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Aortic valve leaflet disruption techniques in transcatheter aortic valve replacement

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ABSTRACT With continued technological advancement and technical improvement of transcatheter aortic valve replacement (TAVR), it has become a desirable treatment option for aortic valve stenosis. Its minimally invasive approach compared to surgical aortic valve replacement offers the treatment to a broader patient population, mainly non-surgical candidates. A feared complication of TAVR is the occlusion of coronary artery ostium by the native aortic valve leaflet due to its displacement by the expanded transcatheter valve. Bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction (BASILICA) is a technique developed to mitigate this risk by creating a lengthwise laceration of the left and/or right aortic valve leaflets prior to TAVR. Patient outcomes following TAVR with BASILICA have been promising. Meticulous preoperative examination, patient selection, and hemodynamic management are imperative. With continued refinement, BASILICA may further expand the application of TAVR to patients at high risk for coronary occlusion associated with the procedure.

Since the very first human transcatheter aortic valve replacement (TAVR) procedure in 2002, more than 200,000 TAVRs have been performed worldwide.[1] Though it was reserved for select non-surgical candidates in the early stages of development, its application is expanding considerably in recent years. Large randomized controlled studies have compared outcomes of TAVR versus surgical aortic valve replacement (SAVR) for intermediate and high-risk patients and found no significant difference in primary outcome of morbidity from major stroke or mortality at one year and two years, respectively.[2,3] Furthermore, a study of similar design involving low-risk patients found that TAVR patients had significantly lower rate of death, stroke, or rehospitalization at one year.[4] Another evolving application of TAVR is to salvage a failing bioprosthetic valve, known as valve-in-valve (ViV) procedure.[5] Minimally invasive aspect of TAVR confers a major advantage over SAVR, and the patient outcomes have been promising thus far. Despite its advantages, TAVR is associated with several notable risks. Firstly, without follow-up data from past six years, the durability of TAVR valves is uncertain. Therefore, current recommendations still favor SAVR for younger patients with longer life expectancy.[6,7] However, one of the most consequential intraoperative complications of TAVR is the occlusion of coronary artery. With the placement of the prosthetic valve, an existing aortic valve leaflet may displace outward and directly occlude the adjacent coronary ostium or block the entire sinus of Valsalva, resulting clinically significant coronary obstruction. The left coronary ostium is much more frequently affected than the right coronary ostium, likely due to its lower height of the ostium in relation to the leaflet.[8] Most cases of coronary obstruction manifest as severe hypotension immediately following the deployment of the prosthetic valve.[8–10] The incidence is less than 1% in TAVR performed on native aortic valves, but it increases over 3-fold in ViV TAVR procedures.[11,12] Majority of patients with TAVR-related coronary obstruction in the past have received emergent percutaneous coronary intervention and a much smaller number received coronary artery bypass grafting.[8] Despite these measures, the 30-day mortality of coronary obstruction in patients undergoing ViV TAVR is reported to be 48.6%, which is likely much higher than in patients with coronary obstruction during native valve TAVR.[8,11]

Given the high rate of catastrophic outcomes associated with coronary obstruction, efforts must be devoted to preventive strategies. Several factors have been identified which include pre-existing surgical bioprosthetic aortic valve, older age, female gender,

no history of coronary artery bypass grafting, and higher risk profile according to the logistic European System for Cardiac Operative Risk Evaluation (log-EuroSCORE).[10] The patient characteristics are likely significant due to the anatomic variability associated with them which include significantly smaller aortic annulus areas, sinus of Valsalva diameters, sino-tubular junction diameters, and lower left coronary artery heights as.[10] In ViV patients, the prior surgical valve location, manipulation of the aortic root, and implantation of coronary grafts may affect these parameters considerably.[12] With knowledge of these factors contributing to the risk of coronary obstruction, meticulous protocols are applied to stratify patient risk, as well as to plan the procedure appropriately.[13,14]

Bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction (BASILICA) is a novel technique developed to create a lengthwise laceration down the middle of an aortic valve leaflet from the base to the tip.[15] The goal of this technique is to prevent coronary obstruction by creating a separation in the existing valve leaflet through which the coronary artery can remain open and perfused when the leaflet is displaced outward by the transcatheter valve and the details have been previously described.[14,15] Briefly, this is accomplished by traversing an electrified guidewire through the mid-base of the valve leaflet of interest. The guidewire is then captured by a ring snare pre-positioned at the aortic outflow tract through a separate catheter. Then the guidewire and snare are both manipulated to position the cutting segment of the electrified guidewire in contact with the valve leaflet, which creates the valve laceration with electrocautery (Figure 1).

Initial testing of BASILICA in swine revealed successful laceration of the aortic valve leaflet without collateral injury on necropsy, except in the first trial while refining the technique.[15] Clinical trial was subsequently performed and showed promising results.[16] Of 30 patients, all subjects were free of coronary obstruction, despite being categorized as high risk based on preoperative evaluation.[16] Due to the relatively small sample size, several questions remained unanswered regarding the safety of BASILICA, such as the risk of stroke and major vascular complications. However, many centers began to perform BASICILA over the recent years, including here at UC Davis Medical Center. As a result, the multicenter international BASILICA registry has accumulated data on 214 patients who underwent the procedure at 25 centers in North America and Europe.[17] Analysis of the registry revealed that leaflet laceration was performed successfully in 94.4% of the patients and among those patients, 4.7% of patients experienced partial or complete coronary occlusion.[17] The patients with coronary obstruction were successfully treated with coronary stents, but one patient died from cardiogenic shock despite the interventions. Considering the previously established mortality ranging between 40% and 50% in patients who experience coronary obstruction due to TAVR without BASILICA, the mortality of 10% in patients who experience coronary obstruction with BASILICA bolsters the benefits of this procedure.[18] The authors' explanation for this finding is that the obstruction resulting after BASILICA is not flow-limiting and the

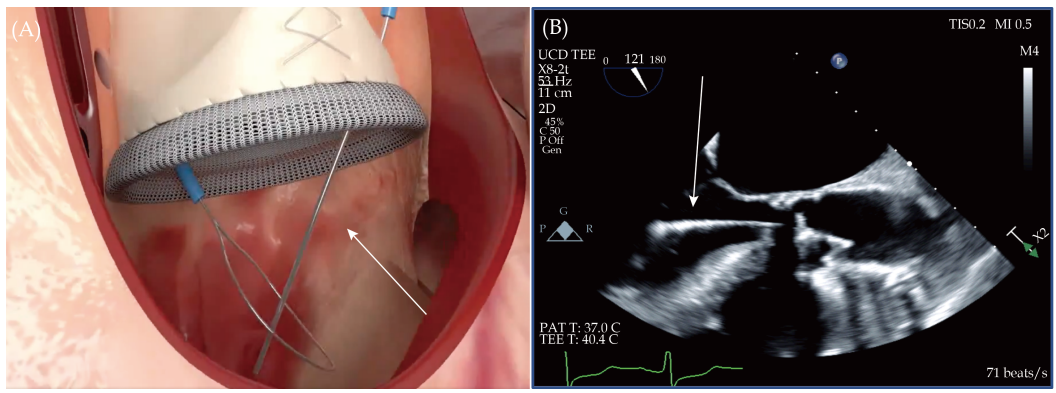

Figure 1 Schematic illustration (A) and transesophageal echocardiography (B) of mid-esophageal long axis view showing the electrocautery apparatus (arrow) in place for BASILICA. BASILICA: bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction.

space created by BASILICA often allows placement of coronary stents through the struts of the transcatheter valve, instead of the traditional "snorkel" stent.[17] Overall, the 30-day mortality and incidence of stroke reported through this registry were 2.8% and 2.8%, respectively.[18] This is similar to the data of all patients undergoing TAVR reported by the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry.[18] Considering that patients who underwent BASILICA are at higher risk than the average TAVR patients, this result supports the implementation of BASILICA for this subset of patients.

BASILICA requires meticulous planning and certain patient factors make the procedure less feasible. A large portion of the failed BASILICA were attributed to failure to traverse the electrified guidewire through the leaflet due to the extensive calcification. Hence, it may be a relative contraindication for the procedure. Anesthetic planning is also an important component in taking care of these hemodynamically fragile TAVR patients. This is highlighted by the authors of the BASILICA registry analysis, who attributed one of the deaths to cardiogenic shock resulting from the anesthesia induction.[18] Although moderate sedation may be considered, there is a strong preference for general anesthesia (GA) with endotracheal intubation. In case of severe hemodynamic compromise that requires emergent surgical intervention or mechanical circulatory support, GA with a secure airway is necessary. Furthermore, transesophageal echocardiogram (TEE) can be performed much more safely with a secured airway with an endotracheal tube. Particularly in this patient population, critical intraoperative complications, such as wall motion abnormalities can be detected early using TEE to direct clinical management. Table 1 highlights some complications and associated TEE findings during BASILICA.

A hemodynamically precarious portion of the procedure is the time between the completion of BASILICA and the deployment of the transcatheter valve. With the laceration of one or two aortic valve leaflets, severe aortic regurgitation can be expected (Figure 2). The anesthesiologist's awareness of this change is critical and pharmacologic support should be readily available. Avoidance of bradycardia, limiting the systemic vascular resistance, and providing inotropic support are generally necessary for patients with severe aortic regurgitation. This portion of the case can range from 8 min to 30 min, with variability in duration heavily influenced by the proficiency of the proceduralist, degree of calcification of the aortic valve leaflets, and whether the patient is receiving solo or doppio BASILICA.[15] With the successful placement of the aortic valve, almost an immediate change in hemodynamics is expected with resolution of severe aortic regurgitation and stenosis. If pharmacologic support has been initiated by the anesthesiologist, a rapid reversal of the hemodynamic support may be necessary to avoid hypertension and its complications. In addition to labile hemodynamics, data suggests that BASILICA is associated with higher risk of stroke.[14] Increased manipulation of calcified leaflets is more likely to dislodge embolic debris, and the benefits of cerebral embolic protection device could be considered.

Quantification of the overall morbidity and mor-

Table 1 Possible complications and associated transesophageal echocardiogram findings during bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction and transcatheter aortic valve replacement.

Complication	Transesophageal echocardiogram findings
Coronary ostial obstruction	Ventricular wall motion abnormality in the regions supplied by obstructed coronary artery
Penetration through aorta or cardiac chamber	Pericardial effusion +/- tamponade Intracardiac shunt
Partial tear of aorta	Aortic dissection flap Unexpected aortic insufficiency Ventricular wall motion abnormality
Mitral valve leaflet/Chordae damage	New mitral regurgitation with torn chordae/leaflet
Aortic annulus rupture	Pericardial tamponade
Patient-prosthesis mismatch	Peak prosthetic aortic valve velocity > 3 m/s Mean pressure gradient over manufacturer's expected range Dimensionless index < 0.3 Normal aortic valve acceleration time

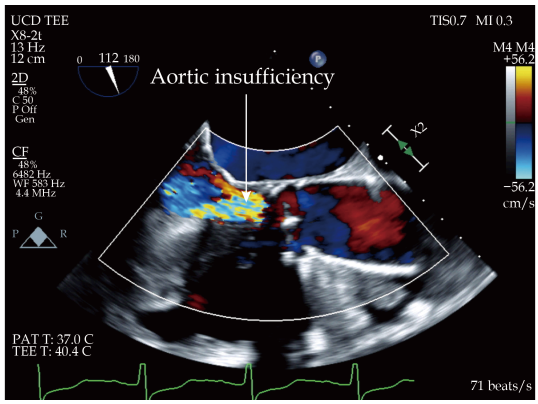

Figure 2 Transesophageal echocardiography of mid-esophageal long axis view with color flow doppler window showing severe aortic insufficiency (arrow) immediately following BASILICA. BASILICA: bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction.

tality of BASILICA is difficult, though its higher procedural risk compared to TAVR alone is hardly debatable. Currently, perhaps the greatest hinderance to widespread use of BASILICA is the limited data regarding its efficacy and patient outcome. Any novel procedure undergoes a period during which data is intensively gathered and analyzed. However, the technical complexity of BASILICA and the available surgical option for many patients will result in fewer centers performing it and thereby prolonging this phase. A larger database for BASILICA to address theoretical concerns will be an important step towards the growth of this procedure.

CONCLUSIONS

In summary, implementation of BASILICA has shown favorable results thus far. The cases performed here at UC Davis Medical Center under GA yielded successful outcomes. The safety and efficacy of BASILICA in patients at high-risk for coronary obstruction suggest that BASILICA has the potential to further expand the application of TAVR. At the very least, this technique warrants continued attention to follow-up its long-term effects and feasibility.

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