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EDITORIAL

Variation in Ultrasound Diagnostic Thresholds for Carotid Stenosis in the United States

Article, see p 946

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Consider the case of C.S., a 69-year-old man who has a moderately severe 50% to 69% left internal carotid stenosis, which has been followed for years by his physician with serial duplex scans at accredited Vascular Laboratory A. When that physician retired, C.S. transitioned his care to another physician, who ordered his annual carotid duplex scan to be performed at accredited Vascular Laboratory B. C.S. was alarmed when the report released to his electronic medical record stated that he now had a >70% left internal carotid stenosis. The peak systolic velocity in the left internal carotid artery is 210 cm/s on both examinations.

Carotid duplex ultrasound was developed in the 1970s at the University of Washington by a team led by Dr D. Eugene Strandness Jr,[1] and although catheter-based arteriography remains the gold standard imaging modality for carotid artery disease, major societal guidelines now recommend carotid duplex ultrasound as the initial diagnostic imaging modality to evaluate the severity of carotid stenosis.[2,3] Furthermore, if carotid duplex ultrasound is unequivocal in the identification of 50% to 99% stenosis in symptomatic patients and 70% to 99% stenosis in asymptomatic patients, carotid duplex findings are sufficient to make decisions regarding further management, including intervention.[2] Because carotid duplex ultrasound is widely available and noninvasive, it is the most common imaging examination performed worldwide to diagnose carotid disease.[4] Consequently, the criteria used for classifying stenosis severity by carotid duplex ultrasound must be accurate and reproducible.

Ultrasound accrediting organizations such as the Intersocietal Accreditation Commission (IAC) and the American College of Radiology attempt to standardize the performance of vascular ultrasound examinations, but they do not require the use of a single set of carotid duplex criteria for the classification of carotid stenosis. Instead, they stipulate that each accredited laboratory have a set of interpretation criteria that are used by all members of the technical and medical staff and are either derived from the literature or developed and validated internally.[5,6] Therefore, it is not surprising that among accredited vascular laboratories, there is wide variability in carotid interpretation criteria.[7] Even with the publication of proposed standardized velocity criteria for carotid duplex ultrasound by a multispecialty panel in 2003,[4] only 24% of IAC-accredited vascular laboratories were using these standardized criteria in 2011, and there were 17 sets of diagnostic criteria in use among 117 laboratories, with the remaining facilities using locally developed (6 laboratories) or unreferenced or hybrid criteria (29 laboratories).[7] Whereas there is clearly wide variability in the diagnostic criteria used in accredited facilities for carotid duplex ultrasound, the clinical implications of this variability are unclear.

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The current study by Columbo et al[8] not only describes the variation in velocity thresholds used for determining carotid stenosis severity in accredited laboratories but also estimates the potential clinical impact of this variability. Using data from a random sample of 338 vascular testing centers accredited by the IAC, diagnostic velocity thresholds were applied to peak systolic velocity values obtained from 2 populations: a population-based cohort (4791 patients ≥65 years of age) representative of patients who are typically tested because of risk factors for carotid disease (the Cardiovascular Health Study[9]) and a population-based cohort (28 483 patients) who underwent surgery for asymptomatic carotid stenosis (the Vascular Quality Initiative registry [www.vqi.org]). Diagnostic thresholds for ≥50% stenosis were applied to the Cardiovascular Health Study group, given that this is the stenosis threshold at which patients would usually begin long-term surveillance; and diagnostic thresholds for ≥70% stenosis were applied to the Vascular Quality Initiative registry group, given that this is the stenosis threshold at which carotid revascularization may be considered in the asymptomatic patient.

The results of this investigation on the diagnostic velocity thresholds for carotid duplex ultrasound are disturbing. The authors found that the 2003 Society of Radiologists in Ultrasound Consensus Conference[4] criteria were being applied by 46% of facilities, an increase from the 24% reported in 2011.[7] However, among the 338 IAC-accredited vascular laboratories, 60 discrete stenosis category/peak systolic velocity pairs were in use.[8] When applied to the Cardiovascular Health Study group, the 5th percentile peak systolic velocity threshold for ≥50% stenosis (125 cm/s) would assign a diagnosis of "moderate carotid stenosis" twice as often as the 95th percentile peak systolic velocity threshold (150 cm/s). In the Vascular Quality Initiative registry group, 9.8% of patients who underwent a carotid endarterectomy for asymptomatic stenosis had a peak systolic velocity falling between the 5th and 95th percentile peak systolic velocity thresholds for ≥70% stenosis (230 cm/s and 275 cm/s, respectively). This implies that 1 in 10 patients may not have been considered for carotid revascularization had they received their carotid duplex ultrasound in an accredited vascular laboratory with different interpretation criteria. These findings are similar to those of a study published in 2014 in which diagnostic velocity thresholds from 10 institutions in New England were applied to a series of 15 534 carotid duplex scans performed at the University of Massachusetts.[10] The differences in diagnostic criteria used to interpret these scans resulted in significant variation in the classification of carotid artery stenosis and, by implication, significant variation in the potential number of subsequent carotid interventions.

A number of factors contribute to variability in the results of carotid duplex ultrasound examinations, including scanning protocol, sonographer skill, and instrumentation used. Accreditation seeks to minimize this variability by requiring participating vascular laboratories to comply with detailed standards for ultrasound imaging, qualifications of sonographer and physician personnel, selection and maintenance of equipment, quality assurance, and reporting.[5,6] Assuming that the accredited laboratories included in this study were in good standing and adhered to the standards outlined by the IAC, the findings of this study are even more impressive, as the only major factor left to explain the variability in carotid stenosis classification is the interpretation criteria or diagnostic velocity thresholds used. With 60 distinct stenosis category/peak systolic velocity pairs in use in the 388 accredited vascular laboratories, it is not surprising that our patient, C.S., had a high probability of receiving disparate reports on the severity of his carotid stenosis, even when the peak systolic velocity remained the same on serial tests. A study published in 2014 found that of 7327 outpatient facilities billing Medicare for cerebrovascular testing in a 5% random Outpatient Limited Data Set for the United States in 2011, only 22% were IAC-accredited, with significant variation in rates of accreditation by region.[11] Data are not available for the prevalence of accreditation by all accrediting bodies, but it should be noted that accreditation is not a requirement for reimbursement of carotid duplex ultrasound examinations by the Centers for Medicare and Medicaid Services.[12]

In the decades since it was introduced in the 1970s, duplex scanning has become an integral part of the management of patients with carotid disease, from initial screening to follow-up after intervention. Although the instrumentation has improved significantly and scanning protocols have been refined, considerable variability remains in the velocity thresholds used to classify the severity of internal carotid artery stenosis. Standardization of the criteria used for interpreting carotid duplex ultrasound examinations would avoid the distressing predicament of our patient, C.S., and reduce the variability identified in the results of examinations performed in different vascular laboratories. However, it is important to point out that standardization of diagnostic velocity thresholds would not improve the overall accuracy of carotid duplex scanning. Although there is a definite correlation between the velocities obtained by duplex ultrasound and percent stenosis on arteriography, this relationship is highly variable.[13] Therefore, it is unlikely that further refinements in the diagnostic velocity thresholds will lead to improved accuracy compared to arteriography. The principal rationale for standardization of velocity thresholds is to achieve consistency in the interpretation and reporting of carotid duplex scans.

EDITORIAL

The study by Columbo et al[8] illustrates how the wide variability in carotid velocity thresholds can lead to differences in clinical care and contributes to the growing body of work supporting standardization. An initiative is currently being undertaken by IAC Vascular Testing, which is designed to validate a specific set of carotid velocity criteria that can be recommended for use by all IAC-accredited facilities.[14,15] The endorsement of IAC Vascular Testing and its sponsoring organizations would be a major step toward standardized velocity criteria and improved consistency for carotid duplex ultrasound. This would avoid confusion and improve vascular laboratory practice for sonographers, interpreting physicians, referring providers, and our patients.

ARTICLE INFORMATION

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Disclosures

Dr Kim is a member of the Board of Directors of the Intersocietal Accreditation Commission: Vascular Testing. Dr Zierler is a former member of the Board of Directors and past President of the Intersocietal Commission for the Accreditation of Vascular Laboratories.

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