Treatment of Cardiogenic Shock in Severe Aortic Stenosis With the Edwards INTUITY Valve

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We report the first known cases of successful implantation of the Edwards INTUITY (Edwards Lifesciences LLC, Irvine, CA) rapid-deployment valve in 3 patients with aortic stenosis presenting under emergency cardiogenic shock. At the 6-month follow-up, the 3 patients showed improved left ventricular function and improved functional capacity.

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Acute cardiogenic shock (CS) in patients with severe aortic stenosis and left ventricular (LV) systolic dysfunction is associated with a poor prognosis. Recent guidelines suggest that percutaneous aortic balloon valvuloplasty can provide a temporary “bridge” to aortic valve replacement or transcatheter aortic valve implantation (TAVI) or be used as palliative treatment (level of evidence IIb C) [1, 2]. However, aortic balloon valvuloplasty is associated with a high rate of procedural complications [2]. In CS patients in particular, readmission rates for heart failure are high, and in-hospital and 2-year mortality rates of 56.5% and 80.4%, respectively, have been reported [3]. Moreover, although encouraging results have been reported in patients presenting in CS who undergo TAVI [4], in our experience, TAVI requires accurate imaging to ensure successful implantation and avoidance of paravalvular leaks. This is not always achievable in an emergency setting.

On the basis of a recent study [5], we used the Edwards INTUITY rapid-deployment valve (Edwards Lifesciences LLC, Irvine, CA) in 3 patients with aortic stenosis in CS. The valve is implanted by means of a delivery system and 3 guiding sutures that ensure correct positioning and sealing. The system is intended to reduce operative duration, enable minimally invasive surgical techniques, and ultimately improve patient outcomes.

Case Reports

Patient 1

Our first patient was an 82-year-old man on the waiting list for a TAVI procedure. He presented with severe aortic stenosis (aortic valve area, 0.5 cm²), a peak pressure gradient (PPG) of 74 mm Hg, a mean pressure gradient (MPG) of 44 mm Hg, chronic renal disease (stage 3 to 4) requiring dialysis, systemic hypertension, type 1 diabetes, dyslipidemia, and chronic obstructive pulmonary disease.

The patient was in CS and underwent an emergency procedure, prompted by deterioration in LV function (LV ejection fraction [LVEF], 0.24; akinesis of the apex and inferoposterior wall; systolic blood pressure <60 mm Hg), and deterioration in respiratory function that required intubation and inotropic support in intensive care. His logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) and EuroSCORE II values were 67.7 and 36.6, respectively.

The patient underwent a full sternotomy, using mild hypothermic (32°C) cardiopulmonary bypass (CPB) and selective and retrograde warm cardioplegia. After annular decalcification, a 21-mm Edwards INTUITY valve was implanted. Aortic cross-clamp time was 35 minutes and CPB time was 90 minutes. The patient was weaned from CPB with inotropic support.

Postoperative transesophageal echocardiography confirmed a PPG of 16 mm Hg and an MPG of 6 mm Hg, with no paravalvular leaks. The patient was discharged on day 10 and at 6-month follow up was in New York Heart Association Functional Class I, with an LVEF of 0.45, a PPG of 12 mm Hg, an MPG of 7 mm Hg, and an effective orifice area index of 0.95 cm²/m².

Patient 2

Our second patient was an 81-year-old woman, also on the waiting list for a TAVI procedure. She presented with systemic hypertension, diffuse coronary artery disease, prior myocardial infarction, Parkinson disease, LV hypertrophy, and severe aortic stenosis with a PPG of 80 mmHg, an MPG of 43 mm Hg, and an LVEF of 0.48. Her logistic EuroSCORE and EuroSCORE II values were 68.3 and 56.4, respectively.

Coronarography confirmed a critical occlusion of the left anterior descending coronary artery. An acute myocardial infarction with an ST segment elevation developed, followed by acute pulmonary edema and CS, which required intubation in intensive care. The patient, who was hemodynamically stable, underwent a full sternotomy, mild hypothermic CPB, and antegrade and retrograde warm cardioplegia. Coronary revascularization with a left internal mammary artery-to-the left anterior descending bypass graft, followed by implantation of a 19-mm Edwards INTUITY valve, was performed successfully with an aortic cross-clamp time of 55 minutes and CPB time of 75 minutes. Significant inotropic support and dialysis were required in the postoperative period, and the patient was discharged from intensive care on day 11.

Drs Martinelli, Labriola, and Cassese disclose financial relationships with Edwards Lifesciences.
Transthoracic echocardiography confirmed residual akinesis of the apex and an LVEF of 0.40. The valve was positioned correctly and functioning normally (PPG, 20 mmHg; MPG, 10 mmHg; no paravalvular leaks). At the 6-month follow-up, the patient was in New York Heart Association Functional Class II with an LVEF of 0.50, a PPG of 13 mm Hg, an MPG of 6 mm Hg, and an effective orifice area index of 0.9 cm²/m².

**Patient 3**

Our third patient was an 81-year-old man who was referred to our unit with a diagnosis of dilated cardiomyopathy. He presented with subcritical coronary artery disease, moderate to severe contractile LV dysfunction, severe aortic valve stenosis/sufficiency, moderate to severe functional mitral regurgitation, chronic atrial fibrillation, and severe respiratory dysfunction. Acute pulmonary edema and CS rapidly developed, which required mechanical ventilation and inotropic support. His logistic EuroSCORE and EuroSCORE II values were 66.8 and 57.4, respectively.

An emergency full sternotomy with mild hypothermic CPB and antegrade and retrograde warm blood cardioplegia was performed. Carpentier type IIIb mitral regurgitation, localized to the P3 scallop, was remodeled by implantation of a 28-mm ETLogix annuloplasty ring (Edwards Lifesciences). A patent foramen ovale was closed with a direct suture, and the aortic valve was replaced with a 23-mm Edwards INTUITY valve. Aortic cross-clamp time was 80 minutes and CPB time was 140 minutes.

Weaning from CPB required insertion of an intraaortic balloon pump due to hemodynamic instability. Surgical reexploration was required for bleeding as well as an implantable cardioverter-defibrillator on day 7 before discharge from intensive care on day 9.

At the 6-month follow-up, the patient was in New York Heart Association Functional Class II, with an LVEF of 0.75 cm²/m²; no evidence of paravalvular leaks.

Weaning from CPB required insertion of an intraaortic balloon pump due to hemodynamic instability. Surgical reexploration was required for bleeding as well as an implantable cardioverter-defibrillator on day 7 before discharge from intensive care on day 9.

The 6-month follow-up, the patient was in New York Heart Association Functional Class II with an LVEF of 0.35. The mitral annuloplasty showed no recurrent regurgitation, and the aortic valve was functioning normally (PPG, 11 mm Hg; MPG, 6 mm Hg; effective orifice area index 0.75 cm²/m²; no evidence of paravalvular leaks).

**Comment**

New implant technologies, such as TAVI and rapid-deployment valves, represent additional treatment options for aortic stenosis patients presenting under emergency CS. We decided to treat 3 such patients with the Edwards INTUITY rapid-deployment valve for four reasons.

Firstly, this procedure has been shown to shorten myocardial ischemic time compared with standard aortic valve replacement [5], which we consider to be a key therapeutic aim in these patients.

Secondly, we wanted to ensure optimal hemodynamics after aortic valve replacement in these patients with already severe LV dysfunction. A previous study [5], reported very low transvalvular gradients and large effective orifice areas 1 year after implantation of the Edwards INTUITY valve. This was confirmed in all 3 of our patients in CS, and although data are not available, we speculate stent expansion in the LV outflow tract plays a role in enabling a smooth blood flow compared with traditional prostheses.

Thirdly, avoidance of device-related postoperative complications is particularly important in CS patients. In our patients, successful implantation was achieved with a good safety profile, in line with low rates of postoperative and short-term adverse events reported previously [5].

Finally, no additional diagnostic studies were required before the intervention, which allows treatment decisions to be made and initiated quickly in accordance with current guideline recommendations [6].

Aortic valve replacement with the Edwards INTUITY rapid-deployment valve in patients with aortic stenosis in CS can be achieved with a favorable safety profile. Although further reports are needed to confirm our observations, rapid-deployment valves have the potential to become the first-line treatment in these critical patients.

**References**