

Transcatheter cardiac occluders – Best standards to establish safety, performance and benefits of new devices

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Abstract

The field of transcatheter cardiac occluders has advanced and expanded significantly in recent years. Structural heart occluders are a standard treatment option for a range of congenital or iatrogenic disorders such as atrial and ventricular septal defects, patent foramen ovale, left atrial appendage closure and paravalvular leak. The need for guidance in this sector is driven by the lack of commonly accepted methodologies to establish safety and performance of cardiac occluders. A new dedicated standard - ISO 22679: Cardiovascular implants – Transcatheter Cardiac Occluders, has been developed by an expert group of engineers, scientists, regulators and clinicians, to ensure quality assurance and appropriate analysis of device-associated risks for patients and physicians. This lecture presents an outline of the new ISO 22679 standard, that can be used to produce a risk-based strategy for accelerating the development, validation and approval of occluder devices in a global market. Learning and following this standard, developers can perform complete and correct assessment of the product's physical, mechanical, chemical, and biological properties of transcatheter cardiac occluders and of their materials and components. Recommended in-vivo animal evaluations are also provided, including choice of animal model; study duration; device size; sample size; applicability and relevance based on similarities or differences between animal model and humans for device use; and also, alternative implantation site or techniques. Extensive guidelines are provided to design and conduct clinical trials, including imaging assessment, target population and follow-up duration and methods, as well as objective criteria for establishing safety, usability and clinical benefits.

Biography:

Dr. Monica Tocchi is a medical doctor and cardiologist, with a postdoctoral degree in Cardiovascular Pathophysiology from the University of Rome, Italy. She has co-authored Breakthrough studies on endovascular procedures, coronary stents, atrial fibrillation ablation, and point of care testing for risk prediction in cardiovascular disease. She is founder and CMO of Meditrial, an international consulting company. She has been served as regulation experts in the International Standardization Organization (ISO) for more than 15 years.

Speaker Publications:

1. "Cardiac troponin T and C-reactive protein for predicting prognosis, coronary atherosclerosis, and cardiomyopathy in patients undergoing long-term hemodialysis"
2. "Immediate and long-term clinical and angiographic results from Wiktor stent treatment for the bifurcation narrowing"
3. "Prospective randomized comparison of predischARGE coronary angiography versus exercise treadmill test in chest pain patients without ischemic ECG changes"

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