Trends in Cardiovascular Medicine 29 (2019) 237–238

Contents lists available at ScienceDirect

Trends in Cardiovascular Medicine

journal homepage: www.elsevier.com/locate/tcm

Editorial commentary: Evolving technologies for percutaneous left atrial appendage occlusion

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Percutaneous left atrial appendage (LAA) occlusion is an innovative "local therapy" for the prevention of thromboembolism in patients with atrial fibrillation (AF). It may be considered new for some physicians but its history goes back to the early 2000s. The first-in-man implantation of a dedicated LAA occlusion device (PLAATO) was performed in August 2001 in Frankfurt by Horst Sievert. [1] Despite the initial promising results with PLAATO, the device was withdrawn from the market in 2005 due to the lack of the required resources to perform large clinical studies. The Watchman device was first tested in human clinical studies in 2002 and the first enrollment in a pilot study was performed in October 2003 at the Mayo Clinic. [2] Although Bernhard Meier used Ampatzer Septal Occluders for LAA closure since 2002, the first dedicated Ampatzer device, the Amplatzer Cardiac Plug (ACP) was first implanted in human by Kavin Walsh in Dublin a few years later, in 2008. [3]

Based on the favorable results of PROTECT-AF (the first randomized clinical trial with the Watchman device) and other large registries with the Watchman and Amplatzer devices (ACP and its successor, Amulet), percutaneous LAA occlusion has been gradually introduced in clinical practice, mainly for patients who are not eligible for long-term anticoagulation therapy. [4] In this issue of Trends in Cardiovascular Medicine, Chow et al. present "An Overview of Current and Emerging Devices for Percutaneous Left Atrial Appendage Closure". [5] The article is a comprehensive review of several LAA occluders, focusing in their technical characteristics, current clinical data and future perspectives. It attracts the reader's attention and surely reflects the interest of device industry to produce a "perfect" occluder. The questions that genuinely arise are if such a device exists and what might be its principal features and advantages?

The main challenge of percutaneous LAA occlusion is the anatomical variability of the LAA, which is so enormous that often the LAA is called "the patient's fingerprint". [6] Moreover, the LAA is commonly a thin–walled, fragile cardiac structure and percutaneous access requires a trans-septal puncture. A "perfect" LAA occluder should have the following features: it should be conformable to variable anatomies to allow for complete closure, fully recapturable and repositionable, atraumatic, stable, non-thrombogenic, visible on cardiac imaging, and should not interfere with radiofrequency of cryo-balloon AF ablation. The device should be tested in a large randomized clinical study, in patients eligible and in patients non-eligible to anticoagulation therapy. It should have low major procedural complications rate (<1%) and high feasibility in preventing thromboembolism. It should be relatively cheap, user-friendly, widely available, and its manufacturer should offer a robust clinical training program for physicians who want to start using it. Obviously, the question if such device currently exists is a rhetorical one. The currently available devices have many but not all of these features. Therefore, knowledge of each device's special characteristics may facilitate clinical decision making for optimal results.

As the elderly population is growing fast, AF-related stroke and systemic thromboembolism has become a major health and socio-economic problem. [7] It has high mortality and it leads in significant patient disability, affecting millions of individuals and families, worldwide. Oral anticoagulation is currently the gold standard therapy but has many limitations, mainly due to bleeding complications and almost half of the patients who need it do not use it at all. The main indication for percutaneous LAA occlusion is previous major bleeding and high bleeding risk. However, patients with similar indications may vary substantially in terms of their medical history and actual clinical needs. For example, a 60-year-old patient with CHA_2DS_2VASc score of 2, who has multiple nose bleeding events while treated with triple therapy (aspirin + clopidogrel + anticoagulant) is very different from an 85-year-old patient with a CHA_2DS_2VASc score of 4 and intracerebral bleeding on single aspirin therapy. The former may safely take dual antiplatelet therapy for 3 months after LAA closure, whereas the latter cannot. A patient with severely dilated left atrium, low ejection fraction, spontaneous contrast on echocardiography and incomplete LAA closure with a non-well apposed occluder may need closer monitoring for device thrombosis as compared to a patient with normal cardiac dimensions and function with an optimally implanted device. Therefore, acquaintance with the patient history, medical records and evaluation of LAA closure quality may be proved equally important to knowing how to use a particular device.

Performing a large randomized clinical trial has become very expensive, especially when medical devices are involved. In addition, it usually takes many years for these trials to show clinical results, whereas relevant science and technology is growing extremely fast. Randomized clinical trials may not be a panacea but it is surely the best tool we have to evaluate new therapies. In or-

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https://doi.org/10.1016/j.tcm.2018.09.009

der for physicians, patients, industry, health authorities or other shareholders to draw meaningful conclusions from clinical trials, it is very important to use a widely accepted terminology, with universal definitions end clinical endpoints. [8] In this way, every device may undergo objective and unbiased scrutiny before being offered to patients. In light of more, upcoming evidence in the field of percutaneous LAA occlusion, it is prudent to reserve this therapy for patients who will really benefit from it. Choosing the right device for the right patient and being extremely meticulous in procedural safety will allow this technology to grow and contribute to the great battle against AF-related stroke and systemic thromboembolism.

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