First-in-man implantation of Edwards Sapien 3 valve in BioIntegral Biopulmonic valve

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Case Presentation

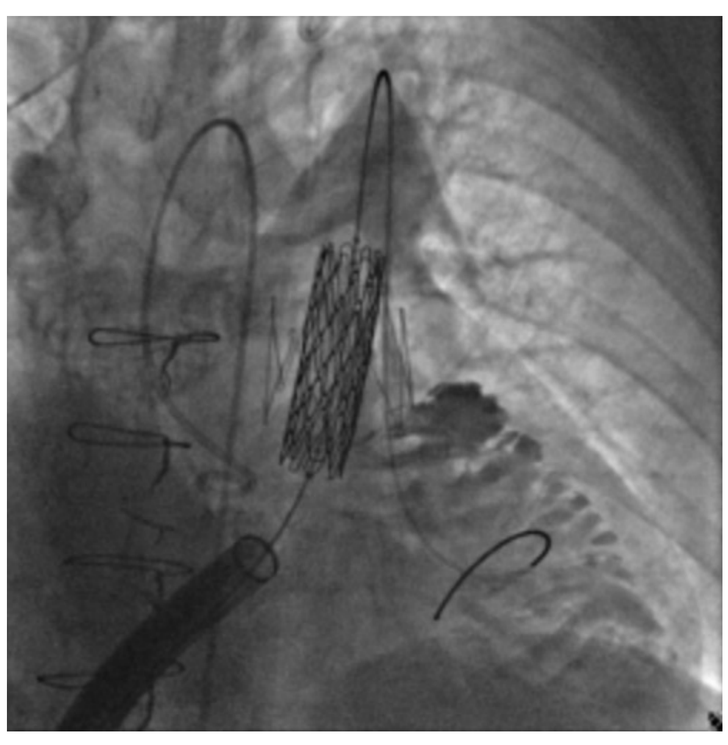
A 42-year-old female with **tetralogy of Fallot** underwent total correction at the age of one with a transannular patch of the pulmonary valve. Twenty-eight years later, she had an injectable **bioprosthesis** (**BioIntegral Biopulmonic n° 27**) surgically inserted (off-pump) in the **pulmonary** position due to pulmonary valve insufficiency. Subsequent well-being with regular cardiological follow-up and one pregnancy delivered at term without complications. Thirteen years later she was referred to our outpatient clinic for exertional dyspnea.

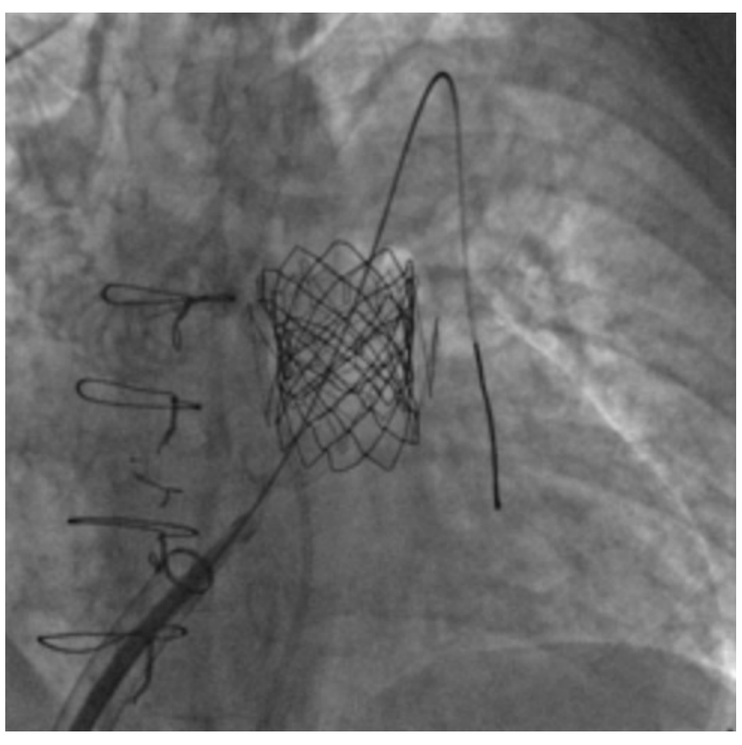
Diagnostic workup

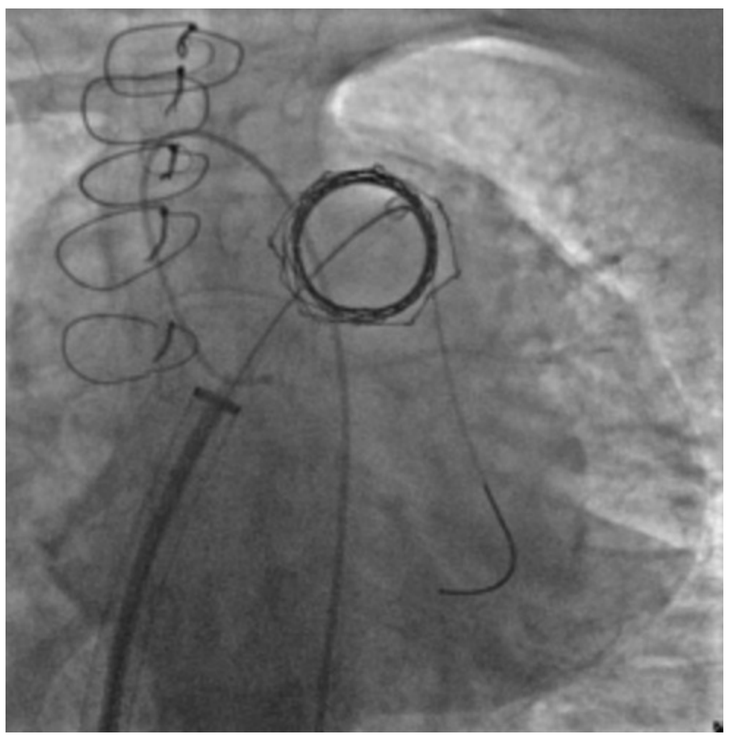
At physical examination, the patient had a 4/6 systolic ejection murmur. Transthoracic echocardiography revealed severe transprostethic stenosis (mean gradient 50 mmHg – maximum gradient 78 mmHg). Based on the clinical and instrumental assessment, the patient was deemed suitable **for valve-in-valve transcatheter pulmonary valve replacement** (TPVR). Cardiac CT confirmed the presence of pulmonary stenosis and guided **sizing** for transcatheter **pulmonary valve** replacement.

Therapeutic workup and outcome

A **45 mm covered stent** (Numed-CP stent) pre-mounted on a 26 mm balloon-in-balloon catheter was placed in BioIntegral pulmonary valve preparing a **landing zone** and covering calcification. CP stent was then post-dilatated with a Bard Atlas Gold 26 mm at 10 atm. An **Edwards Sapien 3 26 mm** pulmonary valve was advanced through a Dry Seal 26F and correctly implanted (inflated nominal+1ml). Pressure gradient and pulmonary angiography showed no regurgitation and no residual stenosis. Coronary angiography was done at baseline, after stenting and also after pulmonary valve implantation to exclude coronary compression. The post-operative period was uncomplicated and the patient experienced **complete symptomatic resolution**. Follow-up echocardiography at one month showed normal prosthetic function (peak gradient 18 mmHg) with no sign of pulmonary valve insufficiency.







Take-home messages

In this setting **TPVR** is widely accepted as an alternative to surgery. **This is the first report of percutaneous Edwards Sapien 3 valve-in-valve implant in Biointegral Biopulmonic injectable valve**. We documented the safety and efficacy of such procedure prior CP stent placement**.**