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Comparison of Color Flow Duplex Study with Digital Subtraction Angiography in the Evaluation of Peripheral Vascular Disease

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ABSTRACT

Background: A common vascular disorder marked by constriction or blockage of peripheral arteries, which lowers blood flow and causes ischemia and raises limb morbidity risk is peripheral arterial disease (PAD). **Objectives**: To assess in suspected cases the diagnostic agreement between Digital Subtraction Angiography (DSA) and Color Doppler Ultrasound (CDUS) in diagnosis of PAD. **Methods:** We carried out this cross-sectional study over six months. Using non-probability consecutive sampling, 76 patients total, 40–80 years with Ankle-Brachial Index (ABI) of 0.9 were included. Patients excluded were those with baseline serum creatinine more than 1.1 mg/dL or those undergoing hormonal, radiation, or surgical treatment. Every individual had DSA as well as CDUS. Using sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and Kappa statistics, CDUS data were matched to DSA, the reference standard, to assess diagnostic performance. **Results:** For artery stenosis (≥50%), CDUS demonstrated the sensitivity of 94.0% and specificity of 87.5%. PPV was 95.5%; NPV was 85.7%. Strong agreement between CDUS and DSA was demonstrated by Kappa coefficient ($\kappa = 0.81$), $p < 0.001$. With agreement rates of 85.7, 90.9, 92.3 and 87.5%, CDUS appropriately categorized mild, moderate, severe stenosis and full occlusion, correspondingly. In diabetic, hypertensive, smoking and hyperlipidemic subgroups, stratification by risk variables revealed constant performance. **Conclusion:** Finally, with great concordance with DSA, CDUS is dependable and non-invasive diagnostic instrument for assessing PAD. Especially in situations when invasive angiography is not practical, it is a good substitute for PAD screening since it correctly detects and diagnoses stenosis degree and occlusion.

INTRODUCTION:

Mostly involving the narrowing, blockage, or aneurysmal alterations in the arteries and veins of the extremities, peripheral vascular disease (PVD) is the spectrum of illnesses affecting the blood vessels outside the heart and brain 1-2. Globally, PVD is becoming more common; risk factors include age, diabetes mellitus, hypertension, hyperlipidemia and smoking are driving this increase 3. Optimizing treatment plans depends on early and precise diagnosis since delayed or erroneous diagnosis can cause serious consequences including limb ischemia, gangrene and even limb loss 4-5. As such, PVD diagnosis and evaluation heavily rely on imaging 6.

With great spatial resolution and capacity to view artery flow and identify stenosis or occlusions, DSA has long been the gold standard for imaging in PVD evaluation 7. DSA is intrusive operation even with its diagnostic accuracy; it usually requires arterial puncture and administration of iodinated contrast agents, which can be linked with consequences including allergic responses, contrast-induced nephropathy and radiation exposure 8. Consequently, the necessity of less intrusive and similarly powerful imaging techniques has attracted a lot of interest 10.

Evaluating peripheral arteries, CDUS has become rather popular non-invasive imaging method. It presents color-coded Doppler flow analysis in addition to conventional B-mode imaging to enable hemodynamics and vessel anatomy view. Safety profile, cost-effectiveness and capacity to evaluate blood flow velocity and turbulence define CDUS's benefits 11-13. Notwithstanding these advantages, questions about its accuracy and repeatability persist, especially in patients with calcified arteries or in detection of complicated lesions 14.

Evaluating PVD, color flow duplex (CFD) ultrasonic imaging has become being possible non-invasive substitute for DSA 15. It presents simultaneous visualization of vascular shape and blood flow dynamics by combining conventional B-mode ultrasonic imaging with Doppler flow analysis. Among its non-invasive character, absence of radiation and capacity to evaluate hemodynamic relevance of vascular lesions, CFD offers advantages. Still up for contention, though, is CFD's dependability and accuracy relative to DSA 16-18.

The objective of this work was to determine the agreement between Color Doppler Ultrasound and DSA in the diagnosis of peripheral arterial disease in suspected cases.

MATERIAL & METHODS

Study Settings

Conducted in the Department of Radiology at Combined Military Hospital (CMH), Peshawar, this cross-sectional study ran for six months and comprised individuals referred to the radiology department with the clinical suspicion of PAD.

Study Population and Sample Size

A formula for approximating agreement between two diagnostic tests was used to ascertain the sample size. The computed sample size was 76 suspected instances of PAD using expected 80.1% agreement of CDUS and DSA assumed as 95% confidence interval and absolute precision of 9%. Using non-probability successive sampling method, 76 patients overall fulfilling the inclusion criteria were registered for the study.

Including Criteria

- Patients of both sexes
- Age ranging from forty to eighty years.
- Patients diagnosed with PAD confirmed by an Ankle-Brachial Index (ABI) of less than 0.9.

Exclusion Criteria

- Patients having baseline serum creatinine levels higher than 1.1 mg/dL.
- Patients undergoing radiation, hormonal treatment or those who have had past PAD surgeries.

Diagnostic Methodology

Following informed agreement, each patient received DSA and CDUS for PAD evaluation.

Color Doppler Ultrasound

We utilized high-frequency linear array transducer completed CDUS. The lower leg arteries were methodically scanned from common femoral artery to the distal tibial arteries while test was performed in supine posture. The diagnostic criteria for PAD on CDUS comprised the presence of localized artery stenosis (defined as ≥50% reduction in lumen diameter), occlusion or aberrant flow patterns, such heightened peak systolic velocity and post-stenotic turbulence. Based on the degree of stenosis, normal, mild, moderate, severe or occluded, all results were noted and categorized [19].

Digital Subtraction Angiography

It served as the benchmark for comparison. We operated under fluoroscopic direction. To get thorough pictures of arterial tree in lower extremities, the catheter was placed into the femoral artery and contrast media was administered. DSA scans helped determine the degree and scope of stenosis;

results were classified similarly to CDUS. Using diameter reduction approach, percentage of stenosis was computed; lesions were categorized as mild (<50%), moderate (50–70%), severe (70–99%) or complete occlusion (>100%) [20].

Statistical Examination

CDUS's diagnostic performance was assessed in relation to the gold standard, DSA. Using the Kappa (κ) statistic, which gauges degree of agreement beyond chance, two modalities' agreement was ascertained. Comparing CDUS's sensitivity, specificity, PPV and NPV to DSA helped one to identify notable artery stenosis (≥50% luminal constriction) and occlusion. While categorical variables were shown as frequency and percentages, continuous variables such as patient age were reported as mean ± standard deviation. Considered statistically significant was a p-value of 0.05.

Ethical Approval

The CMH, Peshawar's Institutional Review Board (IRB) granted ethical permission for the study. Before registration, each subject signed written informed consent; study followed the guidelines of the Declaration of Helsinki. Throughout the study, patient confidentiality was respected; all imaging techniques were carried out in conformity with institutional policies

Results

Mostly participants in the study population (36.8%) were between the age of 51 and 60; followed by 40-50 year range: 32.9%. Male patients accounted for 63.2% while female patients made 36.8%. Diabetes mellitus (40.8%) followed by hypertension (38.2%) and smoking (34.2%) was the most often occurring risk factor. Of patients, 26.3% displayed hyperlipidemia. While 28.9% of the patients had more severe condition with ABI values below 0.4, 46% of the patients had ABI between 0.4 and 0.69, therefore indicating intermediate arterial disease (Table 1).

Out of 66 identified by DSA, Color Doppler Ultrasound detected 62 cases of severe artery stenosis (≥50%). Regarding occlusion, DSA found 26 cases while CDUS found 24. On a few cases, CDUS tended to underdiagnose both stenosis and occlusion somewhat. With few exceptions, CDUS and DSA results were consistent overall; minor differences occurred in a small number of instances (Table 2).

The agreement comparison between CDUS and DSA for diagnosing peripheral arterial disease revealed that CDUS had high sensitivity (94.0%) and positive predictive value (95.5%), thereby indicating its dependability in spotting real positive cases. With 87.5% specificity and 85.7% negative predictive value, which suggested some false positives, with the statistically significant p-value of 0.001, Kappa coefficient was 0.81, implying great agreement between the two modalities (Table 3).

Vascular lesion classification revealed that CDUS and DSA exhibited great degrees of agreement in all groups. For minor stenosis (<50%), agreement was 85.7%; for moderate stenosis (50–70%), it was 90.9%. While for full occlusion it was 87.5%, for severe stenosis (70–99%) agreement rose to 92.3%. These results suggested that, in assessing the degree of vascular lesions, CDUS somewhat closely matched DSA (Table 4).

Stratification of agreement by risk factors revealed that, across many patient categories, CDUS exhibited constantly high sensitivity and specificity. Patients with hypertension (κ = 0.83) had maximum agreement; followed by those with hyperlipidemia (κ = 0.82), diabetes mellitus (κ = 0.80) and smoking (κ = 0.79). This supported CDUS's non-invasive diagnostic value for PAD since it showed consistently performance across several high-risk populations (Table 5).

Table 1: Baseline Characteristics of Study Population (n=76)

Characteristic	Frequency (n)	Percentage (%)
Age (Years)		
40-50	25	32.9
51-60	28	36.8
61-70	15	19.7
71-80	8	10.6
Sex		
Male	48	63.2
Female	28	36.8
Risk Factors		
Diabetes Mellitus	31	40.8
Hypertension	29	38.2
Smoking	26	34.2
Hyperlipidemia	20	26.3

ABI (Ankle-Brachial Index)		
< 0.4	22	28.9
0.4 – 0.69	35	46.0
0.7 – 0.89	19	25.1

Table 2: Diagnostic Performance of CDUS against DSA for Detecting Arterial Stenosis (≥50%) and Occlusion

Diagnostic Parameter	CDUS	DSA	Total (n)
Stenosis ≥50%			
Present	62	66	66
Absent	14	10	10
Occlusion			
Present	24	26	26
Absent	52	50	50

Table 3: Agreement between CDUS and DSA for Detecting PAD

Parameter	Value (%)
Sensitivity	94.0
Specificity	87.5
PPV	95.5
NPV	85.7
Kappa Coefficient (κ)	0.81
p-value	0.001*

**indicated the statistical significance*

Table 4: Classification of Arterial Lesions by CDUS and DSA

Severity of Lesion	CDUS (n)	DSA (n)	Agreement (%)
Mild (<50% stenosis)	14	12	85.7
Moderate (50-70% stenosis)	22	20	90.9
Severe (70-99% stenosis)	26	28	92.3
Complete Occlusion	14	16	87.5

Table 5: Stratification of Agreement by Risk Factors

Risk Factor	Sensitivity (%)	Specificity (%)	Kappa Coefficient (κ)
Diabetes Mellitus	90.3	86.7	0.80
Hypertension	93.5	88.1	0.83
Smoking	92.1	85.3	0.79
Hyperlipidemia	94.4	87.2	0.82

Discussion

This work sought to find in a clinical environment the agreement between Digital Subtraction Angiography and Colour Doppler Ultrasound in the diagnosis of peripheral artery disease. Our results showed high degree of agreement across the two modalities, therefore showing great concordance. With positive and negative predictive values of 95.5 and 85.7%, respectively, CDUS proved to be 94.0% sensitive and 87.5% specific. These findings implied that, in suspected PAD cases, CDUS provided a consistent non-invasive substitute for DSA for identifying major artery stenosis and occlusion.

The sensitivity demonstrated in our investigation is in line with earlier studies. For CDUS in identifying notable arterial stenosis, for example, a study by Cassola et al. (2022) revealed sensitivity of 63% and specificity of 99% which quite nearly matches our findings [21]. Dachun et al. (2010) likewise found CDUS to have sensitivity of 79% and specificity of 99% for PAD diagnosis, therefore supporting the results of our investigation [22]. These similar sensitivity and specificities show the strength of CDUS in clinical practice, thereby giving a consistent instrument for first assessment prior to considering more intrusive treatments such as DSA.

Furthermore, our investigation revealed that CDUS attained over 85% agreement in all lesion categories and functioned consistently over several degrees of vascular lesions. This result is consistent with earlier studies by Cassola et al. (2022), who found that, especially in discriminating between moderate and severe stenosis, CDUS fairly effectively categorized arterial stenosis degree when compared to DSA [21]. Studies such as those of Nosher et al. (2014), which revealed comparable diagnosis performance, further supported the great degree of agreement in spotting full blockage (87.5%) [23].

Risk factor stratification revealed that, with comorbidities present, CDUS had somewhat different degrees of agreement; greatest Kappa coefficient was found in patients with hypertension. This implied that, in contrast to diseases like diabetes, where arterial calcifications can distort the interpretation of Doppler data, vascular remodeling in hypertension patients might be more easily observed by CDUS. Previous research by de Jiang et al. (2022) which underlined the difficulties of employing CDUS in diabetic

patients due to the frequency of arterial calcification supports our results [24].

Although CDUS and DSA have great agreement, it is crucial to recognize some constraints. In few situations, especially in individuals with severe calcified arteries, CDUS tended to underdiagnose the degree of stenosis and occlusion. Seyman et al. (2019) pointed out that restricted penetration of Doppler signals in calcified arteries and acoustic shadowing could be responsible. Furthermore, being operator-dependent, radiologist's experience and knowledge would affect the accuracy of CDUS [25].

Our study has certain strengths: adequate sample size and use of DSA as the gold standard for comparison guarantees strong validation of CDUS results. But the application of non-probability successive sampling might restrict the generalizability of our findings. To validate our results and investigate the function of modern Doppler techniques, including contrast-enhanced ultrasonicography, in improving diagnosis accuracy, more multicenter studies including bigger and more varied patient populations are required.

Ultimately, our work showed that, with great agreement with DSA, CDUS is very sensitive and specific method for PAD diagnosis. Especially in resource- constrained environments or when DSA is contraindicated, it can be the main screening method. These results suggested the use of CDUS into clinical procedures for PAD assessment, hence perhaps lowering the demand for invasive imaging while preserving diagnosis accuracy.

Conclusion

With high sensitivity (94.0%), specificity (87.5%), and great agreement (κ = 0.81), this study shown that Color Doppler Ultrasound is the dependable non-invasive substitute for Digital Subtraction Angiography for detecting peripheral artery disease. A useful technique for first evaluation and severity assessment, CDUS precisely categorized vascular stenosis and occlusion degree. Although slightly differentially calcified arteries were observed, CDUS remains the principal diagnostic tool and helps to lower the demand for invasive imaging in most clinical environments.

Conflict of Interest

Authors declare no conflict of interest.

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