Why Patients Know More About Cars Than Peripheral Artery Disease

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Americans who are interested in purchasing a motor vehicle often investigate automobile manufacturers, car models, and even competitive pricing using the World Wide Web. When one uses an Internet search engine to investigate Toyota, the largest automobile manufacturer in the world, there are >93,000,000 results. Virtually every possible question one would have about a Toyota vehicle is discoverable before ever visiting a local Toyota dealership.

In this issue of Circulation, Subherwal and a team of renowned clinical scientists representing some of the brightest vascular trialists in the world highlight this painful reality. Using the clinicaltrials.gov database, the majority of trials in PAD, for example, did focus on device approval, but these studies have historically ignored the importance of supervised exercise and atherectomy, drug-eluting stents, drug-coated balloons are embarrassingly weak.

In this issue of Circulation, Subherwal and a team of renowned clinical scientists representing some of the brightest vascular trialists in the world highlight this painful reality in crystal-clear detail. Using the clinicaltrials.gov database, the extent of trials in the peripheral vascular realm represents a paltry 1.7% of all investigations. Admittedly, this may underestimate early-stage trials and also excludes, for reasons unclear to me, trials of dialysis access salvage interventions, a critically important and much needed area of research. Nonetheless, this underscores the fact that trials are often initiated by the interests of commercial manufacturers who opt for market approval of products rather than pursuing the challenging areas in which patient need is greatest. The limited number of trials assessing the safety and efficacy of intervention for acute venous thromboembolism is such an example. Only 4% of all studies in the clinicaltrials.gov database focused on venous thromboembolism, and, of those, only a very few looked at the treatment of venous thromboembolism rather than prevention. However, even the layperson frequently reads about apparently healthy people who die suddenly from pulmonary emboli.

Sponsors cannot be singularly faulted. The process of device approval does not necessarily facilitate tackling the most dire of patient conditions. Pathways for device approval and reimbursement are often so murky and uncertain that sponsors either choose not to invest in such strategies or, as is further suggested by Subberwal et al, take their initiatives offshore to international venues. Subberwal et al suggest that the percentage of trials including US patients dropped by 10% from 2007 to 2010. There are many potential explanations for this, but regulatory and reimbursement uncertainties, coupled with perceived tax advantages in other markets, certainly play a role in these decisions.

Physicians must also be accountable for this trend. As noted in this study, the majority of trials in PAD, for example, did focus on device approval, but these studies have historically ignored the importance of supervised exercise and optimal medical therapy. The Claudication: Exercise Versus Endoluminal Revascularization (CLEVER) trial is 1 rare exception.

Commonly, physician investigators remain “guilty” of presuming to already know the answer to a question. A relevant example is that of optimal antithrombotic therapy after endovascular intervention. Several years ago, an attempt to complete a trial designed to answer the question of single versus dual antiplatelet therapy in this important and rapidly evolving patient cohort was made. The trial could not enroll because physicians felt that every patient required dual antiplatelet therapy. At the time of this publication, we still have no level 1 data guiding us on the choice of postendovascular intervention antiplatelet therapy, and, ironically, the effect of aspirin has now emerged as a question in the PAD population.

Despite the sobering data presented by Subherwal et al, this comes as no surprise to those of us in the field. After all, we know that patients with PAD do not receive the same intensity of atherosclerotic risk factor intervention when compared with patients with isolated coronary heart disease. However,
the shockingly small number of trials dedicated to acute stroke management, representing only 0.29% of all clinicaltrials.gov trials, is sobering. This is 1 of the most common and feared disorders among adults, and yet the true advances in therapy have been minor, as reflected in this small number of trials.

As suggested by the authors, concerted efforts to reverse this trend are needed. We must align the interests of physicians, commercial manufacturers, regulators, payers, and most importantly patients to design trials that will add to the much-needed knowledge base for the vascular patient. We need to ask questions that truly matter and study issues that are currently unanswered. We must ensure that all regions of the country will have the opportunity to offer clinical trials of new diagnostic methods and therapeutic strategies. Time is of the essence because the population continues to age and risk factors for peripheral vascular disease continue to become more prevalent. Society must consider what is more important—understanding how to manage and acute stroke to avoid convalescence in a long-term care facility, or ride in a near-driverless vehicle.12

Disclosures
Dr Jaff is a noncompensated advisor to Abbott Vascular, Boston Scientific, Cordis, Covidien Vascular, and Medtronic Vascular, a paid consultant to Cardinal Health, an equity shareholder of PQ Bypass, and a board member of VIVA Physicians, a 501(c)3 not-for-profit education and research organization.

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