JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 4, NO. 8, 2011

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC.
DOI: 10.1016/j.jcin.2011.05.019

Clinical Outcomes Using a New Crossover Balloon Occlusion Technique for Percutaneous Closure After Transfemoral Aortic Valve Implantation

Philippe Genereux, MD, Susheel Kodali, MD, Martin B. Leon, MD, Craig R. Smith, MD, Yanai Ben-Gal, MD, Ajay J. Kirtane, MD, SM, Benoit Daneault, MD, George R. Reiss, MD, Jeffrey W. Moses, MD, Mathew R. Williams, MD

New York, New York

Objectives This study sought to evaluate the technical success and clinical outcomes of an adjunctive crossover balloon occlusion technique (CBOT) combined with the 10-F Prostar percutaneous closure device (PCD) on the incidence of vascular and bleeding complications in patients after transfemoral transcatheter aortic valve implantation (TAVI).

Background Vascular closure following large-vessel access has most commonly been performed using a surgical cut-down and repair procedure.

Methods Between November 2008 and September 2010, 58 consecutive patients with severe aortic stenosis underwent TAVI via a retrograde femoral artery approach using the Edwards-SAPIEN transcatheter valve. Among these patients, 56 were treated with a CBOT using the "pre-close" technique and the 10-F Prostar system. The technical success of this new CBOT and the 30-day frequency of clinical events, including all-cause mortality, major vascular complications, and major bleeding (defined according to a modified version of the Valve Academic Research Consortium criteria), were assessed.

Results Successful closure was obtained in all but 3 patients (94.6%). The 30-day frequencies of mortality, major vascular complications, and major bleeding were 7.1%, 14.3%, and 5.4% respectively. No deaths were directly related to access site complications. Fourteen patients (25%) received at least 1 transfusion during the index hospitalization, of which 8 (57.1%) were not related to vascular complications. The mean and median hospital lengths of stay were 7.8 and 6.0 days.

Conclusions This new percutaneous adjunctive CBOT combined with the Prostar PCD resulted in controlled, safe, and successful percutaneous closure in most patients after TAVI. (J Am Coll Cardiol Intv 2011;4:861–7) © 2011 by the American College of Cardiology Foundation

From the Columbia University Medical Center/New York-Presbyterian Hospital and the Cardiovascular Research Foundation, New York, New York. Dr. Genereux has received speaker honoraria from Edwards Lifesciences. Dr. Leon is a nonpaid member of the Scientific Advisory Board of Edwards Lifesciences and Medtronic Vascular. Dr. Smith is a nonpaid member of the Scientific Advisory Board of Edwards Lifesciences. Dr. Kodali have received consulting fees/honoraria from Edwards Lifesciences and Medtronic. Dr. Williams is a consultant for Edwards Lifesciences and Medtronic. All other authors have reported they have no relationships relevant to the contents of this paper to disclose.

Manuscript received January 14, 2011; revised manuscript received April 11, 2011, accepted May 25, 2011.

JACC: CARDIOVASCULAR INTERVENTIONS, VOL. 4, NO. 8, 2011
AUGUST 2011:861–7

Transcatheter aortic valve implantation (TAVI) has been increasingly recognized as an alternative therapeutic option for patients with severe aortic stenosis (AS) and cardiac symptoms (1–4). Recently, the first multicenter, randomized controlled trial of TAVI in patients with severe AS who were not suitable candidates for surgery demonstrated that transfemoral, balloon-expandable TAVI reduced mortality and cardiac symptoms compared with standard therapy (5). However, vascular and bleeding complications were frequent in this randomized trial (PARTNER [Placement of Aortic Transcatheter Valves]) and in other studies, and represent a significant limitation of transfemoral TAVI (6–8). Due to the combination of large-diameter delivery systems and diseased peripheral vasculature in these elderly patients with AS, an elective surgical approach to vascular access and closure was the strategy of choice in the early TAVI experience. More recently, fully percutaneous techniques have been explored in suitable patients, and if safe and effective, may be the preferred alternative to reduce local access site complications and to accelerate patient ambulation. Although both the 10-F Prostar percutaneous closure device (PCD) (Abbott Vascular Inc., Santa Clara, California) and PerClose Proglide (Abbott Vascular) devices have been used for percutaneous closure involving large sheaths, these devices have been associated with serious adverse outcomes in cases of device failure (9–14). To improve percutaneous large-sheath access site closure, an adjunctive crossover balloon occlusion technique (CBOT) was developed and tested in patients after TAVI procedures (15,16). The purpose of this report is to assess the technical success and clinical outcomes after CBOT combined with the 10-F Prostar PCD in a consecutive series of suitable patients undergoing TAVI procedures via the transfemoral approach.

Abbreviations and Acronyms

AS = aortic stenosis

CBOT = crossover balloon occlusion technique

PCD = percutaneous closure device

TAVI = transcatheter aortic valve implantation

Methods

Patient population. Between November 2008 and September 2010, a total of 58 consecutive patients with severe AS underwent TAVI via the retrograde femoral artery approach using a 23- or 26-mm Edwards SAPIEN transcatheter valve (22- or 24-F sheath, respectively) as part of the PARTNER trial. Fifty-six of these patients were systematically treated with CBOT and a Prostar PCD system; 2 others underwent an elective surgical repair due to femoral artery pathoanatomy that was unsuitable for percutaneous closure. TAVI and CBOT were performed by an experienced team composed of interventional cardiologists and cardiothoracic surgeons at a single center (Columbia University Medical Center/New York Presbyterian Hospital, New York, New York).

Description of the CBOT. CBOT was systematically performed in each patient according to the following steps (Fig. 1): 1) fluoroscopy-guided puncture of the common femoral artery following angiographic localization of the "ideal" entry site with an iliac angiogram; 2) insertion and deployment of a 10-F Prostar PCD to "pre-close" the vessel; 3) transfemoral placement of the delivery sheath, then TAVI performed, and TAVI delivery catheter removed; 4) delivery sheath withdrawn into the common iliac artery over a 0.035-inch J-tip guidewire; 5) using a hydrophilic guidewire (J-Tip Glidewire, Terumo Medical Corporation, Somerset, New Jersey) from the contralateral side, a crossover catheter (Accu-Vu Omni Flush, AngioDynamics, Latham, New York) was advanced into the TAVI delivery sheath; 6) a stiff 0.035-inch guidewire was advanced through the crossover catheter and into the TAVI delivery sheath; 7) the crossover catheter was exchanged for a long crossover sheath (7-F or 8-F); 8) Prostar PCD sutures are tied as described in the conventional manner; 9) the TAVI delivery sheath was withdrawn gradually to just above the arteriotomy site while performing intermittent contrast injections through the crossover sheath to assess vascular injury; 10) a peripheral balloon (8 to 12 mm in diameter depending on common femoral or external iliac size) is inserted through the crossover sheath and inflated at low pressures (0.5 atm) just above the TAVI delivery sheath to allow a nontraumatic occlusion of the vessel before knot delivery; 11) the TAVI delivery sheath was removed and knots advanced to the arteriotomy; 12) peripheral balloon was deflated and hemostasis assessed via injection through crossover sheath; 13) if needed, a hydrophilic wire from the contralateral site was used to cross the puncture site and was positioned in the superficial femoral artery. The peripheral balloon was then advanced over this wire and inflated at the arteriotomy site to optimize closure; and 14) withdrawal of the wire, balloon, and crossover sheath.

Endpoints and definitions. The technical success of CBOT vascular closure was defined as the absence of significant early (during the procedure) or late (after the procedure) arteriotomy site complications requiring an unplanned surgical repair. We also assessed the 30-day frequency of all-cause mortality, major vascular complications, and major bleeding complications, defined according to a modified version of the Valve Academic Research Consortium criteria as described in the PARTNER trial (5,15). Vascular complications included complications originating from the TAVI sheath (ipsilateral), contralateral site, or from any other origin. Other endpoints included mean drop in hemoglobin, mean drop in hematocrit, number of blood transfusions, and duration of hospitalization.

Major vascular complications were defined by the presence of any of the following: 1) any thoracic aortic dissection; 2) access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arteriovenous fistula, pseudoan-