LETTERS TO THE EDITORS

Regarding "A randomized study on eversion versus standard carotid endarterectomy: Study design and preliminary results: The Everest Trial"

To the Editors:

I received the April 1998 issue of the Journal of Vascular Surgery and found an error in the first sentence of the article entitled "A randomized study on eversion versus standard carotid endarterectomy: Study design and preliminary results: The Everest Trial" by Cao et al (J Vasc Surg 1998;27:595-605). The statement was made in the article that "Eversion carotid endarterectomy (CEA) was introduced in 1970 by Etheredge.[1]" As you may observe from the enclosed reprint, we originally described and illustrated (Fig) this method of endarterectomy in an article published in Postgraduate Medicine (1959;26:227-37) 11 years before the article by Etheredge appeared. In his article (Am J Surg 1970;120:275), Etheredge also failed to refer to our article. That our article is not entirely unrecognized is evident by the fact that at the recent meeting of the American Surgical Association, Dr Dhiraj M. Shah referred to it in his presentation entitled, "Carotid endarterectomy by eversion technique: its safety and durability."

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24/41/92213

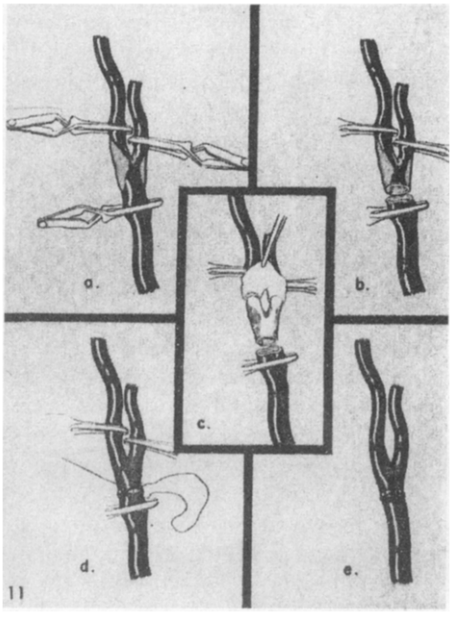

Fig. A technique of eversion carotid endarterectomy from Postgraduate Medicine (1959;26:227-37).

Reply

We read with interest the letter from Dr DeBakey regarding our article (J Vasc Surg 1998;27:595-605) and the original description of eversion carotid endarterectomy. We apologize for the inaccuracy of our statement that attributed the original description of the method to Etheredge (Am J Surg 1970;120:275). It is unfortunate that our statement was on the basis of the latter article that failed to refer to a previous publication, which does contain a description and an illustration of the method of endarterectomy as outlined by Dr DeBakey. However, we would like to acknowledge that referral to an article in Postgraduate Medicine (1959;26:227-237) would have been more appropriate as an indication of the original source of information regarding this matter.

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24/41/92212

Regarding "Variability and reliability of air plethysmographic measurements for the evaluation of chronic venous disease"

To the Editors:

We welcomed and read with interest the above-named article by Yang et al (J Vasc Surg 1997;26:638-42) that appeared recently in the Journal of Vascular Surgery. Because we are familiar with the machine and the test protocol,[1] it is our belief that there are important issues to be discussed before accepting the conclusion of this work.

It is unclear to us exactly what equipment was used by the authors. The APG air plethysmograph Model 1000 or 1000 C from ACI Medical (San Marcos, Calif) is the only commercially available model. The authors described a somewhat different device (possibly a modified version that may use certain components of the original ACI product) and also deviated from the published standard test protocols,[2,3] which could explain the variability of their published data.

First, the original sensing cuffs that were supplied by the manufacturer were made of polyurethane and not polyvinyl chloride. According to Ed Arkans, the President of ACI Medical and an engineer by trade, who was consulted in this matter, cuffs that are made of polyvinyl chloride would show significant "creep" and would not produce a stable output nor repeatable results from 1 test to another. Therefore, they should never be used for sensing.

Second, the calibration method that was described is

also different from the 100-mL method that was supplied with the original product and that was used by other investigators and us. The use of the smaller 50-mL calibration volume does not adequately cover the range of calf venous volumes that are closer to the neighborhood of 100 mL.

Third, the authors waited only 3 minutes between serial tests. This is far too short of time than would be necessary for a patient's arterial inflow to return to resting levels after the exercise protocol of the test. This short waiting time will result in elevated venous volumes and increased venous filling indices. Indeed, after-exercise testing of the author's design showed the greatest measurement variability. A 10-minute to 15-minute period is more appropriate to remove the confounding effect of exercise hyperemia.

Fourth, the authors had the patients' elastic stockings removed just before testing. This practice is not recommended for repeatable results because the effect of the compression garments may last up to 24 hours after their removal.[4] Thus, it is important to instruct patients not to wear their compression stockings the day of the test if one is to expect repeatable serial results.

Finally, the authors chose not to perform the key tests for outflow obstruction and superficial collateralization (by finger occlusion of the long saphenous vein).[5] Those tests, along with the protocols for reflux and calf muscle pump function, are all standard APG tests that provide the examiner with the complete hemodynamic picture of each patient who is examined. In summary, it is our belief that the authors made 2 general errors. They have modified a well-tested manufacturer's device without regard to proper engineering considerations and have also introduced a personal and deviant testing protocol. Both steps resulted in interpretation errors.

In our personal experience, the manufacturer has been quite helpful in identifying protocol problems and in helping with experimental device modifications. They should have been consulted before hemodynamic information was improperly acquired and conclusions published.

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REFERENCES

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4. Labropoulos N, Leon M, Volteas N, Nicolaides AN. Acute and long term effect of elastic stockings in patients with varicose veins. Int Angiol 1994;13:199-23.
5. Nicolaides AN, Sumner DS. Outflow fraction. Investigation of patients with deep vein thrombosis and chronic venous insufficiency. 1st ed. London: Med-Orion; 1991. p. 61.

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Reply

Thank you for the opportunity to reply to the comments made by Dr Goren. Dr Goren's concern appears to be focused on the concept that the APG air plethysmograph as supplied by the manufacturer ACI Medical (San Marcos, Calif) may be more accurate and more reproducible in the performance of repeated tests in patients with chronic venous disease than our study has indicated. Our concern from this study was not with any specific brand or type of air plethysmograph but rather with the inherent variability in the overall methodology in this specific group of patients. Such variability is almost certainly related to problems with this group of patients being able to consistently and accurately reproduce exactly the same degree of muscle contraction during the tiptoe movements and the same leg position, degree of immobility, and relaxation after the tiptoe movement. Variations in these parameters rather than inherent inaccuracy in the equipment is almost certainly the cause of the variation that we observed in this study.

In response to the specific points raised by Dr Goren, the device that we used consisted of the sensing cuff supplied by the manufacturer ACI Medical (Sun Valley, Calif) and a pressure transducer and recorder that was described in the paper. The sensing cuff is constructed from Dr Goren's letter polyurethane and not polyvinyl chloride as we had reported (there is no record of the material on the cuff itself). The air plethysmograph that we used was constructed separately and was not model 1000 or 1000 C or a modification of one of these. The equipment that we used produced accurate and reproducible measures of alteration in cuff volume when tested before application to patients. The same is, I assume, almost certainly the case for the APG air plethysmograph.

The testing protocol used in our study was exactly the same as the protocols that were reported previously, however, additional measurements were made on the tracings in this study, and these have not been previously reported. Before starting these studies, we evaluated the calibration volume and found a linear relationship between the 50-mL and 100-mL calibration volumes. Because the 50-mL calibration is easier to perform, this calibration was used in our studies. Because of this linear relationship, this would not have accounted for the extent of the variation in the volume parameters that were measured. We added to our protocol additional interpretation and analysis of the tracing after the patient had performed 10 tiptoe exercises. This was performed in the hope that it would provide more reproducible data, however, this was not the