studies are usually appropriate, but realistically speaking, why would industry fund studies that have an excellent chance of showing what a number of smaller studies have already shown, especially since they are making a lot of money in that market already? And, if a larger study were negative, wouldn't there be cries to do even larger ones? After all, one can really never prove a negative. There is always the possibility that another slight twist or an even larger study could be positive. If it takes a very large number of subjects to show a significant positive result, the clinical benefit must be difficult to uncover. At some point, one has to conclude that enough is enough and we have to accept the results at hand. In the meantime, large amounts of money are being diverted from better uses in our health care system.

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An Evaluation of the Efficacy of Methods Used in Screening for Lower-Limb Arterial Disease in Diabetes

Response to Williams et al.

We have read with interest the report by Williams et al. (1) on diabetic limbs without critical ischemia. We have recently performed a similar study in 106 diabetic patients with polyneuropathy, 61 of whom had critical ischemia (2), which confirms the poor performance of ankle-brachial pressure index in these patients (1,2). At variance to Williams et al. (1), we were, however, able to demonstrate the usefulness of the pulsatility index to predict critical ischemia. A pulsatility index <1.2 recorded at the ankle arteries predicted critical limb ischemia with reasonably good sensitivity (0.87) and specificity (0.62); the positive and the negative predictive values were 0.64 and 0.86, respectively. We explain our differences to the findings of Williams et al. by the different Doppler devices that were employed. While Williams et al. had used a 8-MHz Doppler probe (1), we used a 10-MHz linear ultrasound probe with a color-flow duplex machine (Accuson 128XP10; Acuson, Mountain View, CA) in our study.

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An Evaluation of the Efficacy of Methods Used in Screening for Lower-Limb Arterial Disease in Diabetes

Response to Janssen and Chantelau

We thank Janssen and Chantelau (1) for their interest in our study (2), which analyzed the efficacy of several commonly used lower-limb arterial screening modalities in diabetes. We demonstrated that qualitative, operator interpretation of the continuous Doppler waveform at the ankle for limbs without critical ischemia was more sensitive than quantitative analysis in detecting peripheral arterial occlusive disease. In our hands, qualitative waveform analysis achieved a sensitivity of 94% and specificity of 66% in the presence of clinically detectable peripheral neuropathy. Pulsatility index and other quantitative waveform analyses invariably failed to detect more severe peripheral arterial occlusive disease, with an overall sensitivity of 52%. In your study of limbs with and without critical ischemia, pulsatility index was demonstrated to achieve greater sensitivity at 87% (3).

There appear to be two fundamental differences between the respective studies. First, this study focused on the ability of commonly used screening methods to detect hemodynamically significant arterial disease not their ability to predict the presence of critical ischemia. Patients with critical ischemia were therefore excluded from our study. Further, we employed a relatively simple, single-crystal, continuous waveform analyzer and not a more complex device with a linear crystal array and color-flow facility. Color duplex imaging with waveform analysis of the lower limb has been demonstrated to be effective in detecting peripheral arterial occlusive disease (4). Our study used this modality as a gold standard not as a screening modality.

It is not surprising, therefore, that the results of quantitative analysis differ between the two studies.

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