



EDITORIAL COMMENT

## Is time for a national multi-institutional mechanical circulatory assistance program?

### *¿Es momento para un programa de asistencia mecánica circulatoria multi-institucional?*

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The treatment of terminal heart failure is currently one of the greatest challenges in clinical practice. There is limited pharmacological arsenal and there are few interventionist or surgical options. During the last two decades, heart transplant has been the most viable option to treat terminal heart failure. However, in Latin American countries there are ideological, economical and even political restrictions that have seriously limited transplant programs. As a bridge to transplant or recovery or as destination therapy, ventricular assist devices (VAD) have become a well acknowledged and established therapeutic modality to treat patients with terminal heart failure.<sup>1</sup>

Various ventricular assist devices have been successfully developed and tested in different countries, mainly in the United States, Europe and Japan. Some developing countries have also been working on the design and testing of VADs, strengthening local mechanical assistance and heart transplant programs. Such is the case of several research centers in Brazil, where the development of certain assist devices has only reached *in vitro* experimental phases, others have been tested in animal models *in vivo*, and others have been tested in clinical assays.<sup>2</sup> The University General Hospital Gregorio Marañón in Madrid has proposed a low cost ventricular assistance system,<sup>3</sup> while Spain has proven the achievements of an aggressive national heart transplant program.<sup>4</sup>

In Mexico, the development of innovative ventricular assist systems has been very limited, not having reached clinical testing and much less marketing phases. The article entitled "In vivo assessment of hemocompatibility of a ventricular assist device in healthy swine - measurement of inflammatory parameters" published in this issue of *Archivos de Cardiología* by Catarina Sacristán and a multidisciplinary group of professionals including biomedical engineers, anesthesiologists, cardiovascular surgeons, hematologists, chemists, immunologists, and anatomical and molecular pathologists, demonstrates the hemocompatibility of three different silicone rubber surfaces of the VAD device: heparin-coated surfaces (Hep-Coat), uncoated substances (Pass-Coat) and passivated coating, in combination with different types of systemic anticoagulation: No anticoagulation, systemic heparin treatment and antiaggregant treatment.

The authors chose inflammation parameters that revealed well-known acute responses upon VAD implantation. Apparently, the surface showing the least inflammatory reaction when in contact with blood was the Pass-Coat, which would be expected. Perhaps a greater time of exposure to these surfaces might reveal greater differences after chronic use of the device. In addition, the similar response to coagulation activation and thrombin generation complex (plasma thrombin-anti-thrombin III

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complex) observed in both groups could also be expected, with a tendency to lesser coagulation activation in heparin and Hep-Coat models. Macroscopic and microscopic analyses revealed no significant coaguli in disposable parts of the VAD. In this model, assistance is venous-venous (right to left jugular veins) and thus the mechanical capacity was not assessed. Only the behavior of the different non-biological surfaces of the system were assessed when making contact with blood. This paper concludes that this innovative and multipurpose ventricular assist device, which is the result of the conjunct efforts of several national institutions, did not induce a major inflammatory response and did not activate the coagulation cascade at least in the short term (6 hours), although it needs to be tested in subacute and chronic models.

This report describes only a small part of a great effort which has produced several publications, the first in 2003,<sup>5</sup> and the patent of the device which began in December of 2004 and was updated in 2007 (Air-pressure powered driver for pneumatic ventricular assist devices US7217236). As a result of various in vitro studies and theoretical analyses, this device has been improved several times. It is my understanding that this is the first national report of a ventricular assist device tested in animals with serious and reliable histocompatibility analyses. This is very relevant, particularly because although ventricular assist devices are used in several medical centers in Mexico, they are almost always imported from other countries where VADs are already commercialized. A very high price is paid to use this technology, which is particularly relevant because economical resources are limited in Mexico. The development of this type of technology in Mexico should be applauded.

The available resources must be divided between several specialized institutions that have slowly acquired experience in treating heart failure patients with mechanical assistance. In order to develop and implement this and other types of specialized and expensive technology, it is necessary to unite economical resources and several types of human talent, which will eventually improve our ability to develop this type of biotechnology.

The effort and participation of several institutions from different states in Mexico are necessary to develop a national mechanical support assistance program. Some institutions can work on technology development, while others will perform histocompatibility and acute response tests or medium to long-term studies in animals, and several other institutions will be required to perform clinical assays. This effort requires trained personnel (biomedical engineers, histopathologists, nurses, cardiologists, cardiovascular surgeons, intensive care specialists, psychologists, cardiovascular rehabilitation specialists, etc.), specialized hospital facilities to offer intensive care for patients with VAD, adequate channels to transfer patients between hospitals with different levels of specialization, and outpatient care programs for VAD patients and their families or caretakers. Bringing together the resources, talents and experience of specialized personnel could lead to the development of specialized technology generated in our country, which could eventually lead to improved care for patients with severe heart failure, improved quality of life and increased survival.

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