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STRUCTURAL

Transcatheter Mitral Valve Implantation Using the HighLife System

Marco Barbanti, MD,[a] Nicolò Piazza, MD,[b] Sarah Mangiafico, MD,[a] Jean Buithieu, MD,[b] Sabine Bleiziffer, MD,[c] Giuseppe Ronsivalle, MD,[a] Salvatore Scandura, MD,[a] Angelo Giuffrida, MD,[a] Antonio Popolo Rubbio, MD,[a] Massimo Mazzamuto, MD,[a] Carmelo Sgroi, MD,[a] Rüdiger Lange, MD,[c] Corrado Tamburino, MD, PhD[a]

ABSTRACT

OBJECTIVES This study is the first report of 2 cases of HighLife (HighLife, Paris, France) implantation in humans.

BACKGROUND Transcatheter mitral valve implantation represents a promising approach to treating mitral regurgitation in patients at increased risk of perioperative mortality. The HighLife transcatheter mitral valve is a 2-component system. The valve is implanted in the mitral position and is anchored by interacting and then reaching an equilibrium position with a previously positioned subannular implant.

METHODS The procedures were successfully performed in a 69-year-old man and a 65-year-old woman with severe functional mitral regurgitation. Both patients were in New York Heart Association functional class IV heart failure with depressed left ventricular ejection fraction and additional comorbidities.

RESULTS The valve was implanted uneventfully in both patients. General anesthesia was used. The subannular implant was deployed through the transfemoral access, whereas the transcatheter mitral valve was released using the transapical access. Patients maintained hemodynamically stable. There were no intraoperative complications. Acutely, post-procedural echocardiograms demonstrated excellent prosthetic valve function with a low transvalvular gradient and no paravalvular leak and left ventricular outflow tract obstruction. Both patients had mild intraprosthetic regurgitation. Patient #1 survived at 5-months follow-up in New York Heart Association functional class II with excellent prosthesis performance. Patient #2 expired 4 days after a technically successful procedure, because the left ventricle did not tolerate the reduction of mitral regurgitation and despite a high dose of inotropic agents the left ventricular function rapidly deteriorated.

CONCLUSIONS Transcatheter mitral valve implantation using the 2-component HighLife system is technically feasible and can be performed safely. Early hemodynamic performance of the prosthesis was excellent. (J Am Coll Cardiol Intv 2017;10:1662–70) © 2017 by the American College of Cardiology Foundation.

Transcatheter mitral valve implantation (TMVI) represents a promising approach to treating mitral regurgitation (MR) in patients at increased risk of perioperative mortality (1). To date, several transcatheter mitral valve systems are under preclinical and clinical investigation (1–5). Each of them carries specific features that have the goal to ensure a predictable delivery and

From the [a]Ferrarotto Hospital, University of Catania, Catania, Italy; [b]McGill University Health Center, Montreal, Québec, Canada; and the [c]German Heart Center Munich, Technical University Munich, Munich, Germany. Dr. Piazza is a consultant and proctor to HighLife and Medtronic; and has consultant equity shares in HighLife. Dr. Buithieu is a consultant to HighLife; and has received consultant fees from HighLife. Dr. Bleiziffer is a consultant for HighLife. Dr. Lange is a consultant for Medtronic, LivaNova, St. Jude Medical/Abbott Vascular, and HighLife; and has an equity share in HighLife. Dr. Tamburino received speaker honoraria from Abbott Vascular, Medtronic, Symetis, Stentys, and Biosensors. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. Drs. Barbanti and Piazza equally contributed to this work.

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an efficient anchoring and sealing to the mitral annulus, while preserving surrounding cardiac structures and the patency of the left ventricle outflow tract (LVOT). The HighLife transcatheter mitral valve system (HighLife, Paris, France) is a 2-component system (6). The design of the valve with implantation of the prosthesis in a previously positioned subannular implant (SAI) is intended to seal without paravalvular leakage and prevent LVOT obstruction. This device has already been tested in acute and chronic animals with promising outcomes (data not published). No human cases have been described in the published data. The present study is the first report of 2 cases of HighLife implantation in humans.

TMVI DEVICE OVERVIEW

The HighLife TMVI technology has been described previously (**Figure 1**) (6). Briefly, the device, which is currently available only in 1 size, is composed of 2 separate components. The valve consists of a nitinol alloy-based, self-expanding frame, covered with a polyester graft and trileaflet bovine pericardium. The frame shape has a pre-formed groove in the annular region so as to create an interference with the loosely placed SAI. The SAI is a polymer tube, covered with a polyester graft with a nitinol hook that allows for the creation of a ring with a single definite length (31 mm). The SAI comprises 2 distal ends mounted on each side of the guidewire loop surrounding the native mitral valve. The first end is tapered with a nitinol clip. The second end has a flared shape designed to host the nitinol clip. When the open ring is pushed forward on the guidewire loop, the 2 ends are brought together until the clip engages the opposite end and closes the ring. The valve is loaded into a 39-F catheter delivery system that is currently introduced through the apical access, whereas the SAI is placed using an 18-F catheter compatible SAI delivery catheter (SDC) that is inserted through the femoral artery and advanced retrogradely into the left ventricle (LV) after having crossed the aortic valve. The SDC is mounted on a guidewire loop encircling the native mitral valve apparatus. This loop is placed in a previous step using a dedicated 18-F catheter loop placement catheter (LPC). The LPC includes 3 components: 1 tube that ends with the nose cone, and 2 sets of tubes (on each side there is an intermediate tube with a 90° hosting a smaller subannular tube that extends into the subannular groove) for the guidewire and the snare, respectively. The interaction between the 2 components (prosthesis and SAI) that "jail" the mitral leaflets confers to the system a stable position and sealing within the mitral valve.

PRE-OPERATIVE ASSESSMENTS

Permission to proceed with transcatheter mitral valve replacement by using the HighLife transcatheter mitral valve system was granted on compassionate grounds by the Italian Ministry of Health and the local ethical committee. Both patients signed dedicated informed consent forms.

Cardiac-gated multislice computed tomography imaging was performed to assess mitral valve apparatus and aortomitral angle, and facilitate the pre-operative planning of fluoroscopic implant angles. Multislice computed tomography examinations were performed using a 64-slice Discovery HD 750 high-definition or volume computed tomography scanner (GE Healthcare, Milwaukee, Wisconsin). Multislice computed tomography data were reconstructed in 10% intervals throughout the cardiac cycle with a section thickness of 0.6 mm and an increment of 0.4 mm using a medium soft-tissue convolution kernel. All data sets were transferred to a dedicated post-processing workstation equipped with FluoroCT 3.0. For mitral annular assessment, mid- to late-diastolic image reconstructions were identified. Specifically, atrial dimensions on 85% to 95% reconstructions were assessed, depending on the presence of atrial contraction with the goal of evaluating the annulus on the last reconstruction before the atrial contraction. Using the late-diastolic reconstructions, the mitral annulus was tracked as previously reported (**Figure 2**) (7).

Patency of the LVOT was assessed both in late diastolic and late systolic images by simulating hypothetical TMVI with the device deployed in the mitral annulus (**Figure 3**). Finally, along the course of the subannular space, all the false chordae tendineae were identified and highlighted with a marker. This step was critical because the loop must be placed excluding the subannular fibrous or fibromuscular structures. Indeed, the entrapment of the SAI in 1 or more basal cords might determine a suboptimal anchoring and sealing of the transcatheter mitral valve.

CASE DESCRIPTIONS

PATIENT #1. Patient #1 (**Table 1**) was a 69-year-old man with previous myocardial infarction and

ABBREVIATIONS AND ACRONYMS

LPC = loop placement catheter

LV = left ventricle

LVOT = left ventricle outflow tract

MR = mitral regurgitation

SAI = subannular implant

SDC = subannular implant delivery catheter

TEE = transesophageal echocardiography

TMVI = transcatheter mitral valve implantation