

# Attempt at Off-Label Balloon Valvuloplasty Post-Dilation for Intuity Sutureless Valve

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## Abstract

Alternatives to traditional aortic valve replacement now form part of the valve surgeon's armamentarium. Sutureless valves offer decreased bypass and crossclamp times, excellent maneuverability, and promising outcomes. We present a case of a sutureless aortic valve replacement for a late failed David procedure, complicated by post-operative development of severe paravalvular regurgitation. We attempted off-label balloon post-dilation to improve expansion of the valve, however paravalvular regurgitation persisted. The patient underwent subsequent aortic valve replacement using a mechanical valve and experienced no further paravalvular leak.

## INTRODUCTION

With the emergence of novel technologies for aortic valve disease, the sutureless aortic valve has come to the fore as an alternative to traditional aortic valve replacement (AVR). Sutureless valves facilitate the implementation of minimally invasive surgical approaches such as an upper mini-sternotomy or right anterior mini-thoracotomy,<sup>1</sup> and have shorter associated crossclamp and cardiopulmonary bypass times.<sup>2</sup> However, paravalvular leak (PVL) is a potential consequence for which no generally accepted therapeutic approach exists. We present a case of an unsuccessful balloon valvuloplasty post-dilation (BVPD) in a patient who developed moderate-to-severe PVL following sutureless AVR.

## CASE REPORT

A 34-year-old man with Marfan syndrome underwent a David procedure in 2006 for an 8.6 cm ascending aortic aneurysm, complicated by excessive bleeding requiring a Cabrol fistula. One decade later, he presented with worsening dyspnea. Transthoracic echocardiography revealed severe mitral regurgitation (MR) and mild aortic regurgitation requiring repeat full sternotomy for surgical repair.

Intraoperative transesophageal echocardiography (TEE) additionally showed severe aortic regurgitation and mitral valve leaflet prolapse. The patient underwent right axillary arterial cannulation with dual-stage femoral venous cannulation given the sternal proximity of the previous Cabrol fistula. Following complex mitral valve repair, the aortic valve was opened revealing severe adhesions along the aortic root secondary to the previous Cabrol shunt. Given limited access for safe suture placement and already prolonged bypass time, we elected to use the sutureless Edwards Intuity valve (Edwards Life Sciences Corporation, California, United States). After valve leaflet removal, the left ventricular outflow tract was sized and a 27-mm Intuity valve was selected. Guiding sutures were placed in the nadir of each cusp remnant, through the sewing cuff of the valve, and the valve was deployed. The attached balloon was inflated to 5 atmospheres of pressure for 10 seconds. Visual inspection demonstrated proper deployment. The patient was weaned easily off bypass and post-bypass TEE demonstrated mild aortic PVL and minimal MR.

The patient came back to the intensive care unit in a stable condition and was extubated. All vasopressors were weaned within 24 hours. On post-operative day (POD) 2, the patient's bloodwork revealed ongoing intravascular hemolysis. Transthoracic Echocardiogram showed moderate-to-severe PVL circumferentially halfway around the valve. By POD 3 the patient showed no signs of improvement and re-intervention appeared warranted.

In light of the patient's complex aorta's root anatomy, we elected to proceed with the less invasive percutaneous approach as our first-line strategy. The PVL was too large to attempt an Amplatzer Septal Occluder device (St. Jude Medical, Minnesota, United States), therefore off-label BVPD was attempted with a 30-mm Z-MED II balloon (B. Braun Medical, Melsungen, Germany) via the femoral artery. The procedure was performed with appropriate flaring of the valve's skirt component (Figure 1), but without improvement in PVL.

On POD 4 the patient continued to hemolyze necessitating surgical re-operation. Aortic root inspection revealed a peri-annular gap extending across a third of the valve's circumference toward the non-coronary sinus area. We replaced the valve with a 27-mm On-X Mechanical Valve (CryoLife, Georgia, United States). Post-bypass TEE showed a well-functioning prosthesis without PVL. His post-operative course was uneventful and he was discharged 12 days after the initial operation.

## COMMENT

Sutureless valves offer advantages in operative approach and time, however rates of PVL range from 0.5 to 15.8% and no clear consensus currently exists regarding management of this complication.<sup>2, 3</sup> We report a case of an Intuity sutureless AVR complicated by post-operative moderate-to-severe PVL causing persistent hemolysis. Subsequent BVPD was attempted in anticipation of expanding the valve's skirt component but was unsuccessful in eliminating PVL.

Transcatheter AVR (TAVR) has the highest rate of PVL among AVR modalities<sup>3</sup> leading to clear recommendations in management. Two strategies, BVPD and deployment of a second transcatheter valve, "valve-in-valve", have independently been shown to reduce PVL and improve overall survival.<sup>4</sup> BVPD is warranted when PVL is moderate-or-greater and may reduce residual regurgitation by 75.6% in select patients.<sup>5</sup>

Less literature exists regarding management of PVL following sutureless AVR. Surgical techniques are described for removal and reimplantation of a supra-annular malpositioned Perceval sutureless valve (LivaNova, London, United Kingdom).<sup>6</sup> Two cases successfully used BVPD intra-operatively for PVL, but differ from this case in their direct access through the aortotomy.<sup>7, 8</sup> Another study showed elimination of PVL on POD8 using BVPD in a Perceval sutureless valve.<sup>9</sup> The only report of post-operative BVPD in an Intuity valve was 6 months after initial implantation.<sup>10</sup> Alternatively, valve-in-valve for PVL in sutureless valves poses theoretical risks of valve instability and dislocation, and is not routinely performed.<sup>11</sup>

In conclusion, despite widespread use of sutureless valves, appropriate therapeutic modalities for PVL are largely undescribed. To our knowledge, we are the first to report an attempted BVPD in an Intuity valve for post-operative PVL, and the only group to describe a failure of BVPD in the sutureless population. Although potentially beneficial, a word of caution is important as both the success rate and the complications remain largely unknown. Further case reports documenting successful and unsuccessful treatment attempts are necessary to inform surgical decision making.

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## DISCLOSURES

No conflicts of interest to disclose.

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## FIGURE LEGENDS

**Figure 1** : Balloon valvuloplasty fluoroscopy. A) Inflation of the 30mm Z-MED II balloon in the sutureless valve, with B) appropriate flaring of valve's skirt component.

