

## LETTER TO THE EDITOR

# Training on the Use of Transendocardial Delivery of Biologics for Cardiac Regeneration

The delivery of biologics for cardiac regeneration is an emerging aspect of interventional cardiology, and we were interested to read the recently published recommendations of the International Society for Cardiovascular Translational Research (ISCTR) Task Force by Dib et al (1).

The ISCTR Task Force is to be commended for their efforts in creating the published recommendations. Although we support their pre-clinical recommendations, we do not agree with the recommendations for clinical experience in the use of transendocardial delivery of biologics. Animal lab experience, although valuable, is not representative of the challenges involved in performing clinical cases. In addition, we believe that the interventionist in training must become proficient in diagnostic *mapping* under the supervision of highly experienced operators before undertaking clinical *injection* procedures. Only after proficiency in mapping is demonstrated should the trainee continue to performing proctored clinical cases. In addition, we believe that trainees should successfully perform more proctored cases than recommended by the ISCTR Task Force before obtaining certification.

Our recommendations for more proctored cases are based on our extensive experience with these procedures. We have been performing endocardial mapping for acute and chronic ischemia at the Texas Heart Institute since 1998. Our experience in using mapping procedures in a cell therapy setting comprises multiple large animal studies and clinical trials, including the first U.S. Food and Drug Administration–approved trial in the U.S. in patients with chronic ischemia. Furthermore, we developed criteria and a protocol for the identification of viable myocardium and therapeutic

injections with NOGA mapping. In 2000, we launched the Mapping Excellence Program to train physicians throughout the world in endocardial mapping. As a training site for NOGA endocardial mapping and injection, we have developed a successful training program that includes a didactic overview, hands-on training in the animal laboratory, written and video materials, testing, and certification. Upon completion of the program, physicians are encouraged to send us their maps for review and feedback before initiating their clinical injection programs.

The ISCTR's suggested recommendations are an excellent beginning. However, we believe that the suggested training guidelines are not stringent enough to ensure the safety of patients undergoing the NOGA-guided delivery of biologics. We suggest further dialogue and refining of the guidelines.

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doi:10.1016/j.jcin.2010.08.002

## REFERENCE

1. Dib N, Menasche P, Bartunek JJ, et al., on behalf of International Society for Cardiovascular Translational Research. Recommendation for successful training on methods of delivery of biologics for cardiac regeneration. A report of the International Society for Cardiovascular Translational Research. *J Am Coll Cardiol Intv* 2010;3:265–75.