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Original Research Paper

Radio-Diagnosis

COMPARATIVE STUDY OF ULTRASONOGRAPHY COLOUR DOPPLER VS COMPUTED TOMOGRAPHY ANGIOGRAPHY IN LOWER LIMB PERIPHERAL ARTERIAL DISEASE

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ABSTRACT Peripheral arterial disease (PAD) is the most common condition affecting the arteries of the lower extremity. [1,2] PAD is a chronic vascular disease characterized by an impaired circulation in the lower extremities with a broad spectrum of symptoms. [3,4] Arterial flow compromise from stenosis and blockages can lead to limb ischemia. It refers to any condition that obstructs blood flow in arteries, excluding those supplying the heart and brain. Those affected face a significantly elevated risk of coronary artery disease and stroke - up to four times higher than average. [5,6]. A comprehensive clinical assessment, along with Doppler ultrasound and CT angiogram, provides an accurate diagnosis. Imagingplays a crucial role in preparing for interventions among individuals diagnosed with lower extremity peripheral arterial disease.. [10,11] Intra-arterial contrast angiography is considered the benchmark for examining lower limb arterial conditions. Nevertheless, it has limitations related to arterial puncture, ionizing radiation exposure, and the possible kidney harming effects of iodinated contrast agents.[5] Multiple non-invasive imaging modalities, including doppler/duplex ultrasonography, multidetector computed tomography angiography (MDCTA), and magnetic resonance angiography (MRA), are available for grading lower extremity arterial disease.[4]

KEYWORDS : Peripheral Arterial Disease (PAD), Lower Extremity Arterial Disease, Imaging Modalities· Intra-arterial Contrast Angiography

INTRODUCTION

Duplex ultrasonography has a high specificity of 95% and a somewhat lower sensitivity of 88% for detecting hemodynamically significant lesions (> 50% stenosis or occlusion). [12] Recent advances in Duplex Ultrasound like better post-processing capability, transducer technology, image resolution, signal strength and spectral analysis capabilities have improved its ability to visualize and grade abnormalities, thus extending the scope for non-invasive assessment of peripheral arterial disease. [5]

Peripheral arterial disease impacts a significant portion of the adult population, with its manifestations in the lower extremities varying from being asymptomatic to severe cases involving critical leg ischemia and potential limb loss. [7] Typical symptoms of intermittent claudication are present in less than 20% of individuals diagnosed with peripheral arterial disease, while approximately a third experience atypical exertional leg symptoms. Diabetes and ischemia-related peripheral arterial disease stand as the primary culprits behind nontraumatic lower extremity amputations. [8]

Management strategies are governed by the severity of the disease and differ for patients with lower limb arterial disease. Patients with intermittent claudication are often managed conservatively, while patients with limb threatening ischemia are treated with angioplasty, surgical revascularisation or amputation.[9] The severity of the disease determines the selection of treatment, which may include a combination of therapies. Patients facing limb-threatening ischemia necessitate a thorough evaluation to establish an appropriate treatment strategy.

Following the progress in CT technology, it is now feasible to

image entire limbs swiftly. The enhancements in CT angiography have been particularly appealing due to rapid advancements in technology. With faster acquisition times, thinner slices, improved spatial resolution, and more advanced multidetector CT scanners, scanning of the complete vascular system can be achieved within a shorter timeframe while reducing the required contrast medium substantially. [13] Optimizing intravenous contrast in conjunction with blood flow and CT scanning results in increased spatial resolution and coverage exceeding 120 cm.[14] Various presentation methods have been created and can be employed, such as multiplanar reformation, maximum intensity projection, surface-shaded display, and the latest addition being volume rendering. Computers equipped with graphic capabilities showcase 3D images through volume-rendered images and curved planar images. CT angiography enables imaging of the complete arterial system and has demonstrated strong agreement with digital subtraction imaging. [15]

Duplex Ultrasonography poses no risks, unlike Computed Tomography and Angiography which involves ionizing radiation and the use of contrast agents.

Recent enhancements in Duplex Ultrasound such as improved postprocessing capability, transducer technology, image resolution, signal strength, and spectral analysis have enhanced its capacity to detect and classify abnormalities. This has expanded its potential for non-invasive evaluation of peripheral arterial disease. [13]

Several studies validate contrast material–enhanced Multi Detector CT Angiography as a noninvasive alternative to conventional Digital Substraction Angiography for imaging the vascular tree. [16-20] Unfortunately there is a paucity of high-quality trials comparing the accuracy, reliability and reproducibility of non- invasive evaluation using Duplex ultrasound and Computed Tomography Angiography (CTA) in the investigation of peripheral arterial disease. In advent of same, the present study was planned to evaluate the role of duplex ultrasonography in comparison with MDCT angiography in the assessment of lower limb ischemia.

MATERIAL AND METHODS

The present study was undertaken in the Department of Radiodiagnosis, Amaltas Institute of Medical Sciences, Dewas after valid approval of ethics committee of the institution.

Study Design: - The design of present research study was Prospective comparative study.

Study Centre: - The study was conducted at A tertiary care center (Amaltas Institute of Medical Sciences, Dewas, (M.P.) Department of Radio-diagnosis in rural population in central India.

Duration Of The Study: - Study was undertaken for a period of 18 months after the approval from the ethical committee.

METHODOLOGY:

Source of Data: Prospective comparative study was conducted on 43 subjects with lower limb peripheral arterial disease who presented to OPD of Department of Radio-diagnosis at Amaltas Institute of Medical Sciences, Dewas, M.P. Patients satisfying the inclusion and exclusion criteria were enrolled after taking an informed written consent. The patient was explained about the advantages and disadvantages of the procedure in their vernacular language before getting the consent. After taking the consent patient was investigated thoroughly. Once patient was found fit written informed consent is taken and investigation is performed i.e. USG colour Doppler & CT Angiography.

Sample Size: All the patients of age > 18 years who presented with lower limb peripheral arterial disease to the OPD of Department of Radio-diagnosis at Amaltas Institute of Medical Sciences, Dewas, M.P. during study duration and fulfilled the inclusion criteria were enrolled after taking informed written consent. We conducted a pilot study of 2 months and on an average, we got 3 cases per month. Considering the research period of 18 months we took sample size of 54 taking into consideration a drop rate of 20%. After approval from the Institutional ethical committee, 50 patients fulfilling the inclusion criteria and exclusion were enrolled for the study after taking an informed written consent.

After approval from institutional ethical committee, the present study was undertaken on 54 patients of unilateral or bilateral lower limb arterial disease who satisfied the inclusion criteria were enrolled after taking a written informed consent. A detailed history was taken as per the study proforma. Patient were educated about the type of procedure, their advantages and disadvantages and approximate cost of each technique. After taking the consent patient is investigated thoroughly. Once patient is found fit written informed consent is taken and investigation is performed i.e. USG colour Doppler & CT Angiography.

Ultrasound Colour Doppler: Duplex Ultrasound was done with LOGIQ F8 ULTRASOUND machine band width frequency transducer with a range of 5-13 MHz for lower limb.

Patients was kept on fasting for at least 6 hours, to improve visualization of the aorto iliac region.

CT Angiography: CT angiography was done with GE 16 slice Multi detector CT. Patients was placed in supine position with feet entering the gantry. First Scanogram and plain study were taken. Spiral acquisitions were performed in a single scanning pass from the level of the diaphragm down to the ankles. The average length of scanning for a patient is about 1500 mm. Patients were asked to hold their breath during the first part of the scanning pass. After saline check, 100mL volume of iodinated contrast material (Omnipaque) was administered through a 18-gauge annula in an antecubital vein at a rate of 4.5mL/sec. through pressure injector followed by saline chase. The case-record proforma was filled using the information obtained.

RESULTS

The current study was prospective observational research conducted on 43 individuals diagnosed with lower limb peripheral arterial disease. The participants were recruited from the outpatient department of the Department of Radiodiagnosis at Amaltas Institute of Medical Sciences in Dewas, Madhya Pradesh.

Patients who met the specified inclusion and exclusion criteria were enrolled after providing informed written consent. Before obtaining consent, patients were informed about the benefits and risks associated with the procedures in their native language.

Upon obtaining written consent from eligible patients, they underwent thorough investigation. The diagnostic procedures performed included USG (ultrasonography) with color Doppler and CT angiography. These diagnostic tools were utilized to assess and evaluate the arterial status of the lower limbs in the enrolled patients.

This study aimed to gather observational data on the diagnostic outcomes and to assess the utility of USG with color Doppler and CT angiography in diagnosing peripheral arterial disease in the lower limbs.

The Following Results Were Observed:

Demographic Data

Distribution of Study Population on the Basis of Age Group

In the present study, the largest proportion of subjects was

found in the age group of 40-50 years, comprising 34.9% of the total. This was followed by the age groups of 50-60 years and 60-70 years, both with 25.6% each. The age group of 30-40 years accounted for 14.0% of the subjects.

This study bears resemblance to the research conducted by Gamal El Dein et al., which included 54 participants comprising 24 men (44.4%) and 30 women (55.6%). The age of the participants ranged from 33 to 75 years, with a mean age of 59.56 years and a standard deviation of ±10.3. [1]

In another study done by Dev R et al. out of 40 patients evaluated, majority of patents were between 40 to 60 years of age with mean age of 51 years. This was comparable to results of our study. [74] Singhal R et al. reported that out of 50 patients studied, the majority were in the middle to elderly age group. Specifically, the highest number of patients, 16 out of 50 (32%), belonged to the 61-70 years age group. This indicates a significant representation of older adults in their study population. This was in concordance with our study results. [87]

M.B. Naveen Raj et al. similarly reported that among 40 patients, the largest proportion, 17 patients (43%), were in the age group of 61-70 years. The next largest group was aged 41-50 years, with 9 patients (22%), followed by 51-60 years and more than 70 years, each accounting for 6 patients (15%) respectively. The age group under 40 years had the fewest patients, with only 2 patients (5%). This suggests that peripheral vascular disease is uncommon in younger age groups based on their findings. [89]

Premalatha et al. 2000 studied prevalence of PVD in the Chennai Urban Population and they found that PVD was uncommon until middle-age and then the prevalence rate increased dramatically. This is in concordance with our study. [90]

Distribution of Study Population on the Basis of Gender

In the present study, there was a predominance of male participants, comprising 65.1% of the subjects, while females accounted for approximately 34.9% of the cohort.

Similarly, Dev R et al. also observed a male predominance compared to females in their study. Specifically, out of 40 patients evaluated with both CDUS and CTA, 25 were male and 15 were female. This gender distribution aligns with the findings in our study. [74]

Singhal R et al. reported that out of 50 patients studied 40 (80%) were males and rest females. This was comparable to our study. [87]

M.B. Naveen Raj et al. reported that out of the 40 patients 30 (75%) were male patients and 10 (25%) were female patients. This was comparable to our study.

However, Gamal El Dein et al., reported a higher incidence of females (55.6%) as compared to males (44.4%). This was contrasting to our study. [1]

COMORIBIDITIES

In the present study, the distribution of comorbidities shows that the highest proportion of subjects had a BMI greater than 30 kg/m^2, accounting for 53.5% of the participants. Diabetes was the next most prevalent comorbidity at 46.5%, followed by hypertension at 41.9%. Regarding deleterious habits, smoking was the most prevalent, observed in 44.2% of the subjects. In contrast, alcohol consumption was reported by approximately 37.2% of participants, indicating a lower prevalence compared to smoking.

Premalatha et al. studied risk factors of PVD in the Chennai Urban Population Their analysis showed age >50 years ($P<0.001$) and hypertension ($P = 0.08$) to be associated with PAD, whereas smoking showed no association. Known diabetic subjects had a higher prevalence of PVD (7.8%) compared with newly diagnosed diabetic subjects (3.5%). This is in concordance with our study. However, in our study significant number of symptomatic patient also had smoking associated with them which is discordant with the above study. [90]

In similar studies done by Dev R et al. and Aboyans V C et al. it was reported. That the most common associated risk factor was diabetes mellitus followed by smoking and hypertension. This was comparable to results of our study. [74]

M.B. Naveen Raj et al. reported that among their study participants, 6 patients had gangrene. Out of these, 16 patients were non-smokers, 22 were smokers, and 2 were tobacco chewers. This highlights the association between smoking habits and the incidence of Peripheral artery diseases in their study population. [89]

Price JFet al. studied the relationship between smoking and cardiovascular risk factors in the development of peripheral arterial disease and coronary artery disease (Edinburgh Artery Study). The incidence of peripheral arterial disease was 5.1% in 594 patients studied. This is in agreement with our study. [91]

Singhal R et al. found diabetes (88% pts) and hypertension (54% pts) to be majorly associated with patients in PAD. Smoking (14%) and tobacco chewing (24%) were the other two important factors associated with patient. This was comparable to our study. [87]

Earlier studies evaluating color Doppler imaging have shown varying degrees of sensitivity and specificity. In a similar study done by Singhal R et al. [87] comparable findings are enumerated:

- Overall sensitivity, specificity, PPV and NPV of CDUS compared to CTA in femoro popliteal segments for percentage stenosis was found to be 92.25%, 87.75%, 91% and 89.5% respectively.
- Overall sensitivity, specificity, PPV and NPV for detecting collaterals was 90%, 88%, 46% and 99% respectively.
- Doppler USG is excellent modality in evaluating the extent of disease with overall sensitivity, specificity, PPV and NPV of 94% and 98.5%, 99% and 92.5% respectively.
- Overall sensitivity, specificity, PPV and NPV of Doppler USG compared to CTA for detecting thrombus was found to be 57.25%, 96%, 72.5% and 91.25 respectively.
- Overall Sensitivity, specificity, PPV and NPV of Doppler USG for plaque detection was found to be 89%, 96%, 89% and 93% respectively.
- Overall Sensitivity, specificity, PPV and NPV of Doppler USG compared to CTA for wall calcification was found to be 92%, 93.75%, 87.75% and 92.5% respectively.

Hence, it can be inferred that in our study we found ultrasound to have good correlation with CT in evaluation of PADs in lower limb vessels.

Thus, USG favors to be the 1 st line investigation for evaluation of PADs followed by CT before planning any interventional treatment.

The limitation of the study was small sample size and shorter duration. Hence, a larger scale study is recommended.

CONCLUSION

The current study was prospective observational research conducted on 43 individuals diagnosed with lower limb peripheral arterial disease. The participants were recruited from the outpatient department of the Department of

Radiodiagnosis at Amaltas Institute of Medical Sciences in Dewas, Madhya Pradesh.

Duplex Ultrasound provides high-resolution, precise anatomical and physiological information of the peripheral arteries. It is unlikely to misclassify a whole limb as "normal" and thus inappropriately screen out a patient from further investigation.

Duplex Ultrasound was found to have a high negative predictive value and could exclude a significant lesion, thus helping to avoid other costly diagnostic modalities in a mildly symptomatic patient. It could determine the nature and extent of arterial disease based on which treatment can be planned, either endovascular or surgical.

It may also determine the significance of equivocal lesions identified by MDCT angiography. Combination of Duplex Ultrasound with MDCT angiography has better diagnostic accuracy.

Thus, Duplex Ultrasound is a safe, inexpensive, non-invasive, easily available diagnostic tool with high diagnostic accuracy and is indispensable in the investigation of peripheral arterial disease.

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