Texas Heart Institute International Symposium on Cardiovascular Regenerative Medicine

Emerson C. Perin, Doris A. Taylor

The first Texas Heart Institute International Symposium on Cardiovascular Regenerative Medicine was held September 16 to 17, 2017, in the Denton A. Cooley auditorium at the Texas Heart Institute in Houston, Texas. In attendance were 40 distinguished faculty members from leading US and international academic institutions, members from the Duke/US Food and Drug Administration (FDA) Cardiac Safety Research Consortium, and the FDA/Center for Biologics Evaluation and Research. Also in attendance was Texas State Senator Paul Bettencourt. The audience included clinicians, clinical scientists, and basic scientists interested in the latest advances in the field of cell therapy. Several attendees and faculty were members of the Transnational Alliance for Cell-based Regeneration Therapies in Cardiovascular Syndromes (TACTICS) group, an international alliance of investigators in the field of regenerative medicine, now associated with the European Society of Cardiology Working Group on Cardiovascular and Regenerative and Reparative Medicine (Figure).

To start the meeting, inaugural lectures were given regarding innovation and to provide a general perspective on the field of cell therapy. The remainder of the meeting was organized into the following 3 main sections: regulatory, heart failure, and new concepts/unresolved issues. The regulatory session, which spanned the first half of day 1, was one of the highlights of this meeting. Presentations were given and included a review of the regulatory status in the Netherlands, where cell therapy for refractory angina is currently approved. Making a case for regulatory approval in the United States, it was discussed how cell therapy could be used for the same indication on the basis of results from phase I to phase III rigorous trials. Next, Texas State Senator Paul Bettencourt discussed the creation and implications of "Charlie's Law" that he coauthored and that has been passed in the Texas Legislature. This new law allows for broader access to unapproved cell therapies in the state of Texas for patients with no other options. To conclude these presentations, a member from Center for

Figure. A group of attendees at the first Texas Heart Institute International Symposium on Cardiovascular Regenerative Medicine.

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(*Circ Res*. 2018;122:205-206. DOI: 10.1161/CIRCRESAHA.117.312100.)
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***Circulation Research* is available at http://circres.ahajournals.org** **DOI: 10.1161/CIRCRESAHA.117.312100**

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Biologics Evaluation and Research gave a perspective from the FDA. Because of the rare opportunity afforded by the gathering of this unique group, a significant portion of time was reserved for interaction among the presenters and the audience. An interactive panel discussion included a regulatory debrief and focused discussion on the requirements to support a successful submission and its approval in regenerative medicine. Questions discussed were why this would happen, should this happen, and what will it require? These and many other relevant questions were asked, answered, and debated among clinical scientists, government representatives, and those who work in regulatory affairs.

During the next segment of the meeting, discussions focused on pushing the boundaries of the current methods of statistical analysis, which is particularly relevant to developing complex fields of knowledge. In the afternoon, there was a broad discussion about cell therapy in heart failure, which is currently believed to have the most potential as a clinical application in regenerative medicine. After several short presentations describing the state of the art in clinical cell therapy treatments for heart failure, there was a roundtable and then a discussion about safety issues and unresolved issues. Day 1's sessions closed with a special lecture that expanded on bringing knowledge acquired from other specialties into the field of cardiovascular regenerative medicine. This lecture included a historical perspective on the development of bone marrow transplantation.

Day 2 of the meeting was dedicated to new areas of investigation in the field. Initial results and hypotheses were presented and discussed regarding the use of cell therapy in patients with anthracycline-induced cardiomyopathy, peripheral arterial disease, or aortic abdominal aneurysms, as well as in patients with stroke, congenital heart disease, or nonischemic cardiomyopathy. Presentations were also given on the topics of bioengineering, materials, gene therapy, cell and gene combinations, and novel mechanistic insights into remodeling and inflammation. A specific session dedicated to exosomes included 3 presentations from different perspectives and a discussion regarding this promising offshoot of cell therapy.

The inaugural Texas Heart Institute International Symposium on Cardiovascular Regenerative Medicine was extremely successful in that a balance was struck between the presentation of new, cutting-edge findings and in-depth discussion regarding the current state of the field and how it should proceed. All who were present are looking forward to future yearly meetings held in a similar format.

Disclosures

None.

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Circulation Research
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association®

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Circ Res. 2018;122:205-206
doi: 10.1161/CIRCRESAHA.117.312100
Circulation Research is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7330. Online ISSN: 1524-4571

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circres.ahajournals.org/content/122/2/205

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