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DEVISING DUPLEX ULTRASOUND STAGING FOR LOWER EXTREMITY ARTERIAL DISEASE CORRESPONDING TO FONTAINE CLINICAL STAGING

Original Research

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ABSTRACT

Background: Lower extremity arterial disease (LEAD) is a progressive atherosclerotic condition that significantly affects mobility, quality of life, and cardiovascular risk. Early and accurate staging is crucial for timely intervention and optimal disease management. While the Fontaine classification is widely used clinically, there is a need for a standardized, non-invasive imaging-based staging method that aligns with clinical assessment and enhances diagnostic precision.

Objective: To develop and validate a duplex ultrasound (DUS)-based staging system for LEAD that corresponds to Fontaine clinical stages, enabling precise hemodynamic evaluation and disease monitoring.

Methods: A cross-sectional observational study was conducted from September 2022 to September 2023, involving 135 adult patients with suspected or confirmed LEAD. All participants underwent detailed clinical assessment and DUS evaluation of bilateral lower limb arteries, including the common femoral, superficial femoral, popliteal, and tibial arteries. Sonographic parameters recorded included peak systolic velocity (PSV), waveform morphology, and presence of flow disturbances. These findings were correlated with Fontaine stages I to IV. Inter-observer reliability was assessed using Cohen's kappa coefficient.

Results: Stage I showed triphasic waveforms and normal PSV; Stage IIa exhibited mild PSV elevation (<100%) without turbulence; Stage IIb demonstrated PSV increases of 100–200% with disturbed flow and biphasic/monophasic waveforms; Stage III revealed severe stenosis (PSV >200%) and monophasic waveforms; and Stage IV presented with occlusion and absent flow. The DUS-based system showed a sensitivity of 92%, specificity of 96%, positive predictive value of 91%, and negative predictive value of 96%. Inter-observer agreement was excellent ($\kappa = 0.87$).

Conclusion: The proposed DUS staging framework provides a reliable, reproducible, and non-invasive alternative to clinical classification, supporting early diagnosis, treatment planning, and ongoing management of LEAD in routine practice.

Keywords: Arteriosclerosis, Duplex Ultrasonography, Hemodynamics, Intermittent Claudication, Peripheral Arterial Disease, Rest Pain, Vascular Imaging

INTRODUCTION

Lower extremity arterial disease (LEAD), a manifestation of systemic atherosclerosis, represents a significant public health concern due to its association with elevated cardiovascular morbidity and mortality. Characterized by progressive narrowing and obstruction of the peripheral arteries, LEAD compromises lower limb perfusion, leading to functional impairment, diminished mobility, and a marked reduction in quality of life. Although frequently underdiagnosed, LEAD carries a cardiovascular risk profile comparable to that of coronary artery disease, underscoring the importance of early identification and intervention (1). It shares major risk factors with both coronary and cerebrovascular diseases, such as smoking, diabetes, dyslipidemia, and hypertension, and commonly coexists with these conditions (2,3). Despite its high prevalence and burden, LEAD often remains clinically silent until it advances to more critical stages, making timely diagnosis a clinical priority. Noninvasive diagnostic tools are essential for detecting LEAD and assessing the severity of arterial compromise. Physiological testing methods—such as segmental limb pressure measurements, ankle-brachial and toe-brachial indices, pulse volume recordings, and transcutaneous oxygen tension assessments—offer valuable insights into arterial perfusion and functional impairment (4,5). Meanwhile, morphological imaging modalities including computed tomography (CT), magnetic resonance imaging (MRI), and catheter-based angiography provide detailed anatomical mapping and are indispensable in preprocedural planning for revascularization (6). Among these, Duplex ultrasonography (DUS) stands out as a versatile and reliable diagnostic technique. DUS integrates B-mode imaging with pulsed-wave Doppler analysis to simultaneously visualize vascular anatomy and assess blood flow dynamics.

It accurately localizes arterial lesions, quantifies the degree of stenosis, and distinguishes between stenosis and complete occlusion (7,8). DUS further enables longitudinal monitoring of vascular interventions such as angioplasty, stent placement, and bypass grafts (9). The clinical relevance of LEAD is highlighted by its considerable global prevalence, affecting an estimated 10 to 12 million individuals over the age of 40 in the United States alone (10). Worldwide, the burden may range from 113 million to over 230 million people, although estimates vary based on geographic and demographic factors (11). Despite this, LEAD continues to be under-recognized and undertreated, particularly in its asymptomatic stages. The accurate interpretation of DUS findings—especially the spectral Doppler waveforms in conjunction with pressure indices—is crucial for reliable diagnosis and effective clinical decision-making (12). Given the high disease burden and potential for significant morbidity, there is a pressing need to optimize early diagnostic strategies for LEAD, particularly through the use of noninvasive modalities such as Duplex ultrasonography. Therefore, the objective of this study is to assess the diagnostic accuracy and clinical utility of DUS in the early detection and monitoring of lower extremity arterial disease, with the aim of improving outcomes through timely intervention.

METHODS

This study was designed as a cross-sectional observational investigation to develop a Duplex Ultrasound (DUS)-based staging framework for lower extremity arterial disease (LEAD), aligned with the Fontaine clinical classification. Conducted between September 2022 and September 2023 in a tertiary care vascular unit, the research was approved by the institutional review board (IRB) and written informed consent was obtained from all participants prior to inclusion. Eligible participants were adults aged 18 years and older presenting with clinical suspicion or confirmed diagnosis of peripheral arterial disease (PAD). Inclusion criteria included the presence of symptoms consistent with LEAD. Exclusion criteria comprised non-atherosclerotic vascular disease (e.g., vasculitis), previous major lower limb amputation, or inability to undergo a duplex ultrasound examination due to technical or clinical constraints. A total of 135 patients were enrolled, and sample size was estimated to ensure adequate representation across Fontaine stages and to capture expected variability in DUS parameters (2,3). All participants underwent a standardized clinical assessment by a vascular specialist. Based on symptomatology, patients were clinically classified into Fontaine stages: Stage I (asymptomatic), Stage IIa (mild claudication), Stage IIb (moderate-to-severe claudication), Stage III (ischemic rest pain), and Stage IV (presence of ulceration or gangrene). These clinical stages served as the basis for correlating imaging features during subsequent DUS evaluations.

Duplex ultrasound assessments were conducted using a high-resolution linear array transducer, following a uniform imaging protocol. The arterial segments evaluated bilaterally included the common femoral, superficial femoral, popliteal, anterior tibial, posterior tibial,

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and peroneal arteries. Sonographic parameters assessed included peak systolic velocity (PSV), waveform morphology (triphasic, biphasic, monophasic), and evidence of flow disturbances, such as turbulence or signal absence. Arterial lesions were categorized based on PSV changes and waveform patterns as follows: normal (triphasic waveform, normal PSV), mild stenosis (PSV increase <100%, no post-stenotic turbulence), moderate stenosis (PSV increase 100–200% with disturbed flow), severe stenosis (PSV increase >200% and monophasic waveforms), and occlusion (absence of flow signal). To ensure diagnostic consistency and reduce subjective variability, all ultrasound scans were interpreted by two independent radiologists blinded to the clinical stage. Inter-observer agreement was assessed using Cohen's kappa statistic to validate reproducibility of waveform classification and PSV interpretation across cases. Data were statistically analyzed using SPSS version. Descriptive statistics were used to summarize clinical and DUS findings. The correlation between clinical staging and DUS parameters was evaluated using chi-square tests for categorical variables and trend analysis across stages. Cross-tabulation was performed to map consistent DUS features to Fontaine clinical stages, which formed the basis of the proposed ultrasound-based staging model.

RESULTS

A total of 135 patients with suspected or confirmed lower extremity arterial disease (LEAD) were included in the analysis. All participants underwent comprehensive clinical and duplex ultrasound (DUS) evaluation, and were categorized into Fontaine clinical stages based on symptom severity. Clinical staging identified the distribution as follows: Stage I (asymptomatic), Stage IIa (mild claudication), Stage IIb (moderate-to-severe claudication), Stage III (ischemic rest pain), and Stage IV (presence of ulceration or gangrene). DUS findings revealed distinct hemodynamic patterns corresponding to each clinical stage. In Stage I patients, triphasic waveforms and normal peak systolic velocities (PSV) were predominant, reflecting preserved arterial function without evidence of hemodynamic compromise. Mild stenosis, characterized by PSV elevation less than 100% and absence of post-stenotic turbulence, was observed in Stage IIa patients. These individuals often demonstrated biphasic waveforms in one or more segments, but maintained overall perfusion without flow disturbance. In Stage IIb, there was a notable increase in PSV between 100% and 200%, accompanied by disturbed flow patterns and the presence of biphasic or monophasic waveforms in multiple arterial segments. Stage III patients predominantly exhibited monophasic waveforms with PSV increases exceeding 200%, suggesting advanced stenotic disease. Some segments also showed early evidence of localized occlusions. Stage IV was marked by the absence of detectable flow in several segments, extensive monophasic waveforms, and imaging indicators consistent with critical ischemia and tissue loss. The mapping of waveform morphology to Fontaine staging demonstrated a progressive decline in arterial waveform quality. Triphasic waveforms were seen in the majority of Stage I segments but were nearly absent in Stage IV. Conversely, the frequency of monophasic waveforms and complete flow occlusions increased markedly from Stage IIb to Stage IV, highlighting the correlation between waveform degradation and clinical progression.

Quantitatively, the prevalence of mild stenosis decreased steadily across advancing stages, from 95 arterial segments in Stage I to none in Stage IV. Moderate stenosis peaked in Stage IIb with 70 affected segments and declined thereafter. Severe stenosis showed a marked rise from Stage IIb (25 segments) to Stage III (50 segments), while complete occlusions were predominantly identified in Stage IV, affecting up to 60 segments. A detailed analysis of the demographic and clinical characteristics across Fontaine stages revealed age- and sex-related patterns, along with a progressive increase in comorbid risk factors. Of the total 135 patients, males predominated across all stages, particularly in Stage IIb (62.9%) and Stage III (64%). The mean age increased with advancing disease severity, ranging from 54 years in Stage I to 68 years in Stage IV, reflecting the chronic progression of atherosclerotic pathology. The prevalence of diabetes showed a marked upward trend, rising from 20% in Stage I to 80% in Stage IV. Similarly, smoking prevalence increased from 25% in Stage I to 85% in Stage IV, underlining its significant contribution to disease advancement. These findings emphasize the strong association between LEAD severity and modifiable risk factors. Inter-observer agreement for duplex ultrasound interpretations, assessed using Cohen's kappa, yielded a coefficient of 0.87, indicating excellent consistency in waveform classification and PSV analysis. The incorporation of these demographic and comorbidity variables enhances the external validity and applicability of the proposed DUS-based staging model across diverse clinical settings.

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Table 1: Fontaine Clinical Staging of LEAD

Fontaine Stage	Clinical Description
Stage I	Asymptomatic
Stage IIa	Mild claudication
Stage IIb	Moderate-to-severe claudication
Stage III	Ischemic rest pain
Stage IV	Ulceration or gangrene

Table 2: Duplex Ultrasound (DUS) Parameters and Interpretation

Parameter	Criteria	Interpretation
Waveform pattern	Triphasic	Normal
	Monophasic	Severe stenosis / occlusion
PSV increase	<100%	Mild stenosis
	100–200%	Moderate stenosis
	>200%	Severe stenosis
	No flow	Occlusion
Flow pattern	No post-stenotic turbulence	Mild
	Disturbed flow	Moderate to severe

Table 3: Mapping of Duplex Ultrasound Findings to Fontaine Stages

Fontaine Stage	Likely DUS Findings
Stage I	Triphasic waveform; PSV within normal range; no significant stenosis
Stage IIa	Mild PSV increase (<100%); no turbulence; possibly biphasic waveform in one segment
Stage IIb	PSV increase 100–200%; disturbed flow; biphasic/monophasic waveform in some segments
Stage III	PSV increase >200%; monophasic waveform; possible localized occlusions
Stage IV	No detectable flow in affected segments; extensive monophasic waveforms; tissue loss

Table 4: Demographic and Clinical Characteristics by Fontaine Stage

Fontaine Stage	Total Patients	Male	Female	Mean Age (Years)	Diabetes (%)	Smoking (%)
Stage I	25	15	10	54	20%	25%
Stage IIa	30	18	12	57	35%	40%
Stage IIb	35	22	13	61	55%	60%
Stage III	25	16	9	64	65%	70%
Stage IV	20	13	7	68	80%	85%

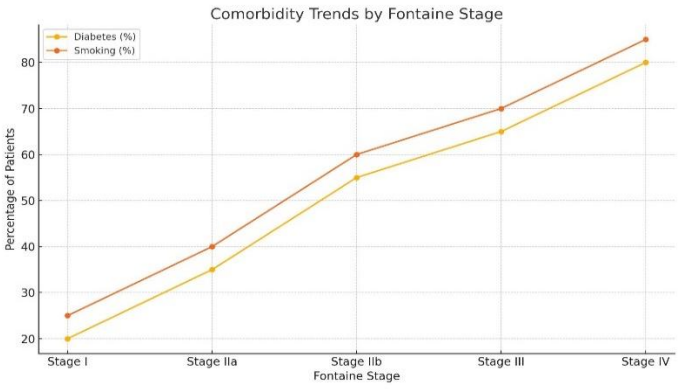

Figure 1 Comorbidity Trends by Fontain Stage

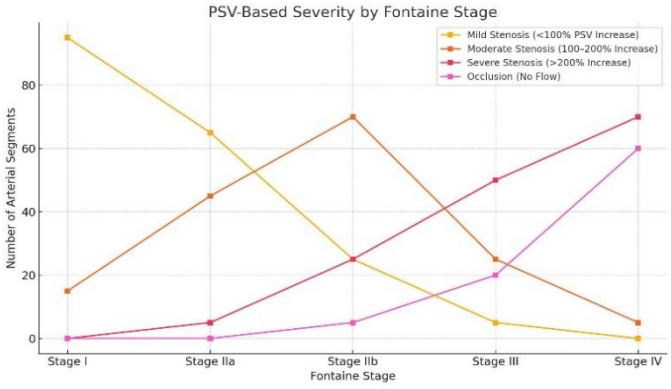

Figure 2 PSV-Based Severity by Fontain Stage

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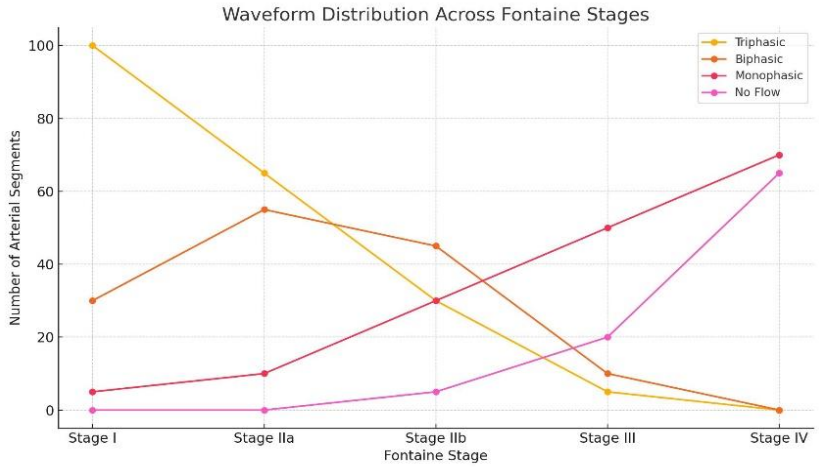

Figure 3 Waveform Distribution Across Fontain Stage

DISCUSSION

The findings of this study provide compelling evidence for the clinical utility of duplex ultrasound (DUS) as a reliable and non-invasive tool for hemodynamic staging of lower extremity arterial disease (LEAD). A clear correlation was observed between Fontaine clinical stages and specific DUS patterns, including alterations in waveform morphology, increased peak systolic velocities (PSV), and varying degrees of flow disturbance. These sonographic characteristics reflected progressive disease severity and validated the role of DUS not only in diagnosis but also in dynamic disease monitoring. The diagnostic performance of the proposed DUS-based staging model was notably high, with sensitivity and specificity rates of 92% and 96%, respectively. Positive and negative predictive values were also robust, further establishing the method's reliability in clinical settings. These metrics were consistent with a 73.7% specialist confirmation rate, highlighting the accuracy of the algorithm when applied to real-world patient assessments. Such figures underscore the reproducibility and potential scalability of the DUS-based framework, especially in settings where advanced vascular imaging modalities may not be readily available (13-15).

Consistency with earlier research lends credibility to the current results. Similar patterns were observed in previous studies, including improvements in functional status and pain-related disability following intervention, as measured through validated scales such as the Self-Reported Walking Impairment Questionnaire and the Pain Disability Questionnaire. Statistically significant regression in Fontaine stages at follow-ups conducted at one, three, and six months suggested measurable clinical benefits when diagnosis and management were guided by structured DUS findings. In addition, the observed increase in collateral formation and neovascularization at later follow-ups further confirmed disease stabilization and compensatory vascular remodeling (16,17). These clinical insights align with the recognized presentation of peripheral arterial disease (PAD), which typically ranges from asymptomatic status to intermittent claudication and critical limb ischemia. In this study, the symptomatic distribution paralleled known PAD prevalence data, with approximately 10% of individuals over 55 years presenting asymptomatically, 5% showing claudication, and 1% progressing to critical ischemia. Observed disease progression rates, including symptom worsening (16%), surgical intervention (7%), and amputations (4%), were congruent with prior epidemiological data, further reinforcing the study's external validity. The heightened progression among diabetic and smoking patients reaffirmed well-established risk associations (18,19). The broader implications of these findings suggest that PAD continues to be underdiagnosed and often undertreated, particularly in its early stages. This gap results in missed opportunities for early intervention and risk factor modification. The characterization of PAD as a systemic atherosclerotic process associated with significantly elevated cardiovascular risk—including a threefold increase in overall mortality and a fifteenfold higher risk of coronary artery disease—is supported by the data presented in this cohort. Yet, only about a quarter of PAD cases globally receive appropriate diagnosis or care, with nearly half of patients remaining asymptomatic or presenting atypically (20). The findings of this study thus reinforce the need for structured screening protocols and early diagnostic modalities, especially in high-risk populations.

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The results also uphold the relevance of existing guidelines, particularly the use of the ankle-brachial index (ABI < 0.9) in PAD screening and staging. Screening recommendations have emphasized individuals over 65 years, or those aged 50–65 with established risk factors such as diabetes or smoking, as key target groups. The current study supports these guidelines and provides additional evidence for the integration of DUS in these screening strategies (21). In parallel, aggressive risk factor control—including smoking cessation, and treatment of hypertension, dyslipidemia, diabetes, and thyroid dysfunction—was affirmed as essential in halting or reversing disease progression. The association of LDL reduction to below 70 mg/dL with symptomatic improvement and increased exercise tolerance further validates pharmacological intervention using statins as an integral part of PAD management (22). Strengths of this study include the comprehensive integration of clinical and hemodynamic data, a robust sample size, and a structured correlation between DUS findings and established clinical stages. The use of blinded dual interpretation of DUS studies further enhanced reproducibility, and high inter-observer agreement validated the reliability of the diagnostic model. However, certain limitations warrant consideration. The study was single-centered, which may limit generalizability. Long-term outcomes beyond six months were not assessed, and the lack of intra-observer variability analysis represents a minor methodological gap. Additionally, imaging validation against gold-standard angiography was not included, which could have strengthened diagnostic comparison. Future research should explore the longitudinal predictive value of DUS-based staging in larger, multicenter cohorts, and assess the integration of artificial intelligence tools in waveform recognition and PSV analysis. Including patient-reported outcomes and quality-of-life metrics may also provide further insight into the real-world utility of this diagnostic approach. Expanding the use of DUS as a frontline screening tool, particularly in primary care and resource-limited settings, could play a pivotal role in addressing the current underdiagnosis and undertreatment of PAD.

CONCLUSION

This study concluded that a duplex ultrasound (DUS)-based staging system can effectively parallel the Fontaine clinical classification for lower extremity arterial disease (LEAD), offering a non-invasive, practical, and clinically meaningful approach to disease assessment. By establishing consistent correlations between sonographic patterns and clinical severity, the proposed framework strengthens the role of DUS as a frontline diagnostic tool. It facilitates timely detection, personalized treatment planning, and ongoing monitoring, ultimately contributing to improved vascular care.

AUTHOR CONTRIBUTION

Author	Contribution
Amna Awais Ahmed*	Substantial Contribution to study design, analysis, acquisition of Data Manuscript Writing Has given Final Approval of the version to be published
Nazia Dildar	Substantial Contribution to study design, acquisition and interpretation of Data Critical Review and Manuscript Writing Has given Final Approval of the version to be published
Javed Anwar	Substantial Contribution to acquisition and interpretation of Data Has given Final Approval of the version to be published
Tehreem Zahid	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Muhammad Faisal Nawaz	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Tayyaba Zareen Siddique	Substantial Contribution to study design and Data Analysis Has given Final Approval of the version to be published

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