Regional Pathologies and Globalization of Clinical Trials: Has the Time for Regional Trials Arrived?

To the Editor:

We read with great interest the series of articles written by Drs Califf and DeMets1,2 regarding the lessons learned from cardiovascular clinical trials performed during last 2 decades. Indisputable evidence obtained from several large clinical trials conducted mostly in white populations with chronic heart failure (CHF) clearly demonstrates the benefits of combined therapeutic options such as angiotensin-converting enzyme (ACE) inhibitors, β-blockers, and spironolactone. A marked reduction in mortality and morbidity has been followed by a reduction in the clinical and economic burden of CHF. Because these studies were performed mostly in developed countries, it remains unclear whether the reduction in CHF mortality and morbidity is also observed with other pathologies, such as Chagas’ disease.

CHF due to Chagas’ disease remains a staggering public health problem in Central and South America. Chagas’ disease is the major cause of disability secondary to tropical diseases in young adults from Latin America. In this region, 750,000 productive life years and US $1,200 million/year are lost to Chagas’ disease. In addition, 20 million people are currently infected by Trypanosome cruzi, and 100 million are exposed to the disease.3 CHF secondary to Chagas’ cardiomyopathy is the most frequent and severe clinical manifestation of Chagas’ disease and is associated with a poor prognosis compared with other pathologies. Small case-controlled studies using ACE inhibitors in patients with CHF secondary to Chagas’ cardiomyopathy have been reported.4 However, these studies lack the appropriate design and power to provide any guidelines on the management of CHF secondary to Chagas’ disease.

We have been struggling to obtain funds to conduct a clinical trial aimed at assessing the effects of β-blockers on mortality and morbidity in patients with Chagas’ CHF. This task has proven to be quite disappointing given the lack of interest of both local and international pharmaceutical companies, and only partial support has been obtained from the Colombian Institute for the Advancement of Science and Technology (COLCIENCIAS).

The scientific community is starting to respond by carrying out clinical research in several fields that developing countries recognize as their needs. A clear example of this contribution is the INTER-HEART project, a multicenter study aimed to identify risk factors for acute myocardial infarction in different ethnic populations.5 Globalization of knowledge and evidence-based medicine should be matched by attempts to provide solutions for regional pathologies in addition to global health problems.

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