Value of the duplex waveform at the common femoral artery for diagnosing obstructive aortoiliac disease

Sandra Spronk, MSc,[a] Pieter T. den Hoed, MD, PhD,[b] Leenoud C. W. de Jonge, MD,[c] Lukas C. van Dijk, MD, PhD,[d] and **Peter M. T. Pattynama, MD, PhD,[d]** *Rotterdam, Netherlands*

Purpose: **To evaluate the accuracy, predictive value, and observer agreement of the duplex ultrasound waveform at the common femoral artery as a marker of significant aortoiliac disease in a large group of consecutive patients who underwent a diagnostic workup for peripheral arterial disease in a vascular unit.**

Methods: **In 191 consecutive patients (381 aortoiliac segments), we classified the duplex ultrasound waveform at the common femoral artery as triphasic, biphasic, sharp monophasic, or poor monophasic. The waveforms were then compared with the findings of magnetic resonance angiography of the aortoiliac segment and peripheral runoff vessels. We calculated the diagnostic accuracy of the duplex waveform for detecting >50% obstructive disease of the aortoiliac segment and determined the observer agreement for classifying the duplex waveforms done by two independent observers.**

Results: **Magnetic resonance angiography showed obstruction in 152 (39.9%) of 381 aortoiliac segments in 191 patients. The presence of a poor monophasic waveform, encountered in 91 (24.3%) of 375 segments, was a reliable sign of significant aortoiliac disease, with a positive predictive value of 92%. Other waveforms were nondiagnostic for aortoiliac obstructive disease. The sharp monophasic waveform reliably predicted occlusive disease of the superficial femoral artery that was seen in 17 of 23 instances. There was good observer agreement for classifying duplex waveforms (κ_w= 0.85; 95% confidence interval, 0.80 to 0.89).**

Conclusion: **The poor monophasic duplex waveform at the common femoral artery is in itself an accurate marker of aortoiliac obstructive disease. Other waveforms are nondiagnostic for aortoiliac disease. (J Vasc Surg 2005;42:236-42.)**

Various noninvasive imaging modalities are in current use for the diagnostic workup of patients suspected of having peripheral arterial disease. These studies include magnetic resonance angiography (MRA), computed tomography angiography (CTA), and duplex ultrasound (DUS) scans. Although MRA and CTA are increasingly used for noninvasive vascular imaging, DUS has proved to be cost-effective and accurate for the detection of significant vascular stenoses and is therefore often used as the first diagnostic modality.[1-4] Problems may arise, however, when evaluating the aortoiliac arteries that cannot be visualized in their entirety in the 5% to 25% of patients who are extremely obese, have abundant intestinal gas, or who have particularly tortuous or calcified iliac arteries.[5,6]

It would be attractive if one could rapidly evaluate the aortoiliac arteries for the presence of significant obstructive disease without having to visualize these arteries along their entire length. This would reduce the number of indeterminate results of DUS scans, reduce the examination time for a complete DUS examination, and might also reduce the existing moderate observer variability (κ = 0.43 to 0.53) when the aortoiliac segment is evaluated.[7]

Potentially, such a rapid evaluation of the aortoiliac arteries might be provided by assessing the duplex waveform as measured distally at the level of the common femoral arteries (CFAs).[8-11] It is known that the waveform distal to a significant obstruction often changes in character, for example, from a normal triphasic waveform proximal to a stenosis to a monophasic waveform distal to the stenosis. However, only few data in the literature have addressed the question of how accurate a marker of the femoral artery DUS waveform is to show or exclude significant aorto-iliac obstruction .

The aim of the present study was, therefore, to evaluate the accuracy, predictive value, and observer agreement of the DUS waveform at the CFA as a marker of significant aortoiliac disease in a large group of consecutive patients who had a diagnostic workup for peripheral arterial disease in a vascular unit.

METHODS

Study design and patients. From October 2001 until March 2004, 250 consecutive patients who had an ankle-brachial index (ABI) <0.9 at rest or a decrease in ABI of >30% after exercise were referred to the noninvasive vascular laboratory of a large community hospital by our vascular surgeons for screening of peripheral arterial disease. Of these, 234 patients had both a full DUS examination and MRA of the aortoiliac segment and peripheral runoff and

From the Ikazia Hospital, Vascular Laboratory,[a] Ikazia Hospital, Department of Surgery,[b] Ikazia Hospital, Department of Radiology,[c] Erasmus Medical Center, Department of Radiology.[d]

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Correspondence: Sandra Spronk, Ikazia Hospital, Vascular Laboratory, Montessoriweg 1, Rotterdam 3083 AN Netherlands (e-mail:sandraspronk@planet.nl).

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Table I. Patient characteristics and severity of ischemic disease

Characteristic	*N = 191 (%)*
Age (yrs)	67 ± 12 (34-96)*
Male sex	106 (55.5)
Hyperlipidemia	38 (19.9)
Cardiac disease	15 (7.9)
Smoking	110 (57.6)
Hypertension	46 (24.2)
Diabetes mellitus	51 (26.7)
ABI at rest*	0.70 ± 0.22
ABI postexercise*	0.55 ± 0.36
Fontaine classification:	
I: asymptomatic	0 (0)
II: claudication	111 (58.1)
III: Ischemic rest pain	77 (40.3)
IV: Tissue loss	3 (1.6)

ABI, Ankle-brachial index.
Data are numbers of patients and percentages in parentheses.
*Mean age ± SD, range in parentheses.

formed the population of the current study. For the purpose of another, unrelated clinical trial in our institution, these patients were to undergo both examinations irrespective of the DUS or MRA results. The study we refer to is a therapeutic trial comparing exercise training with percutaneous transluminal angioplasty. Patients gave written informed consent to be part of this study and for their study data to be reported in the literature for the purpose of scientific articles.

MRA has been validated with angiography in our institution in an earlier stage. This resulted in acceptable disagreement (<10%) between the two methods, and therefore, we decided to use the MRA as the reference standard. Our results were in agreement with existing data in the literature on MRA accuracy. In a meta-analysis of the literature published in 2000, the pooled sensitivity of the MRA was 97.5%, and the pooled specificity was 96.2% relative to digital subtraction angiography.[4]

We did not perform MRA in 16 patients because of recognized contraindications such as the presence of a pacemaker or claustrophobia. In all patients, DUS examinations and MRA were performed within a 4-week period.

Of the 234 eligible patients, 43 were excluded from analysis because the hard-copy prints of the DUS scan (n = 16) or of MRA (n = 13) were not available or because the MRA was classified as nondiagnostic due to imaging artifacts of metallic vascular stents (n= 14). Therefore, in this retrospective analysis, we compared the results of DUS waveforms obtained at the CFAs of 191 patients (381 limbs), with the results of full aortoiliac MRA as the gold standard. There were 106 men (55.5%). The mean patient age was 67 ± 12 years (range, 34 to 96). The severity of ischemic disease according to the Fontaine classification, the vascular risk factors, and relevant comorbidity of the patients are summarized in Table I.

Duplex ultrasound scans. Color duplex examinations were performed at the CFA with a 5-MHz transducer (Aloka SSD-2000, Aloka, Tokyo, Japan) by one of three registered vascular technologists according to a standardized routine examination protocol in our institution.

Duplex waveforms were obtained 10 to 20 mm proximal to the femoral bifurcation at the location where color change suggested the highest velocity. Care was taken to obtain DUS measurements at <60° Doppler insonation angles. The patients made one visit to the vascular laboratory in which the duplex waveform of the CFA was recorded on a video print and archived in the patients' records.

For the purpose of this study, the video prints of the DUS waveforms were retrieved, anonymized, and presented to two independent vascular technologists (K.G., W.D.) who were blinded to the patient's identity, clinical findings, and the results of the MRA. The left and right CFA waveforms in a given patient were treated as two separate examinations. The duplex waveform was classified into one of four categories:[12]

1. Triphasic: three waveform "phases" consisting of a sharp systolic forward up rise and fall, an element of reverse flow during diastole, and an element of forward flow during diastole (Fig 1).
2. Biphasic: two waveform "phases" consisting of a sharp systolic forward up rise and fall and an element of reverse flow during diastole (Fig 2).
3. Sharp monophasic: one waveform "phase" with a sharp systolic rise, the lack of a reverse diastolic element, and a fast diastolic fall, expected in arterial segments proximal to an obstruction (Fig 3).
4. Poor (blunted) monophasic: the loss of "sharpness" in systole, the lack of a reverse diastolic element, and a slow diastolic fall expected in arterial segments distal to an obstruction (Fig 4).

Magnetic resonance angiograms. MRAs were obtained on a 1.5T MR system unit and by using dedicated MR hardware for peripheral MRA (Gyroscan Intera 1.5 TN; MobiTrak; Philips Medical Systems, Best, The Netherlands). A T1 weighted three-dimensional gadolinium-enhanced gradient echo sequence was employed with transverse time-of-flight scout views and by using the system's array body coil. Parameters were repetition time, 5.9 milliseconds; echo time, 1.62 milliseconds; flip angle, 35°; and slice thickness, 1.5 mm. Acquisition times were between 1.31 minutes and 2.37 minutes. MRAs of the aortoiliac segment and the lower limbs were obtained in 26 seconds with a 75% rectangular field of view of 450 × 315 mm and a matrix of 512 × 512. This resulted in a voxel size of 0.80 × 3.05 × 1.5 mm^3 before interpolation. The calculated voxel size after interpolation was 0.80 × 1.5 × 1.5 mm^3.

Forty milliliters of gadolinium diethylenetriaminepentaacetic (DTPA) acid contrast material were infused at a rate of 2 milliliters/second using a power injector. Maximum intensity projections in multiple projections and source images were stored on hard copy. For analysis, the hard-copy films were retrieved and independently read by

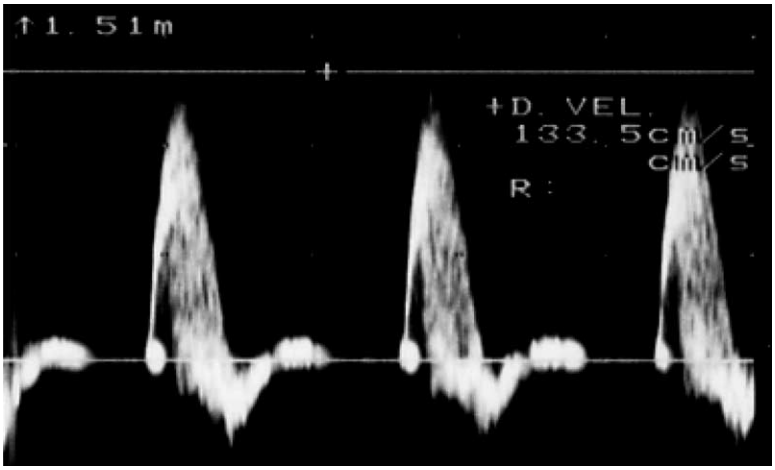

Fig 1. Triphasic: three waveform "phases" consist of a sharp systolic forward up rise and fall, an element of reverse flow during diastole, and an element of forward flow during diastole.

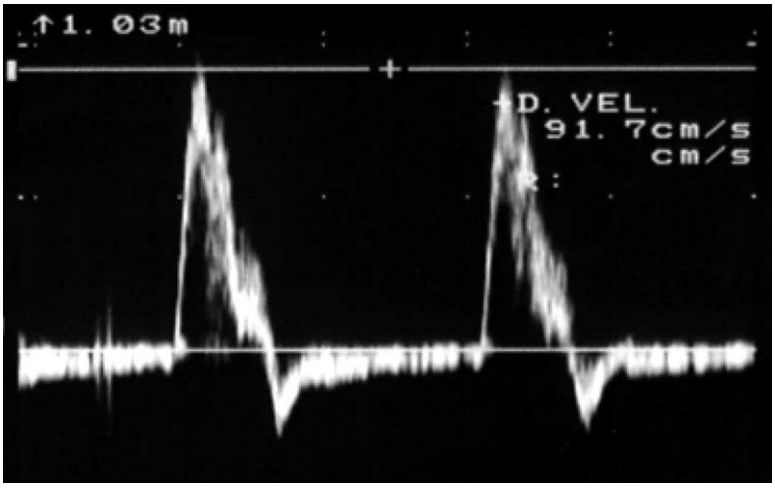

Fig 2. Biphasic: two waveform "phases" consist of a sharp systolic forward up rise and fall, and an element of reverse flow during diastole.

two experienced radiologists who were blinded to the results of the DUS examinations and to the clinical information (P.M.T.P., L.C.W.J).

The arterial tree was divided in the following segments for analysis: the aortoiliac segments, consisting of the distal aorta, the common iliac artery, and the external iliac artery; and the more distal segments, consisting of the CFA, the superficial femoral artery (SFA), and the popliteal artery. The segments were scored as either normal or as obstructed whenever a >50% diameter stenosis was present. The most severe stenosis in each segment was chosen for classification. Each limb consisted of the aortoiliac segments and the more distal segments.

Any resulting disagreements between the two readers were resolved by a third independent reader (L.v.D, an experienced radiologist) who was blinded to the results of the DUS scan, clinical information, and the specific readings of the two other radiologists. The final MR results were taken as the gold standard in the evaluation of this study.

Statistical analysis. Two-way contingency tables were made comparing the duplex waveform at the CFA versus the presence of significant obstructive disease in the corresponding aortoiliac segment on MRA. The accuracy, sensitivity, specificity, and positive predictive value as well as the negative predictive value of the duplex waveform for detecting >50% obstructive disease of the aortoiliac segment was calculated separately for the two DUS scan readers.

The analysis was done three times. In the first analysis, all triphasic and sharp monophasic waveforms (expected in arterial segments proximal to an obstruction) were grouped together as "normal," and all biphasic and poor monophasic waveforms were regarded as "abnormal." In the second

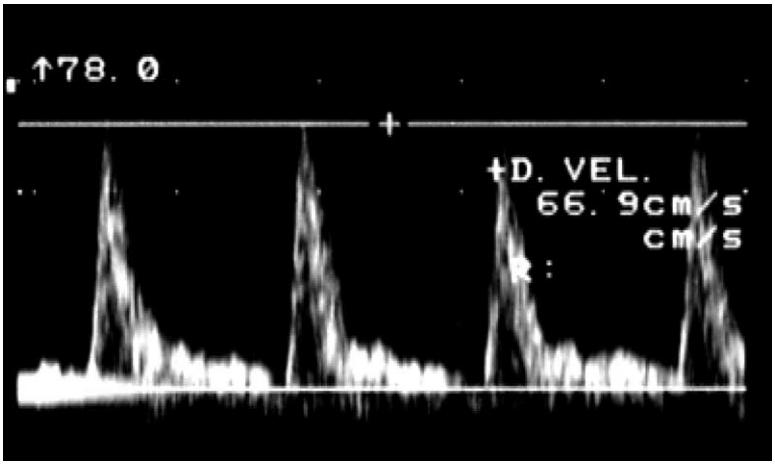

Fig 3. Sharp monophasic consists of a sharp systolic rise, the lack of a reverse diastolic element, and a fast diastolic fall.

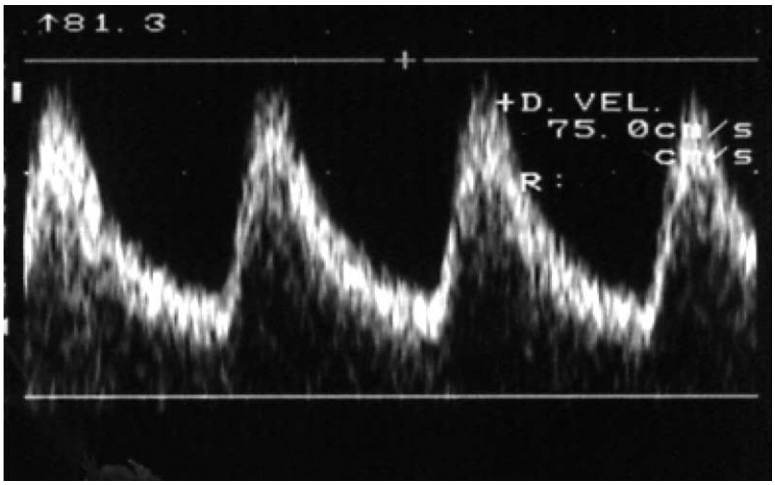

Fig 4. Poor (blunted) monophasic waveform shows the loss of "sharpness" in systole, the lack of a reverse diastolic element, and a slow diastolic fall.

analysis, triphasic, biphasic, and sharp monophasic waveforms were regarded as normal. Finally, the duplex waveforms were grouped as in the second analysis but this time for comparing the presence of aortoiliac stenotic disease versus the presence of total occlusive disease in the corresponding aortoiliac segment on MRA. Separate analyses were performed to adjust for the potential confounding effects of downstream disease[13-15] and also for the effect of disease severity (claudication vs critical ischemia).

The weighted kappa statistic (κ_w) was used to test for observer agreement for assessing the duplex waveform. If duplex waveform prints were classified as nondiagnostic by one of the two DUS readers, the classified duplex waveform was used for the analyses. Calculations were performed with the Statistical Package for the Social Sciences (SPSS) software release 11.0.1 (SPSS, Chicago, Ill) for Windows (Microsoft, Bellingham, Wash) and the Statistical Analysis System (SAS) 8.2 software (SAS Institute Inc., Cary, NC) for Windows (Microsoft).

RESULTS

The MRAs showed that 152 (39.9%) of 381 aortoiliac segments in 191 patients had obstruction, in particular, >50% stenosis in 125 and occlusion in 27 segments, three of which were aortic occlusions. Downstream disease due to significant SFA obstruction was present in 221 (58%) of 381 SFA segments (ie, >50% stenosis in 141 and occlusion in 80 segments), whereas significant popliteal artery obstruction was present in 74 (19.4%) of 381 limbs (ie, >50% stenosis in 50 and occlusion in 24 segments). Disagreements between the two MRA readers were found in the aorta (4%), iliac segment (14%), SFA segment (9%), and popliteal segment (8%) and were resolved by the third independent reader.

Table II. Duplex waveforms at the common femoral artery versus the presence of significant aortoiliac obstruction

CFA duplex waveform	*No aortoiliac obstruction*	*Aortoiliac obstruction present**	*Total*
Triphasic	156	51	207
Biphasic	42	12	54
Sharp monophasic	19	4	23
Poor monophasic	7	84	91
Nondiagnostic	5	1	6
Total	229	152	381

CFA, Common femoral artery.
*Defined as >50% diameter stenosis or occlusion as seen on contrast-enhanced magnetic resonance angiography.

Table III. Duplex waveforms at the common femoral artery versus the presence of significant aortoiliac obstruction*

CFA duplex waveform	*No aortoiliac obstruction*	*Aortoiliac obstruction present†*	*Total*
Triphasic, biphasic, and sharp monophasic grouped together.	217	67	284
Poor monophasic	7	84	91
Total	224	151	375
	(%)	*95% confidence interval*	
		Lower	*Upper*
Sensitivity	56	48	63
Specificity	97	94	98
Positive predictive value	92	85	96
Negative predictive value	76	71	81
Accuracy	80	76	84

CFA, Common femoral artery.
*Analysis 2 (see text). The poor monophasic duplex waveform classified as "abnormal", all other waveforms grouped together as "normal".
†Defined as >50% diameter stenosis or occlusion as seen on contrast-enhanced magnetic resonance angiography.

Duplex ultrasound scans. A total of 6 (1.6%) of 381 duplex waveforms prints were classified as nondiagnostic by both DUS readers and were excluded from analysis. The interobserver agreement for assessing the duplex waveform characteristics at the CFA of the remaining 375 limbs was very high (κ_w= 0.85; 95% CI, 0.80 to 0.89). A total of 28 (7.3%) duplex waveform prints were classified nondiagnostic by one of the two DUS readers due to CFA occlusive disease, aortobifemoral bypass graft, femoral artery patch, or because of artifacts on the prints.

The interobserver agreement for assessing the monophasic waveform was also very high (κ = 0.92; 95% CI, 0.88 to 0.97), whereas by differentiating between the sharp monophasic waveform and the poor monophasic waveform, the interobserver agreement was still high (κ = 0.80; 95% CI, 0.68 to 0.92).

Analysis. The results of the four duplex waveform categories compared with the MRA findings are summarized in Table II for DUS reader 1. The values for reader 2 were similar, attesting to the very high interobserver agreement, and are not separately shown. It can be immediately seen from Table II that the presence of a "normal" triphasic duplex waveform at the CFA did not exclude significant obstructive aortoiliac disease, which was present in 51 (24.6%) of 207 segments. By contrast, a poor monophasic waveform was closely correlated with aortoiliac disease, with high positive predictive value of 92% (84 of 91 aortoiliac segments).

Thus the most useful analysis was to group triphasic, biphasic, and sharp monophasic waveforms together as "normal" and the poor monophasic waveform as "abnormal." This classification had high specificity (97%) and positive predictive value (92%), but low sensitivity (56%) and negative predictive value (80%) (Table III). Thus, only the poor monophasic waveform had diagnostic importance, and whenever it was encountered, it reliably identified aortoiliac disease.

More specific diagnosis of stenotic versus occlusive aortoiliac disease proved not feasible by using the duplex waveform. The poor monophasic waveform was associated with occlusive disease in 31 and with stenotic obstruction in 53. It is of note that triphasic and biphasic waveforms were seen in 3 of 34 and 0 of 34 aortoiliac occlusions, respectively.

As an additional finding, it was of interest that the sharp monophasic duplex waveform at the CFA was associated with occlusion of the superficial femoral artery (11 total occlusions and 6 segmental occlusions) in 17 (73.9%) of 23 instances.

Once the waveforms were grouped as in the second analysis (only the poor monophasic waveform grouped as abnormal), further subanalysis showed differences between 74% and 50% sensitivity and between 65% and 88% specificity. Although the differences are fairly large, we could not demonstrate a significant difference, probably because of the small number of patients in the subgroup. In addition, no significant difference could be demonstrated in predicting aortoiliac disease between patients with claudication versus those with critical ischemia (sensitivity, 57% vs 56% and specificity, 87% vs 86%)

DISCUSSION

Duplex imaging of the CFA is an easily performed test with high observer agreement for classification of the duplex waveform. The current study shows that such classification has diagnostic value in those patients in whom a poor monophasic waveform is present. In our study, we saw this waveform in approximately one quarter of patients. The presence of the poor monophasic waveform accurately identifies obstructive disease in the proximal aortoiliac vessel segments with positive predictive value of 92%. The other duplex waveforms have no diagnostic value for predicting the status of the proximal

vessels: even a "normal" triphasic waveform is seen in almost a quarter of patients with aortoiliac obstruction or occlusion.

For clinical decision making, the relevant issue is if a hemodynamically significant stenosis is present; and usually, >50% diameter stenosis is implied as meaning it is. In addition, it is of interest if this is stenotic disease or complete occlusion. We have designed the scoring sheets of the reference standard accordingly.

Although one would expect the poor waveform in the CFA with an occlusion, as we report here, we encountered some patients who had occlusion but a biphasic or triphasic CFA waveform. Also, our findings demonstrated that a more specific diagnosis of stenotic versus occlusive aortoiliac disease was not possible by using the duplex waveform. A more accurate grading would therefore not feasible.

Occurrence of the sharp monophasic waveform has value in a way that it marks occlusion of the SFA. Knowledge of these flow characteristics may also be helpful in reducing DUS examination time or in arriving at a correct diagnosis whenever the iliac arteries cannot be visualized in their entirety.

Our diagnostic algorithm is first to check the CFA waveforms and then to proceed with trying to see the aortoiliac arteries in their entirety. The value of the current results in our practice is that we can be confident that a hemodynamically significant stenosis is present when we measure a poor CFA waveform, even if we do not succeed in visualizing the ipsilateral iliac artery. One might also argue that once a poor CFA waveform is encountered, this patient will need to undergo a more definitive imaging study and the duplex examination can be considered completed. This would be time consuming. Our study specifically warns that this shortcut cannot be taken too far: one cannot exclude the presence of hemodynamically significant disease in the aortoiliac arteries from a triphasic or biphasic CFA waveform.

A previous study compared the duplex waveform interpretation against aortoiliac duplex scanning and found sensitivity and specificity of 95% and 80%.[10] Unfortunately, it is not clearly stated in this study if the second duplex waveform observer also did the assessment of the full DUS. Otherwise, it could have created observer bias and could also clarify the lower observer agreement between the two duplex waveform observers ($\kappa = 0.74$). Another study validated the systolic rise time of the Doppler waveform by correlation with angiograms; however for this study, a group of patients with SFA obstruction was selected.[16]

A more recent study compared the interpretation of the CFA against aortoiliac disease by using arteriography as the gold standard and found sensitivity and specificity of 95% and 89%.[8] It must be noted that in this study, 31% of the significant aortoiliac diseases contained occlusive disease, which is more likely to be detected, whereas this was 18% in our study. We found a substantially lower sensitivity, which implies that a normal duplex waveform cannot exclude significant aortoiliac disease. However, the lower sensitivity is not surprising, because it has previously been described that a duplex waveform recorded at a sufficient distance from a stenosis can normalize.[10,17]

Some limitations of our study should be discussed. A known limitation of MRA findings is that overestimation of stenosis grade is more frequent than underestimation.[18] This might explain some of the false-negative DUS interpretations, but given the sheer amount of false-negative results found here, it would not affect the overall conclusions of the present study. Furthermore, we are aware of the 18% MRA disagreement in the aortoiliac segments and made our reference standard more reliable by requiring a third MRA reader. When we performed a subanalyses for the two different MRA readers versus the duplex results separately, the conclusions were robust, in that these were similar to the conclusions of our study reported here.

Another limitation of this study may be that the waveform interpretations were made directly from the prints and not from real-time DUS scans. Some prints that both DUS readers classified as nondiagnostic because of artifacts might have been assessable in a real-time DUS scan, and this could have caused false noninterpretable waveforms in the study.

CONCLUSIONS

The observer agreement in assessing the DUS waveform at the CFA is very high. The poor monophasic duplex waveform at the CFA is in itself an accurate marker of upstream aortoiliac obstructive disease. The appearance of triphasic and biphasic monophasic waveforms is nondiagnostic for aorto-iliac disease, whereas the sharp monophasic duplex waveform is associated with occlusion of the superficial femoral artery.

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INVITED COMMENTARY

Ted R. Kohler, MD, *Seattle, WA*

Before duplex scanning made it possible to obtain velocity waveforms directly from deep arteries, investigators tried to diagnose aortoiliac disease by using downstream continuous-wave Doppler signals from the common femoral artery. Various methods of waveform analysis were used, such as the Laplace transform and the pulsatility index. It soon became apparent that waveforms can normalize within a few vessel diameters of a significant stenosis or even occlusion. Further, these tests were not able to distinguish high-grade stenosis from occlusion, to detect moderate disease, or to quantify disease in multiple segments. These indirect methods were largely abandoned in the late 1980s when improved technology (low-frequency scan heads and better spectrum analysis) made it possible to apply duplex scanning to aortoiliac segments.

A classification scheme similar to the one used for carotid artery diagnosis was developed for aortoiliac disease and has become widely accepted. Yet some laboratories continue to use analysis of the common femoral waveform to screen for aortoiliac disease because duplex scanning of these segments is time consuming, technologist dependent, and sometimes not technically possible.

The results reported here by Spronk and colleagues demonstrate that little has changed over the past two decades. They have shown that in addition to its inability to distinguish near-occlusions from occlusions and to quantitate disease in multiple segments, indirect testing has a low sensitivity; only 56% of stenoses were detected in this study. Thus, if this screening examination is negative, as it was in 60% of their patients, it is of no diagnostic value; if it is positive, it gives no information about the site and extent of disease, and thus another study is needed to plan treatment. Why shouldn't this additional study be completion of the duplex scan?

Common femoral waveform analysis without scanning the aortoiliac vessels saves time, but is helpful only if the clinician is unconcerned about the extent and location of disease. Even then, this examination is helpful only when there is a poor monophasic waveform, and up to 15% of these may be false-positives (the 95% confidence interval for the positive predictive value was 85 to 96). It is little wonder that indirect tests have given way to direct methods. A poor monophasic waveform is an important marker of proximal disease, but the information it provides is modest compared to that of more modern techniques.