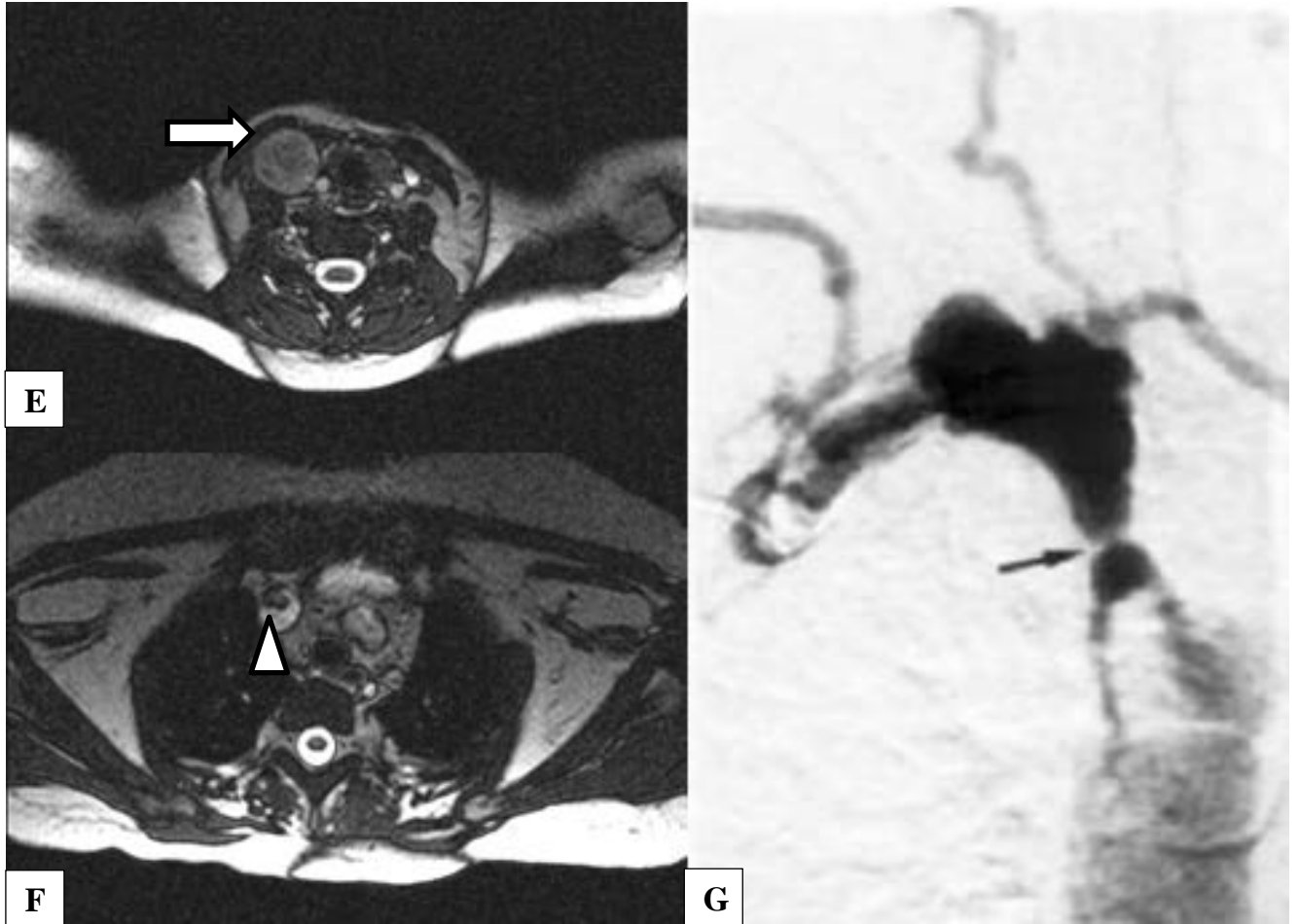
In addition, reports of central vein abnormalities or stenosis in patients on hemodialysis without history of catheters have given rise to the hypothesis that high blood flow rates through fistulas or grafts could directly cause endothelial injury, which in turn leads to neointimal proliferation and stenosis ⁽⁵⁴⁾. There were no cases of central vein stenosis in this study in the absence of the risk factors we identified. This is in contrast to some studies that reported prevalence of central vein abnormalities ranging from 6% to 63% in patients without obvious risk factors for stenosis ⁽⁵⁵⁾. Although factors such as extrinsic compression or hemodynamic stress could contribute to central vein stenosis, our data suggest that their contribution to prevalence of central vein stenosis in the general population of patients with advanced CKD may be less important than previously reported.

It is important to highlight the limitations of our study. First, the design did not allow collection of important variables such as catheter dwell time, and the number or type of invasive vascular procedures that might have been performed on the study participants. Second, this is a single institutional study in which cases were represented at lower proportion than in the general dialysis population. Third, the degree of stenosis was estimated by visual inspection only. Finally, we did not image pelvic and abdominal veins, so our results refer only to prevalence of stenosis of intrathoracic veins.

CASE 1

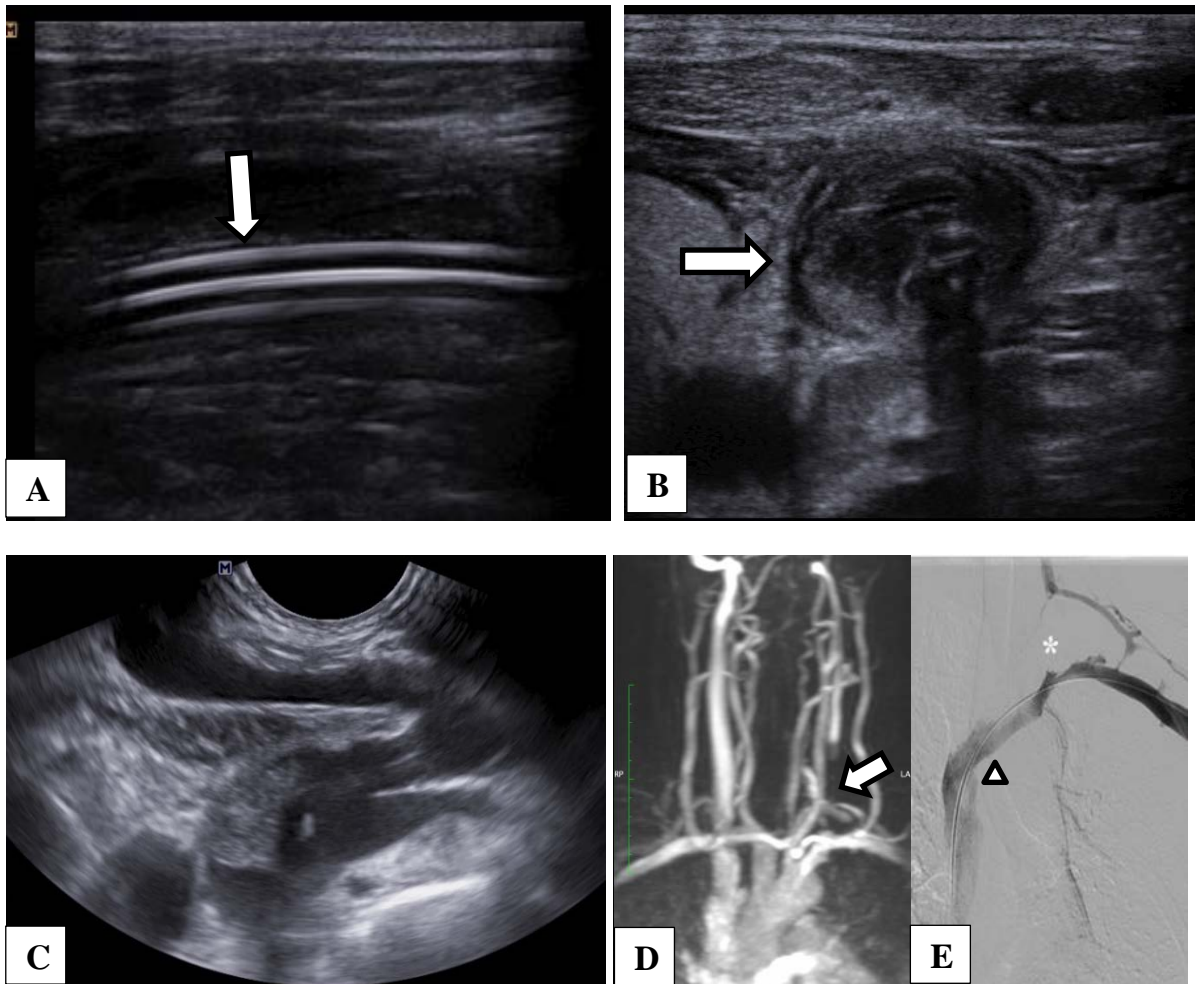


(A-D) Complete occlusion of right Internal Jugular Vein(arrow) with thrombus extending to the right BrachioCephalic Vein(arrowhead) as demonstrated by endocavitary probe in grey scale and colour Doppler imaging.



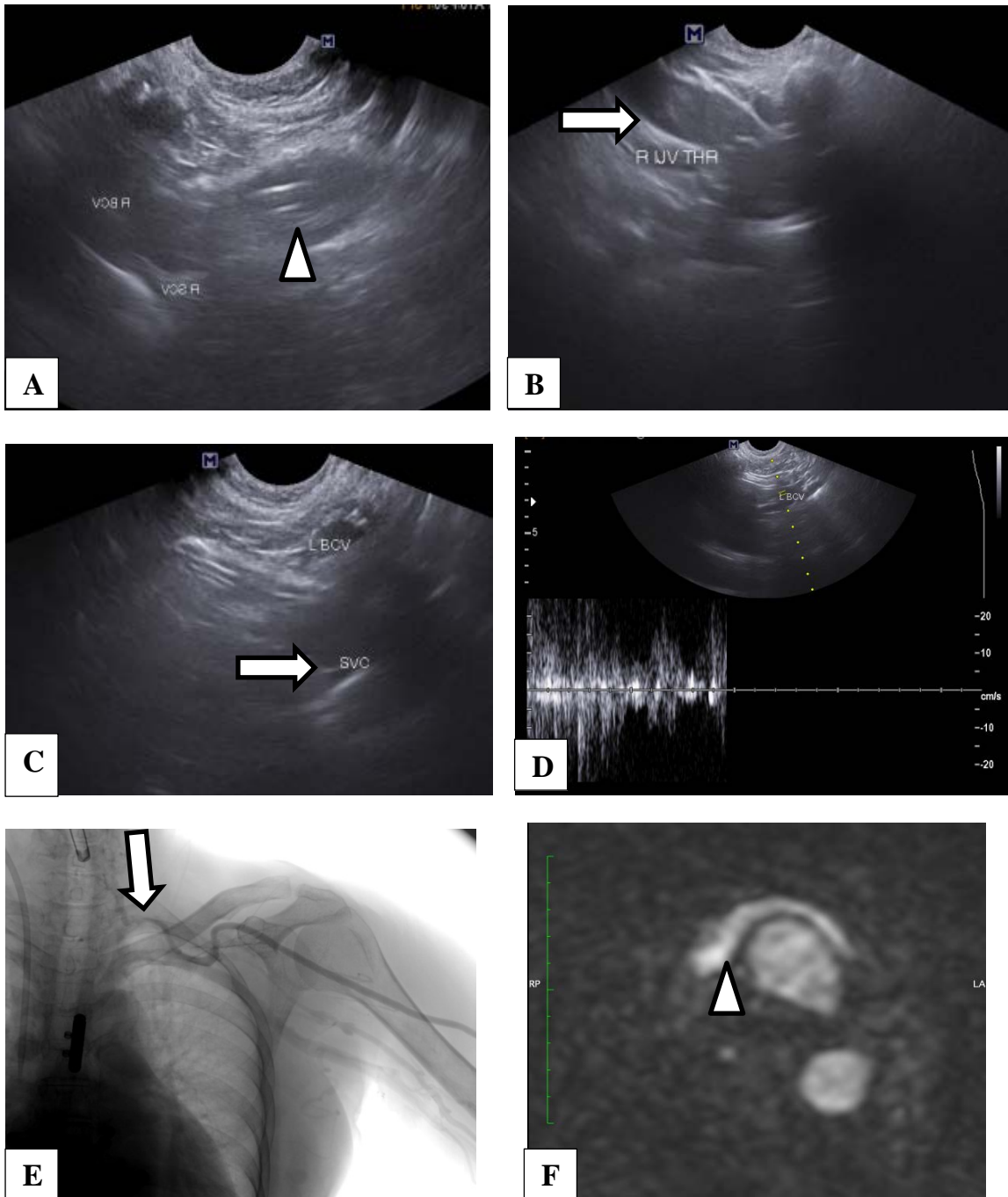
(E-F) Complete occlusion of right Internal Jugular Vein (arrow) with thrombus extending to the right BrachioCephalic Vein (arrowhead) as demonstrated by axial MR imaging of the same patient by TRUFISP sequence. (G) DSV of right Subclavian vein showing stenosis of right Brachio Cephalic vein (black arrow) with distal flow of contrast in SVC.

CASE 2



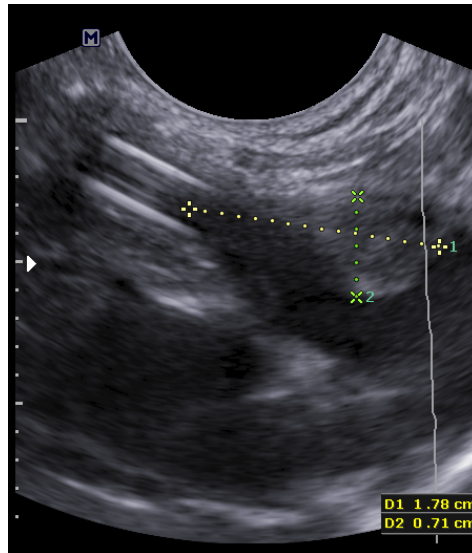
(A-E) Complete occlusion of left Internal Jugular Vein (arrow) with thrombus and CVC insitu as shown by the high frequency linear probe. The thrombus extending to the left BrachioCephalic Vein as partial filling defect (arrowhead) demonstrated by endocavitary probe in grey scale imaging. (D) Coronal 3D PC MRV reconstructed MIP image showing occluded left Internal Jugular Vein (arrow). (E) DSV of left subclavian vein showing occlusion of left Internal Jugular Vein (asterisk) with flow of contrast noted in left BrachioCephalic vein (arrowhead) and SVC.

CASE 3



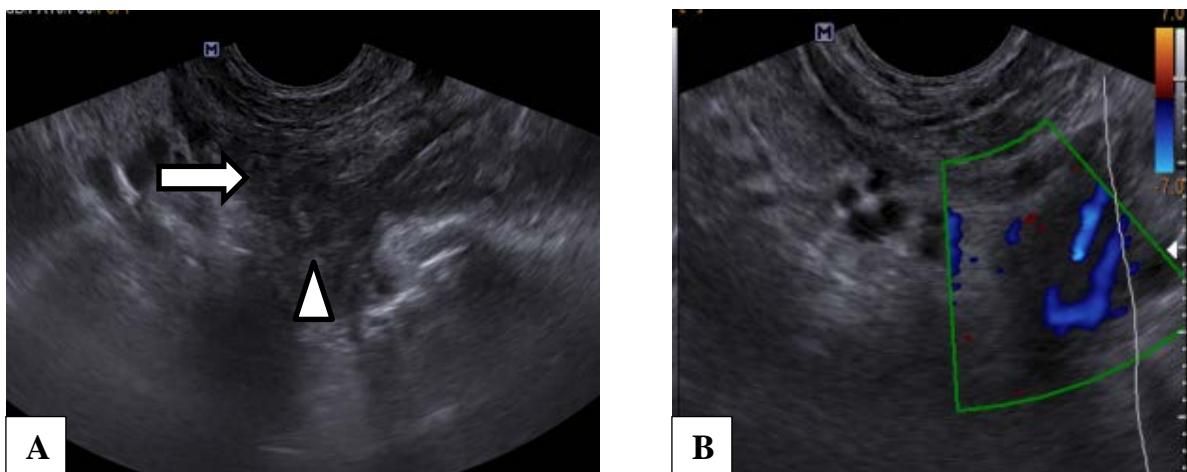
(A-F) Complete occlusion of right Internal Jugular Vein(arrow) with thrombus extending to the right BrachioCephalic Vein(arrowhead) and CVC insitu as demonstrated by endocavitary probe in grey scale imaging. Normal blood flow noted in left BrachioCephalic Vein and SVC(arrow) as shown by endocavitary probe in spectral Doppler imaging. (E) DSV of left Subclavian Vein showing normal flow of contrast (arrow). (F) Axial 3D PC MRV reconstructed image showing normal left BrachioCephalic Vein joining the SVC(arrowhead).

CASE 4



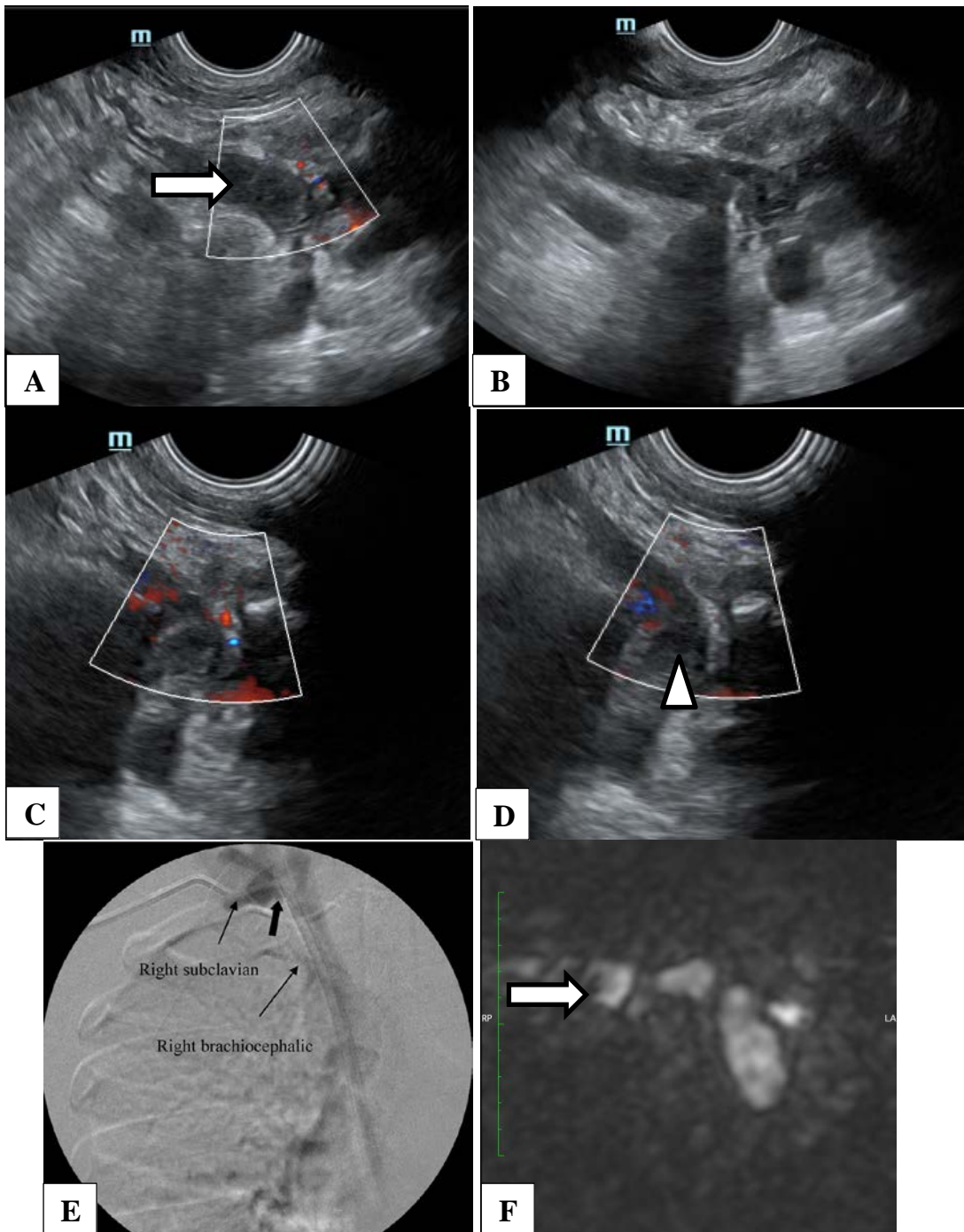
- Complete occlusion of the tip of Central Venous Catheter(CVC) with thrombus (arrow) along with the size of thrombus as demonstrated by endocavitary probe in grey scale imaging.

CASE 5



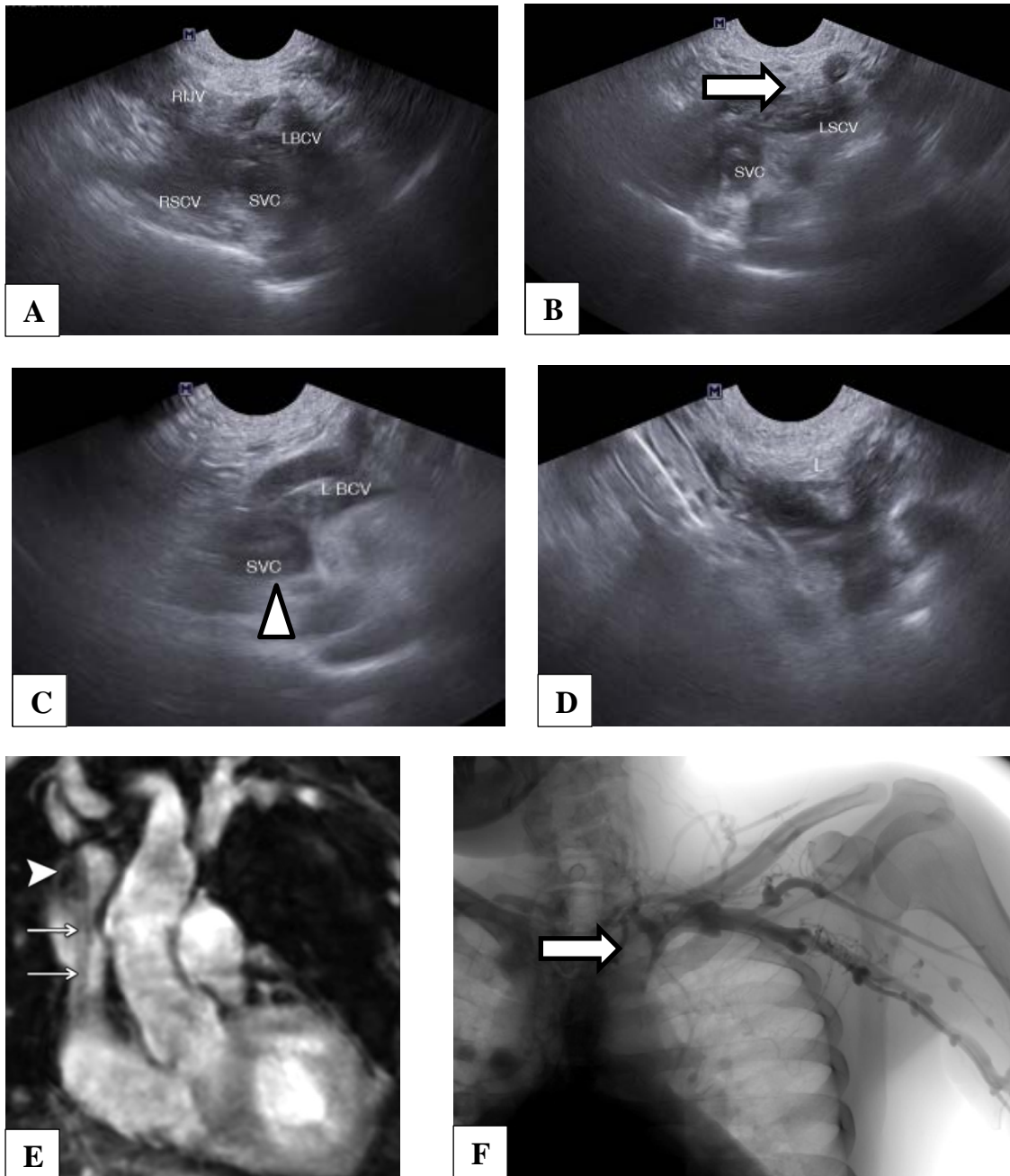
(A,B) Complete occlusion of left Internal Jugular Vein(arrow) and the left BrachioCephalic Vein(arrowhead) with thrombus as demonstrated by endocavitary probe in grey scale and colour Doppler imaging. MRV and DSV could not be done because both are contraindicated with patient having MRI incompatible metal implant and the patient is critically ill.

CASE 6



(A-D) Complete occlusion of right Internal Jugular Vein (arrow) and the right BrachioCephalic Vein (arrowhead) with thrombus as demonstrated by endocavitary probe in grey scale and colour Doppler imaging. (E) DSV showing no flow of contrast in right BrachioCephalic vein (black arrow) with CVC insitu. (F) Filling defect noted in right BrachioCephalic Vein (arrow) as shown by MRV.

CASE 7



(A-D) Complete occlusion of left Subclavian Vein (arrow), the left BrachioCephalic Vein and SVC (arrowhead) as demonstrated by endocavitary probe in grey scale imaging. (E) MRV showing the filling defect in SVC (arrowhead) with CVC insitu (arrow) (F) No flow of contrast noted in left Subclavian Vein, left BrachioCephalic Vein and SVC with formation of collaterals as shown by DSV.

CONCLUSION

To conclude, CKD with its high prevalence, morbidity and mortality is a significant health problem in India. Hemodialysis seems to be a boon for those patients for renal replacement therapy in spite of long waiting list for renal transplant. The vascular access for hemodialysis is achieved by Central Venous Catheter (CVC) which has its own complications like Central Venous Steno-occlusive disease(CVSD). Though Digital Subtraction Venography (DSV) is the gold standard for its diagnosis, it is an invasive procedure with the risk of contrast reactions and radiation exposure.

In this study, Magnetic Resonance Venography(MRV) using 3D non contrast Phase contrast(PC) sequence has more diagnostic accuracy when compared with Doppler in detecting Central Venous Steno-occlusive disease. But MRV is expensive with its own contradictions, artefacts and there is difficulty in doing MRV when the patient is critically ill and is not ambulatory.

So, bedside Doppler in expert hands having its statistical analysis on par with MRV can be a promising tool to detect Central Venous Steno-occlusive disease. However Doppler has its own pitfall in imaging the Superior Vena Cava. It is partly rectified by the endocavitary probe with which the proximal SVC can be visualised to an extent. Thus this study demonstrates the usefulness of bedside doppler in assessing the central veins in hemodialysis patients with Central Venous Catheter.

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ABBREVIATIONS

ABPI	- Ankle Brachial Pressure Index
AVG	- Arterio Venous Graft
AVF	- Arterio Venous Fistula
BCV	- Brachiocephalic Vein
CE	- Contrast Enhanced
CI	- Confidence Interval
CKD	- Chronic kidney disease
CKDu	- CKD of unknown etiology
cm/s	- Centimetre per second
CVC	- Central Venous Catheter
CVSD	- Central venous steno-occlusive disease
DSA	- Digital Subtraction Angiography
DSV	- Digital Subtraction Venography
FOV	- Field of view
IJV	- Internal Jugular Vein
IVC	- Inferior Vena Cava
MIP	- Maximum intensity projection
ml	- Millilitre
mm	- Millimetre
ms	- Millisecond
MHz	- Mega Hertz
MPR	- Multi-planar reformations

MRA - Magnetic Resonance Angiography
MRI - Magnetic Resonance Imaging
MRV - Magnetic Resonance Venography
NPV - Negative predictive value
NSF - Nephrogenic systemic fibrosis
PC - Phase contrast
PE - Pulmonary Embolism
PI - Pulsatility Index
PPV - Positive predictive value
RF - Radio Frequency
RI - Resistive Index
RRT - Renal Replacement Therapy
SCV - Subclavian Vein
SVC - Superior vena cava
TEE - Transesophageal echocardiography
TOF - Time of Flight
TR - Time to Repeat
US - Ultrasound
VA - Vascular Access
Venc - Velocity Encoding

PATIENT INFORMATION MODULE

ASSESSMENT OF CENTRAL VEINS IN HEMODIALYSIS PATIENTS USING DOPPLER , MAGNETIC RESONANCE VENOGRAPHY AND DIGITAL SUBTRACTION VENOGRAPHY – A COMPARATIVE STUDY TO DETERMINE THE USEFULNESS OF BEDSIDE DOPPLER IN EXPERT HANDS.

Investigator: Dr.A.Pon Shankar,
M.D.R.D,
Govt Stanley medical college,
Chennai.
Guide: Dr.C.Nellaiappan (Professor)
Co-Guide: Dr.C.Amarnath(Professor & HOD)
Dr.G.Sathyan(Professor)

Patient information module

You are invited to be a part of this study.

Before you participate in this study, I am giving following details about his trial, which include the aims, methodology, intervention, possible side effects if any.

Patients requiring hemodialysis will be included in this study. A detailed clinical history will be taken following a standardized proforma. A clinical examination and relevant basic investigations will be done. You will be scanned by Doppler, MRV, DSV for assessing central veins.

Result arising from this study will be analyzed and used for academic purposes. You will be given clear instructions at every step and you are free to ask or clarify any doubts. Your identity remains confidential. You are free to withdraw from the trail at any point of time without any prior notification or without any legal or medical implications.

I request you to volunteer for this study.

Thanking you.

Investigator's sign:
(Dr.A.PON SHANKAR)

Patient's sign:
NAME:

PATIENT CONSENT FORM

Study title:

**“ASSESSMENT OF CENTRAL VEINS IN HEMODIALYSIS PATIENTS
USING DOPPLER , MAGNETIC RESONANCE VENOGRAPHY AND
DIGITAL SUBTRACTION VENOGRAPHY – A COMPARATIVE STUDY
TO DETERMINE THE USEFULNESS OF BEDSIDE DOPPLER IN
EXPERT HANDS”**

Patient’s Identification No: _____

Patient’s Name: _____

Patient’s Date of Birth : ___/ ___/ _____

I confirm that I have read and understood the Information sheet for the above study. I have had the opportunity to ask the questions and all my questions and doubts have been answered to my complete satisfaction.

I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason without my legal rights being affected.

I understand that clinical study personnel, the Ethics Committee and the regulatory Authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not restrict the use of any data or results that arise from this study. I agree not to withhold any information about my health from the investigator and will convey the same truthfully.

I agree to take part in the above study and to comply with the instructions given during the study and to faithfully co-operate with the study team , and to immediately inform the study staff, if I suffer from any deterioration in my health or well- being or any unexpected or unusual symptoms.

I hereby consent to participate in this study. I consent to give my medical history, undergo complete physical examination and diagnostic tests including haematological, biochemical and urine examination etc.

Signature/ Thumb Impression of the Patient : _____

Place _____ Date: _____

Patient’s Name &

Address: _____

Signature of the Investigator: _____

Place: _____ Date: _____

Study Investigator’s Name : _____

Institution: Stanley Medical College.

*Signature of the witness _____

Place : _____ Date: _____

*Name and Address of the Witness :

*** Mandatory for uneducated patients (where thumb impression has been provided above)**

சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு :

ஆராய்ச்சி நிலையம் : நுண்கதிர் இயல்துறை,
தமிழ்நாடு அரசு ஸ்டான்லி மருத்துவக்கல்லூரி & மருத்துவமனை, சென்னை -
600 001.

பங்கு பெறுபவரின் பெயர் :

பங்குபெறுபவரின் எண் :

பங்கு பெறுபவர் இதனை குறிக்கவும்.

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது.

நான் இவ்வாய்வில் தன்னிச்சையாகதான் பங்கேற்கிறேன். எந்த காரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகி கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

இந்த ஆய்வு சம்மந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன். இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக்கொள்ளவும் அதை பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கிறேன்.

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின்படி நடந்து கொள்வதுடன் இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன். என் உடல் நலம் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறான நோய்க்குறி தென்பட்டாலோ உடனே அதை மருத்துவ அணியிடம் தெரிவிப்பேன் என உறுதி அளிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம் இடம் தேதி

கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்

ஆய்வாளரின் கையொப்பம் இடம் தேதி

ஆய்வாளரின் பெயர்

ETHICAL COMMITTEE APPROVAL



GOVERNMENT STANLEY MEDICAL COLLEGE & HOSPITAL, CHENNAI -01 INSTITUTIONAL ETHICS COMMITTEE

Title of the Work : Assessment of central veins in hemodialysis patients using doppler , magnetic resonance venography and digital subtraction venography - a comparative study to determine the usefulness of bedside doppler in expert hands.
Principal Investigator : Dr.A.Pon Shankar
Designation : I MDRD
Department : Department of Radiodiagnosis, Govt. Stanley Medical College.

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 21.11.2017 at the Council Hall, Stanley Medical College, Chennai-1 at 10am.

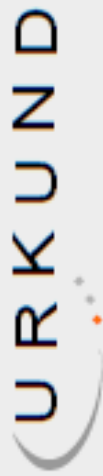
The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The Principal investigator and their team are directed to adhere to the guidelines given below:

1. You should inform the IEC in case of changes in study procedure, site investigator investigation or guide or any other changes.
2. You should not deviate from the area of the work for which you applied for ethical clearance.
3. You should inform the IEC immediately, in case of any adverse events or serious adverse reaction.
4. You should abide to the rules and regulation of the institution(s).
5. You should complete the work within the specified period and if any extension of time is required, you should apply for permission again and do the work.
6. You should submit the summary of the work to the ethical committee on completion of the work.


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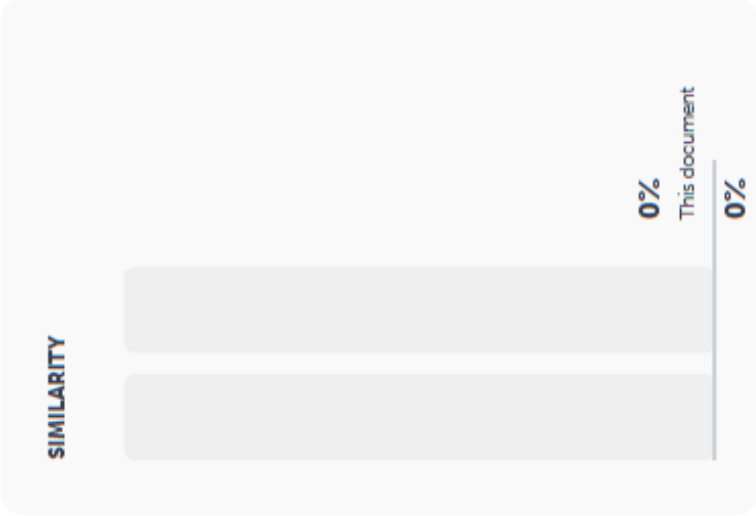


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