

Case Study

SAPIEN 3 TPVR: Treating a patient with complex congenital heart disease using the Edwards SAPIEN 3 transcatheter pulmonic valve delivery system (PDS)



Baseline Characteristics

15-year-old female with Pierre Robin sequence and type II truncus arteriosus presented for TPVR.

- **Surgical history:** 10mm aortic homograft and PFO closure in infancy; conduit replacement with 14mm Contegra and PA bifurcation enlargement for progressive RPA stenosis; infective endocarditis prompting a third conduit replacement with 24mm pulmonary homograft. Mildly small LPA noted; follow-up every 6 months until lost to follow-up for about 5 years. Re-presented for cardiac clearance ahead of a dental procedure.
- **Findings:** Moderate-to-severe conduit stenosis (peak velocity ~4.0 m/s, peak gradient ~64 mmHg, mean gradient ~38 mmHg), severe conduit regurgitation (previously mild), moderately depressed RV function (previously normal).

Device Selection

The procedural goal was to restore the conduit to at least its nominal 24mm diameter, with the intent to implant a 26mm SAPIEN 3 valve.

Given the patient's history of a small LPA, RPA wire placement was planned. The Edwards SAPIEN 3 transcatheter pulmonic valve delivery system (PDS) was selected as a more favorable alternative to a 24 Fr 65cm Gore DrySeal sheath with the Edwards Commander Delivery System, based on its integrated capsule design.

Description of Procedure

- Baseline RV-to-RPA gradient of 45 mmHg peak-to-peak. Lunderquist wire advanced to RPA; MPA imaging confirmed 9mm conduit narrowing with adequate bilateral coronary clearance.
- 16 Fr Gore DrySeal sheath positioned in MPA. Serial balloon dilation from 12mm to 24mm Atlas Gold in 2mm increments with intermittent angiography; no conduit disruption.
- The first 5010 Palmaz stent deployed on 24mm BIB and post-dilated recoiled to 19–20mm. A second 5010 Palmaz stent was deployed on a 24mm BIB then post-dilated with a 24mm then 26mm Atlas Gold to 10 atm; final diameter was 24mm.

- 16 Fr sheath was exchanged for 27 Fr dilator; The 26mm SAPIEN 3 valve was advanced into the stented MPA and was deployed using nominal volume.
- Post-valve RV-to-MPA gradient was 3 mmHg peak-to-peak.

Assessment

The implanters noted the following observations when using the PDS:

- The PDS tracked smoothly to the RPA over the Lunderquist wire without resistance
- No additional maneuvers – such as a right atrial loop – were required to advance the delivery system, which pleasantly surprised the implanting team

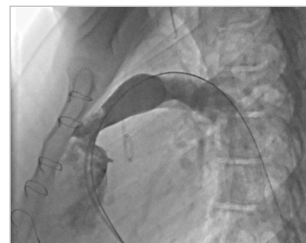


Figure 1.
Initial angiogram

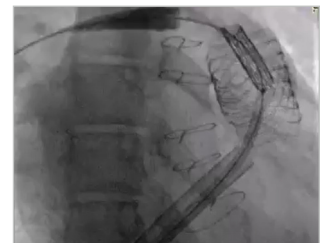


Figure 2.
Uncovered SAPIEN 3 valve



Figure 3.
SAPIEN 3 valve deployment

NOTE: The procedural technique presented herein is the technique used by the respective medical professional. Edwards Lifesciences does not endorse any particular procedural technique or techniques that are not aligned to the instructions for use. The experience described in this particular case study does not provide any indication, guide, warranty, or guarantee as to the outcome of any other procedure using this device.

Important Safety Information:

Edwards SAPIEN 3 Transcatheter Heart Valve System – Pulmonic

Indications: The Edwards SAPIEN 3 Transcatheter Heart Valve (THV) System with Edwards SAPIEN 3 Transcatheter Pulmonic Valve Delivery System (or Edwards Commander Delivery System) is indicated for use in the management of pediatric and adult patients who have a clinical indication for intervention on a dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic valve in the pulmonic position with $\geq$ moderate regurgitation and/or a mean RVOT gradient of $\geq$ 35 mmHg.

Contraindications: The Edwards SAPIEN 3 THV System with Edwards SAPIEN 3 Transcatheter Pulmonic Valve Delivery System (or Edwards Commander Delivery System) is contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.

Warnings: The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. Correct sizing of the valve into the non-compliant RVOT conduit or failing bioprosthesis (landing zone) is essential to minimize risks. Too small of a valve may result in paravalvular leak, migration, or valve embolization; whereas too large of a valve may result in residual gradient (patient-prosthesis mismatch) or RVOT rupture. Accelerated deterioration of the valve may occur in patients with an altered calcium metabolism. Assessment for coronary compression risk prior to valve implantation is essential to prevent the risk of severe patient harm. The physician must verify correct orientation of the valve prior to its implantation; the inflow (outer skirt end) of the valve should be oriented towards the proximal end (handle) of the delivery system to prevent the risk of severe patient harm. Prior to delivery, the valve must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. Valve leaflets mishandled or damaged during any part of the procedure will require replacement of the valve. Patients with pre-existing bioprostheses should be carefully assessed prior to implantation of the valve to ensure proper valve positioning and deployment. Do not use the valve if the tamper evident seal is broken, the storage solution does not completely cover the valve, the temperature indicator has been activated, the valve is damaged, or the expiration date has elapsed. Do not mishandle the delivery system or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g. kinked or stretched), or the expiration date has elapsed. Use of excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored. Patient injury could occur if the Commander delivery system is not un-flexed prior to removal. Care should be exercised in patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials. The procedure should be conducted under fluoroscopic guidance. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. These injuries may be painful, disfiguring, and long-lasting. It is recommended that all prosthetic heart valve recipients be prophylactically treated for endocarditis to minimize the possibility of prosthetic valve infection. Valve recipients should be maintained on anticoagulant/antiplatelet therapy, except when contraindicated, as determined by their physician. This device has not been tested for use without anticoagulation. Do not add or apply antibiotics to the storage solution, rinse solutions or to the valve.

Precautions: Long-term durability has not been established for the valve. Regular medical follow-up is advised to evaluate valve performance. Glutaraldehyde may cause irritation of the skin, eyes, nose and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Material Safety Data Sheet available from Edwards Lifesciences. To maintain proper valve leaflet coaptation, do not overinflate the deployment balloon. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis. Patient venous anatomy should be evaluated to prevent the risk of access that would preclude the delivery and deployment of the device. Patient should be heparinized to maintain the ACT at $\geq$ 250 sec prior to introduction of the delivery system in order to prevent thrombosis. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: Blood dyscrasias defined as: leukopenia, acute anemia, thrombocytopenia, or history of bleeding diathesis or coagulopathy. A known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid™), or clopidogrel (Plavix™), or sensitivity to contrast media, which cannot be adequately premedicated. Positive urine or serum pregnancy test in female subjects of child-bearing potential. Residual mean gradient may be higher in a "THV-in-failing bioprosthesis" configuration than that observed following implantation of the valve inside a native annulus using the same size device. Patients with elevated mean gradient post procedure should be carefully followed. It is important that the manufacturer, model and size of the preexisting bioprosthetic valve be determined, so that the appropriate valve can be implanted and a prosthesis-patient mismatch be avoided. Additionally, pre-procedure imaging modalities must be employed to make as accurate a determination of the inner diameter as possible.

Potential Adverse Events: Potential risks associated with the anesthesia, interventional procedure and imaging include but are not limited to: death; stroke/transient ischemic attack; respiratory insufficiency or respiratory failure; cardiovascular or vascular injury, such as perforation or damage (dissection) of vessels, myocardium or valvular structures including rupture of the RVOT that may require intervention; pericardial effusion/cardiac tamponade; embolic event: air, calcific material, thrombus, device fragments; infection including incisional site infection, septicemia and endocarditis; myocardial infarction; renal insufficiency or renal failure; conduction system injury, arrhythmia, arteriovenous (AV) fistula; systemic or peripheral nerve injury, systemic or peripheral ischemia, pulmonary edema, pneumothorax, pleural effusion, atelectasis; blood loss requiring transfusion; anemia; radiation injury; electrolyte imbalance; hypertension or hypotension; allergic reaction to anesthesia, contrast media, antithrombotic therapy, device materials; hematoma or ecchymosis, syncope, pain, exercise intolerance or weakness, inflammation; angina; fever; cardiac failure. Potential risks associated with the valve, delivery system and/or accessories include, but may not be limited to, the following: cardiac arrest; cardiogenic shock; coronary flow obstruction/transvalvular flow disturbance, device thrombosis requiring intervention; injury to tricuspid valve; device embolization requiring intervention; device acute migration or malposition requiring intervention; endocarditis; hemolysis / hemolytic anemia; THV dysfunction resulting in pulmonary valve symptoms; mechanical failure of delivery system, and/or accessories; emergent and non-emergent re-intervention; dyspnea.

Edwards Crimper

Indications: The Edwards crimper is indicated for use in preparing the Edwards SAPIEN 3 transcatheter heart valve for implantation.

Contraindications: There are no known contraindications.

Warnings: The device is designed, intended, and distributed for single use only. **Do not resterilize or reuse the device.** There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing. Do not mishandle the device. Do not use the device if the packaging or any components are not sterile, have been opened or are damaged, or the expiration date has elapsed.

Precautions: For special considerations associated with the use of the Edwards crimper prior to THV implantation, refer to the THV Instructions for Use.

Potential Adverse Events: There are no known potential adverse events associated with the Edwards crimper.

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician.

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