Accuracy of Duplex Ultrasonography in Estimation of Severity of Peripheral Vascular Disease

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Abstract

Duplex ultrasonography (DUS) is a safe, noninvasive method for imaging vasculature when compared with conventional angiography. Our goal is to assess the accuracy of DUS compared with angiography of the lower extremities. We reviewed a total of 373 lesions in 278 patients from July 2005 through June 2010. Patients underwent DUS followed by angiography within 30 days. Peak systolic velocities (PSV) were stratified into one of four categories and compared with the angiographic findings. Seventy-five chronic total occlusions were found. Of the remaining 298 lesions, a significant relationship was found between PSV and degree of angiographic stenosis ($p < 0.001$). DUS was found to demonstrate a sensitivity of 79.7%, specificity of 79.2%, positive predictive value of 88.2%, and negative predictive value of 66.7% for lesions $\geq 70\%$. The 66.7% of the false-negative lesions with the lowest velocities were below the knee joint. DUS of the lower extremities is accurate in determining the degree of stenosis ranging from mild-to-severe disease. Some limitation may exist in estimating the degree of stenosis below the knee.

Keywords

- duplex ultrasonography
- contrast angiography
- peripheral arterial disease

Peripheral arterial disease (PAD) of the lower limb is a spectrum atherosclerotic disease, ranging from mild plaque formation to chronic total vessel occlusion. Patients may remain asymptomatic in mild forms of the disease, but can develop intermittent claudication, rest pain, or tissue loss, including ulceration and gangrene, as the disease progresses.¹

Duplex ultrasonography (DUS) is a primary screening tool used to evaluate arterial disease in carotid arteries, renal arteries, and peripheral arteries.^{2–8} It is also used as a surveillance tool in postintervention patients to monitor re-stenosis or to detect disease development in another location.^{9–17} DUS is an optimal modality for these applications, as it is noninvasive and safe, with relatively no morbidity. Although DUS has been widely studied in the detection of carotid artery stenosis and has been shown to have a high degree of sensitivity and specificity, to date, no validated criteria have been established for defining the severity of peripheral arterial stenosis in the lower limb.

Conventional contrast angiography is considered the standard diagnostic modality for PAD of the lower limb. An

increasing number of therapeutic procedures involve the use of angiographic guidance. Contrast angiography is associated with risks, primarily related to radiation exposure, arterial puncture, and contrast nephropathy.^{18–21} DUS is useful to evaluate hemodynamically significant lesions and is also an attractive alternative for the treatment planning of PAD of the lower limb, provided that accuracy is demonstrated. DUS can be used as a guide to determine if percutaneous intervention is necessary, which is a valuable addition to the vascular surgeon's armamentarium.

Materials and Methods

Patient Selection

A retrospective review with institutional review board approval was conducted involving patients who were 18 years of age or older presenting to our institution between July 1, 2005, and June 30, 2010. Patients who underwent DUS (Philips HDI 5000 or Philips iU22, Philips Healthcare, Andover, MA; or ATL HDI 5000, Advanced Technology

Laboratories, Bothell, WA) and subsequent conventional angiography (Philips Healthcare or Siemens Medical Solutions, Malvern, PA) within 30 days of the DUS were included in the study. A maximum period of 30 days was selected to minimize possible disease progression between DUS and conventional angiography studies. Exclusion criteria included patients with greater than 30 days between DUS and conventional angiography, patients with technically inadequate DUS examinations, and patients for whom degree of stenosis could not be adequately determined at the time of conventional angiography.

Demographic and comorbid factors were recorded including age, gender, race, tobacco use, hypertension, diabetes mellitus, hyperlipidemia, and coronary artery disease. Hypertension, diabetes, and hyperlipidemia were considered present if the patient was being treated for these conditions at the time of evaluation. Additionally, coronary artery disease was considered present if the patient had previously undergone percutaneous coronary intervention or coronary artery bypass grafting.

DUS evaluations of patients were initially reviewed, followed by angiographic operative dictations and images. If patients were found to have multiple levels of disease, the most proximal stenotic segment was selected for the study as it was assumed that blood flow would be least altered at this segment. Peak systolic velocities (PSV) were recorded as falling into one of the following four ranges: absent flow, < 180 cm/s, 180 to 249 cm/s, or 250 cm/s or greater. Percent stenosis was calculated using North American Symptomatic Carotid Endarterectomy Trial (NASCET) criteria and recorded in four ranges: completely occluded, 0 to 39.9%, 40 to 69.9%, or 70 to 99.9%.² DUS and angiograms were considered to be in agreement if PSV and stenosis ranges correlated (absent flow and complete occlusion, < 180 cm/s and 0 to 39.9%, 180 to 249 cm/s and 40 to 69.9%, $\geq$ 250 cm/s and $\geq$ 70 to 99.9%). Additionally, the identified area of stenosis was classified based on the type of prior intervention at the same level into one of the following three categories: none, previous endovascular intervention, or previous bypass graft.

Duplex Ultrasonography

DUS examinations were performed in an Intersocietal Commission for Accreditation of Vascular Laboratories (ICAVL) accredited vascular laboratory by a registered vascular technologist (RVT) using ATL HDI 5000 (Advanced Technology Laboratories), Philips HDI 5000, or Philips iU22 (Philips Healthcare) scanners. Linear array transducers were utilized with an operating frequency ranging between 7 to 4 MHz and 9 to 3 MHz. Standardized imaging protocols were used including obtaining the signal within the center of the laminar flow, viewing parallel to the vessel wall, and maintaining the Doppler angle at 60 degrees or less. In most cases, 18 segments (iliac, common femoral, profunda femoris; proximal, mid, distal, superficial femoral; popliteal, anterior tibial, posterior tibial, and peroneal arteries) of the native lower extremity vasculature were imaged in each lower extremity. Exceptions did occur in cases of previous ampu-

tation, if there was edema or hematoma overlying the vessel, or if the exam was technically limited due to body habitus of the patient. Additionally, if a bypass graft or grafts were present, these were imaged as well. PSV and waveforms were recorded at the imaged segments. Patients with significant aortoiliac disease were excluded. Examinations were interpreted by certified (RVT or RPVI [registered physician in vascular interpretation]) vascular surgeons.

Lower Extremity Angiography

Arteriography was performed using a digital subtraction angiographic unit (Philips Healthcare or Siemens Medical Solutions) by vascular surgeons. Images were routinely obtained in an anteroposterior (AP) fashion except in cases where physical limitations of the patient (such as patient discomfort and limb contractures) prevented direct AP imaging. Additional images were obtained on oblique axis as needed to further define the arterial anatomy or to better delineate a stenotic lesion. Degree of stenosis was calculated by applying NASCET criteria to the identified lesion.²

Statistical Analysis

Data were collected using Microsoft Excel (MS Office 2003). Sensitivity, specificity, positive predictive value, and negative predictive value were all calculated as well as mean age and standard deviation. Pearson's chi-square test was used to cross-tabulate the flow velocity with the degree of stenosis. Statistical level of significance was assumed at $p < 0.05$. We hypothesized that DUS velocity highly correlates with the degree of stenosis documented by angiography. The degree of correlation between DUS and conventional angiography was evaluated.

Table 1 Population characteristics

Gender, <i>n</i> (%)	
Male	201 (53.9)
Female	172 (46.1)
Ethnicity, <i>n</i> (%)	
Caucasian	206 (55.2)
African American	167 (44.8)
Age (y), mean $\pm$ SD	66.9 $\pm$ 11.97
Range	21–93
Tobacco use, <i>n</i> (%)	282 (75.6)
Diabetes, <i>n</i> (%)	234 (62.7)
Hypertension, <i>n</i> (%)	334 (89.5)
Hyperlipidemia, <i>n</i> (%)	256 (68.6)
Coronary artery disease, <i>n</i> (%)	173 (46.4)
Previous vascular procedure, <i>n</i> (%)	
None	162 (43.4)
Endovascular	140 (37.5)
Surgical bypass	71 (19.0)

Abbreviation: SD, standard deviation.

Table 2 DUS and angiogram results

DUS PSV, <i>n</i> (%)	
> 250 cm/s	178 (47.7)
180–249 cm/s	44 (11.8)
< 180 cm/s	76 (20.4)
Absent	75 (20.1)
Angiographic stenosis, <i>n</i> (%)	
70–99.9%	197 (52.8)
40–69.9%	67 (18.0)
0–39.9%	34 (9.1)
Complete occlusion	75 (20.1)

Abbreviations: DUS, duplex ultrasonography; PSV, peak systolic velocities.

Results

A total of 278 patients with 373 lesions, who had undergone DUS and arteriography within a 30-day time period during the study time frame, were eligible for study inclusion. Patient's demographic data and comorbid conditions are presented in ►Table 1. PSV recordings from DUS and calculated angiographic stenosis data are shown in ►Table 2.

Overall, there was an agreement between DUS and the angiographic findings for 284 (76.1%) of the 373 lesions. There were 75 cases where flow was absent on DUS, which was then subsequently confirmed with angiography to have chronic total occlusions. These 75 patients were excluded before performing statistical analyses, leaving a total of 298 lesions. DUS flow velocities and angiographic stenosis were then compared on the remaining 298 lesions (►Table 3).

Results between DUS velocities and the angiographic stenosis correlated in 211 (70.8%) lesions. A significant relationship did exist between the PSV of studied lesions and the degree of stenosis seen at angiography ($p < 0.001$).

There was a particular interest in lesions greater than 70%, as these generally require some form of intervention. Sensitivity, specificity, positive predictive value, and negative predictive value were then calculated in reference to that particular threshold. DUS for lesions greater than 70% demonstrated a sensitivity of 79.7%, specificity of 79.2%, positive predictive value of 88.2%, and negative predictive value of 66.7%.

Table 3 Correlation between DUS and angiographic stenosis

	Angiographic stenosis			Total
	≥ 70%	40–69%	1–39%	
PSV				
≥ 250 cm/s	157	12	9	178
180–249 cm/s	13	30	1	44
< 180 cm/s	27	25	24	76
Total	197	67	34	298

Abbreviations: DUS, duplex ultrasonography; PSV, peak systolic velocities.

In addition, the 27 false negative, highly stenotic lesions with PSV < 180 cm/s were reviewed more extensively. Of these 27 lesions, the location of 18 (66.7%) was below the level of the knee. This may indicate that DUS is less accurate for identifying lesions > 70% below the level of the knee. If so, then additional imaging would still be required to better define stenoses below the knee.

Discussion

DUS is a noninvasive and safe imaging technique. It is widely available and can be performed with virtually no morbidity when compared with conventional angiography. Though angiography can be both diagnostic and therapeutic, there are well-documented risks associated with its use. It is not uncommon for patients to have both a diagnostic procedure followed by a secondary procedure at which a therapeutic intervention may be performed.

Other types of imaging have been studied including computed tomography angiography (CTA) as well as magnetic resonance angiography (MRA). These studies have also been shown to be sensitive and specific in detection of PAD while being less invasive than standard angiography.^{3,14} However, these diagnostic modalities have risks of contrast-induced nephropathy, additional contrast load, systemic sclerosis, and patient limitations (e.g., pacemakers). Additionally, they are more expensive when compared with DUS and angiography may still be required for an intervention once completed.¹²

Our study demonstrated that DUS is accurate in determining the degree of stenosis present in lower extremity PAD. There was a high percentage of low velocity, false-negative lesions that were below the level of the knee and this does raise concern that DUS may have some limitations in its accuracy at this level. This could be further evaluated by examining the accuracy related to specific named vessels and severity of stenosis.

As this was a retrospective review, our data could be further validated by performing a prospective, blinded study. Waveforms were not utilized as an endpoint and may have been helpful in the evaluation of false-positive findings.

As angiography is a one-dimensional image and ultrasonography is physiologic, a false-positive study could have been better delineated by three-dimensional CTA to evaluate anatomy.

Summary

DUS is an accurate modality in determining the degree of stenosis in the lower extremity vasculature based on PSV measurements. In our study population, arterial lesions ranged from mild to severe. Utilizing DUS as an initial imaging modality over CTA or MRA is more cost effective and additionally would limit morbidity related to these techniques. DUS results can be used to determine whether an endovascular intervention is necessary for further evaluation and to guide treatment. However, DUS may be limited in imaging the vasculature below the knee.

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