Art Sedrakyan

FDA establishes International Consortium of Transcatheter Valve Registries Initiative (ICCR-ICTVR) to fill evidence gaps related to transcatheter aortic valve replacement procedures and devices

With expert input from Art Sedrakyan

While transcatheter aortic valve replacement (TAVR) is becoming increasingly commonplace in the clinic, there are relatively few long-term data available for the devices used in this procedure. This paucity of data is due, in part, to the cost and logistical challenges posed by large, randomized clinical trials. The United States Food and Drug Administration (FDA) noted that "information obtained from clinical trials is often limited due to small size, short followup, and lack of generalizability. Observational studies and registries… are often limited in scope and size to a specific country, region, or health care provider system."[1] In order to deliver these crucial data to interested parties, the FDA has turned to international registries to facilitate inter-registry collaboration that can help all parties provide an effective means of developing 'real-life' clinical evidence. The data collected will help to identify knowledge gaps, patient selection, regional differences in practice, potential problems that may arise with specific techniques, and novel management strategies.

While registries together offer the potential for the analysis of very large data sets, the collection of long-term safety and efficacy, quality of life and device performance data, by this means, is complicated by varied patient populations, numerous devices that are rapidly being updated, and the necessity for common definitions to allow the full recording of datasets. As such, collaboration between the various international registries is crucial to ensure the successful development of an international programme to assess TAVR devices. Moreover, a rigorous and systematic methodology, combined with the requisite expertise, would be vital to provide dependable data.

The FDA convened an initial meeting of the International Consortium of Cardiovascular Registries' (ICCR) Transcatheter Valve Replacement Registry initiative (ICTVR) in April 2013. This meeting, attended by a variety of stakeholders including representatives from academia, industry, payors, physicians and regulators, laid the groundwork for the initiative. Representatives from five national registries in the USA, UK, Germany, Canada and the Netherlands discussed the design and status of their national registries, with a view to developing methodologies that would allow them to collaborate as part of one of the largest registry networks in the world.

The objectives of the ICTVR initiative are four-fold:

1. Development and testing of innovative methodological approaches: to use, develop and adapt relatively new registry analytical tools to study TAVR devices
2. Forum for discussion: to bring together stakeholders in workshops and conferences to discuss gaps in evidence, datasets, and best practices
3. Comparative outcomes studies: to help establish best clinical practice through comparison of both surgical/interventional techniques and TAVR devices. Such data will also be used to inform regulatory decision making
4. Publications: collaboration in the development of peer-reviewed manuscripts and white papers, in order to share the knowledge and expertise developed by the group

Led jointly by the registries and FDA, with inclusion of numerous key stakeholders, this initiative is likely to provide valuable data that will drive clinical excellence in the field of TAVI. Dr Art Sedrakyan,

who is leading the FDA's Medical Device Epidemiology Network (MDEpiNet) Science and Infrastructure Center currently at Cornell University and is the PI of the grant, said that "the programme is unprecedented in cardiovascular interventional medicine. While some collaboration among registries happened in the past they were not planned as comprehensive registry consortia aiming to influence the regulation and also clinical practice internationally. The leaders of German and US TAVR registries serve as two co-chairs of the Steering Committee."

"The registry leaders can use the experience accumulated within International Consortium of Orthopaedic Registries (ICOR, www.icor-initiative.org) that has been a very successful project to date. The ICOR is also initiated by FDA MDEpiNet Science and Infrastructure Canter and is led by 20+ international orthopaedic registries" Dr Sedrakyan told *Confluence*.

REFERENCE:

1. Federal Register. "International Consortium of Cardiovascular Registries" a notice by the Food and Drug Administration on 2 April 2014. Accessed March 2014 at: **https://www.federalregister.gov articles/2013/04/02/2013-07579/international-consortium-of-cardiovascular-registries**