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Abstract: To propose standardized consensus definitions for important clinical endpoints in transcatheter aortic valve implantation (TAVI), investigations in an effort to improve the quality of clinical research and to enable meaningful comparisons between clinical trials. To make these consensus definitions accessible to all stakeholders in TAVI clinical research through a peer reviewed publication, on behalf of the public health. Transcatheter aortic valve implantation may provide a worthwhile less invasive treatment in many patients with severe aortic stenosis and since its introduction to the medical community in 2002, there has been an explosive growth in procedures. The integration of TAVI into daily clinical practice should be guided by academic activities, which requires a harmonized and structured process for data collection, interpretation, and reporting during well-conducted clinical trials. The Valve Academic Research Consortium established an independent collaboration between Academic Research organizations and specialty societies (cardiology and cardiac surgery) in the USA and Europe. Two meetings, in San Francisco, California
(September 2009) and in Amsterdam, the Netherlands (December 2009), including key physician experts, and representatives from the US Food and Drug Administration (FDA) and device manufacturers, were focused on creating consistent endpoint definitions and consensus recommendations for implementation in TAVI clinical research programs. Important considerations in developing endpoint definitions included (i) respect for the historical legacy of surgical valve guidelines; (ii) identification of pathophysiological mechanisms associated with clinical events; (iii) emphasis on clinical relevance. Consensus criteria were developed for the following endpoints: mortality, myocardial infarction, stroke, bleeding, acute kidney injury, vascular complications, and prosthetic valve performance. Composite endpoints for TAVI safety and effectiveness were also recommended. Although consensus criteria will invariably include certain arbitrary features, an organized multidisciplinary process to develop specific definitions for TAVI clinical research should provide consistency across studies that can facilitate the evaluation of this new important catheter-based therapy. The broadly based consensus endpoint definitions described in this document may be useful for regulatory and clinical trial purposes.