*Case Reports*

# Percutaneous Valvuloplasty for Bioprosthetic Tricuspid Valve Stenosis

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*Percutaneous transcatheter tricuspid balloon valvuloplasty (PTTBV) is an accepted treatment option for symptomatic severe native tricuspid valve stenosis, although surgical tricuspid valve replacement remains the treatment of choice. There have been few reports of successful PTTBV for bioprosthetic tricuspid valve stenosis. We present case reports of 3 patients from our hospital experience. Two of the 3 cases were successful, with lasting clinical improvement, whereas the 3rd patient failed to show a reduction in valve gradient. We describe the standard technique used for PTTBV. We present results from a literature review that identified 16 previously reported cases of PTTBV for bioprosthetic severe tricuspid stenosis, with overall favorable results. We conclude that PTTBV should perhaps be considered for a select patient population in which symptomatic improvement and hemodynamic stability are desired immediately, and particularly for patients who are inoperable or at high surgical risk.* ***(Tex Heart Inst J 2017;44(1):43-9)***

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Severe tricuspid valve stenosis (TS) is associated with a mean gradient across the tricuspid valve (TV) of at least 5 mmHg, a calculated TV area of less than 1 $cm^2$, or both.[1] Patients with TS usually present with low-cardiac-output state, syncope or presyncope, and signs consequent to elevated right atrial pressures, such as hepatomegaly, anasarca, lower-extremity edema, and ascites. In a patient with symptomatic TS, intervention should be considered: the American College of Cardiology/American Heart Association 2014 valvular heart disease guidelines give surgical replacement a class I recommendation for both tricuspid bioprosthetic and native-valve stenosis. Percutaneous transcatheter tricuspid balloon valvuloplasty (PTTBV) can be considered in patients with severe, symptomatic, native TS without tricuspid regurgitation (TR), as a class IIb guideline indication.[1] It is less preferable than surgery, because most cases of severe TS have concurrent TR that might worsen after balloon dilation. In addition, there are insufficient data on the long-term outcomes of patients undergoing PTTBV. Data on PTTBV in patients with bioprosthetic TS are more limited still, consisting of isolated case reports. Nonetheless, bioprosthetic PTTBV can be an appropriate consideration for patients who are not surgical candidates or are at high risk of surgery because of comorbidities, and who have mild TR. We present herein case reports of 3 patients, as well as a comprehensive compilation and review of previous cases from the literature.

## Case Reports

### Patient 1

A 47-year-old man presented with symptoms of exertional presyncope and right-sided heart failure. His history was significant for severe familial cardiomyopathy, for which he had undergone orthotopic heart transplantation at the age of 34 years.[2] The patient had then developed severe TR, attributed to valve damage by multiple endomyocardial biopsies, and at age 38 had undergone TV replacement with use of a Carpentier-Edwards bioprosthesis (Edwards Lifesciences LLC; Irvine, Calif).

The patient remained asymptomatic until his current presentation. Transthoracic echocardiography revealed TS with a mean transvalvular gradient of 10 mmHg. The patient refused surgical TV replacement, and was considered at increased risk because

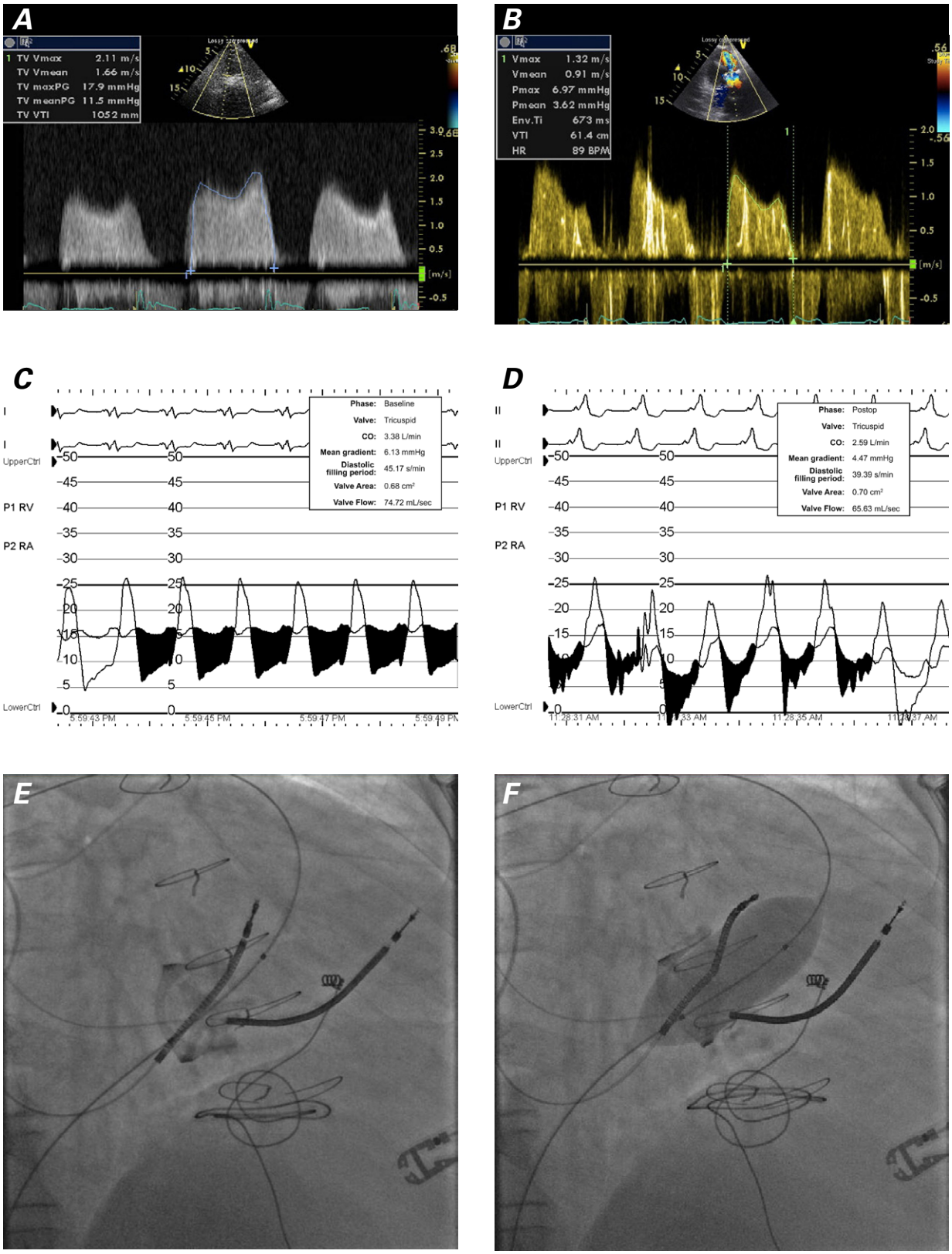


***Fig. 1*** *Patient 2. Transthoracic echocardiograms show peak and mean transvalvular gradients across the tricuspid valve of* ***A****) 18 and 12 mmHg before valvuloplasty and* ***B****) 7 and 4 mmHg after valvuloplasty, respectively. Tracings from a Swan-Ganz balloon-tipped catheter, which was floated through the bioprosthetic tricuspid valve to measure right atrial and right ventricular pressures simultaneously, showed mean tricuspid valve gradients of* ***C****) 6 mmHg before valvuloplasty and of* ***D****) 4 mmHg after valvuloplasty. Fluoroscopic images show* ***E****) wire placement and* ***F****) the Tyshak-X balloon fully inflated across the tricuspid valve.*

this would have been his 4th sternotomy; he was offered PTTBV. Invasive hemodynamic studies showed a reduction of transvalvular gradient from 9 to 4 mmHg after PTTBV. We originally published this case elsewhere[2]; because of the emergence of new details, we are including it in this case series. The patient had marked improvement in symptoms for almost 2 years; however, he eventually presented again with symptoms of TS and was again treated successfully by PTTBV. If the second PTTBV fails, we plan to perform transcatheter heart valve-in-valve implantation in the future.

### Patient 2

A 60-year-old man presented with a 6-month history of exertional syncope and hypotension. He had a history of Ebstein anomaly and had undergone TV replacement with a 33-mm Ionescu-Shiley xenograft in 1982, when atrial septal defect repair was performed concurrently.

In 2006, a cardioverter-defibrillator had been implanted for high-grade heart block and left ventricular systolic dysfunction. Physical examination was notable for central plethora and cyanosis, which improved with supplemental oxygen. Transthoracic echocardiography revealed moderate left ventricular dysfunction and severe TS, with a mean transvalvular gradient of 12 mmHg (Fig. 1A), which dropped to 4 mmHg after PTTBV (Fig. 1B). Right-sided heart catheterization confirmed severe TS with a mean gradient of 6 mmHg across the bioprosthetic TV (Fig. 1C), which decreased to 4 mmHg after PTTBV (Fig. 1D). Fluoroscopic images were obtained during PTTBV to guide wire placement and balloon inflation (Figs. 1E and F). The patient noted immediate resolution of his symptoms and was discharged from the hospital on the day after the procedure. He subsequently did well and 6 months later tolerated general anesthesia for uneventful femoral fracture repair.

### Patient 3

A 65-year-old woman presented with septic shock and recurrent worsening pedal edema. She had a history of heart failure with preserved ejection fraction and of 31-mm Carpentier-Edwards bioprosthetic TV implantation, performed 13 years before her current presentation for severe TR. She had signs of right-sided heart failure, anasarca, and acute kidney injury. Her medical history included human immunodeficiency virus and hepatitis C infection. Transthoracic echocardiograms revealed severe bioprosthetic TS, with a mean gradient of 14 mmHg, and moderate TR. During the course of hospitalization, she was treated with antibiotics for sepsis and with hemodialysis for persistent renal failure. She was deemed to be at excessive surgical risk. Upon right-sided heart catheterization, the mean transvalvular gradient was 8 mmHg, which remained unchanged despite PTTBV (Fig. 2). The patient eventually recovered renal function, was restarted on diuretic agents, and was discharged to a rehabilitation facility for continued care on intravenous antibiotics. She was later admitted multiple times with heart-failure exacerbations that necessitated intravenous diuretic agents.

### Percutaneous Valvuloplasty Technique

The same PTTBV technique was used in all 3 patients. The procedures were performed through the right common femoral vein. A Swan-Ganz balloon-tipped catheter was floated through the bioprosthetic TV and right ventricle to the pulmonary artery, in order to ensure free passage through the right ventricle. A 300-cm, 0.018-in guidewire was introduced through the Swan-Ganz catheter to the distal pulmonary artery, and the Swan-Ganz was then removed and exchanged for a multipurpose catheter. The 0.018-in guidewire was then withdrawn and replaced with an Amplatz Extra-Stiff™ 0.035-in J-tipped wire that was used for

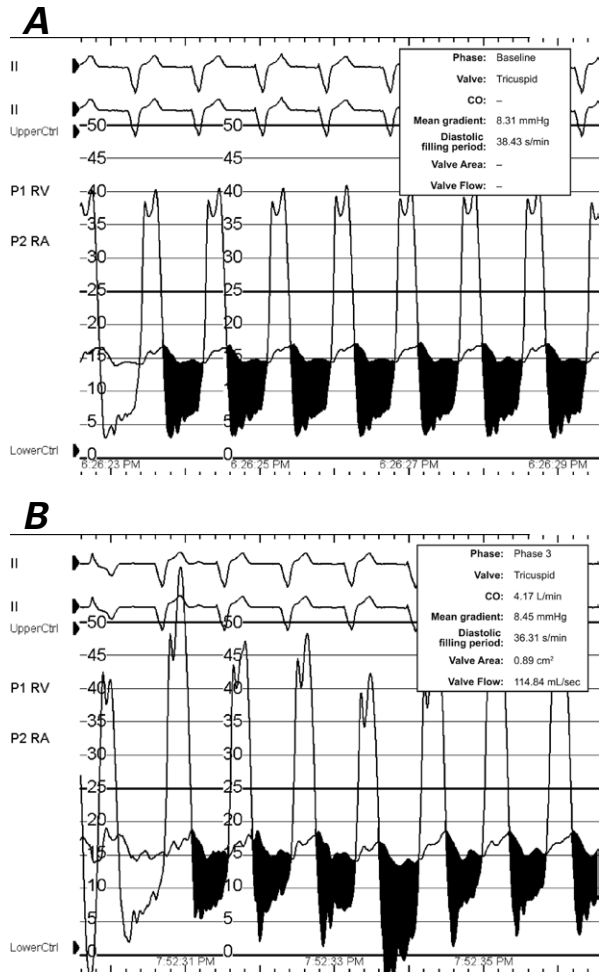


***Fig. 2*** *Patient 3. Tracings from a Swan-Ganz balloon-tipped catheter, floated through the bioprosthetic tricuspid valve to measure simultaneous right atrial (RA) and right ventricular (RV) pressures, show mean tricuspid valve gradients of* ***A****) 8 mmHg before and* ***B****) after valvuloplasty.*

**TABLE I.** Reported Cases of PTTBV in Bioprosthetic Tricuspid Valve Stenosis

| Reference | Age (yr), Sex | Years Since Valve Implantation | Mean Transvalvular Gradient (mmHg) | | Balloon Type, Size (mm) | Immediate Success, Hospital Complications/ Sequelae | Outcomes and Follow-Up |
|---|---|---|---|---|---|---|---|
| | | | Before PTTBV | After PTTBV | | | |
| Feit F, et al.[3] (1986) | 46, M | 10 | 22 | 15 | Meditech, 20 | Yes, none | NA |
| Wren C and Hunter S[4] (1989) | 19, F | 6 | 9 | 5 | Mansfield, 20 | Yes, none | Restenosis in 3 mo; repeat PTTBV with positive results for 3 mo |
| Chow WH, et al.[5] (1990) | 67, F | 7 | 6 | 2.5 | Cook, 23 | Yes, minimal tricuspid regurgitation, none | 6 mo without complications |
| Attubato MJ, et al.[6] (1990) | 35, F | 9 | 11 | 6 | Double balloons (Mansfield, 20; Mansfield, 15) | Yes, none | NA |
| | 29, F | 2 | 8 | 4 | Double balloons (Mansfield, 20; Mansfield, 15) | Yes, none | NA |
| Benedick BA, et al.[7] (1990) | 37, F | 11 | 21 | 7 | Double balloons (Cook, 15; Cook, 15) | Yes, none | Critically ill before PTTBV and initially improved postprocedure; had fatal cerebral hemorrhage on hospital day 14 |
| Slama MS, et al.[8] (1993) | 38, F | 9 | 8 | 4 | Double balloons (Trefoil, 10; Schneider Shiley, 15) | Yes, none | No change in valve area 14 mo after PTTBV; developed right atrial thrombus, prompting repeat valve replacement |
| | 66, F | 8 | 10 | 4 | Double balloons (Trefoil, 10; Schneider Shiley, 15) | Yes, none | Stable low gradients for 16 mo but subsequent symptomatic recurrence necessitating valve replacement |
| MacGregor JS, et al.[9] (1994) | 31, F | 0.5 | 14 | 4 | Mansfield, 20 | Yes, none | Palliative procedure in presence of tricuspid endocarditis with large vegetation; hemodynamically improved after PTTBV but died of sepsis on hospital day 11 |
| Block PC, et al.[10] (1994) | 49, F | 9 | 12 | 4 | Double balloons (NA, 20 and 15) | Yes, none | 10-mo follow-up with excellent results |
| | 42, F | 5 | 10 | 2 | Double balloons (NA, 20 and 15) | Yes, none | 6 mo after valvuloplasty, patient had recurrent symptoms, necessitating surgical valve replacement |
| Egred M, et al.[11] (2006) | 72, F | 19 | 12 | 5 | NA, sequential dilation with 15, 25, and 30 balloons | Yes, none | No symptoms during unspecified follow-up period |
| Yunoki K, et al.[12] (2006) | 59, F | 22 | 14 | 6 | NA, 25 | Yes, none | NA |
| Burstow DJ, et al.[13] (2006) | 52, F | 2.2 | 18 | 6 | Inoue, sequential dilation (24, 26, and 28) | Yes, none | NA |

*Continued on next page*

**TABLE I continued.** Reported Cases of PTTBV in Bioprosthetic Tricuspid Valve Stenosis

| Reference | Age (yr), Sex | Years Since Valve Implantation | Mean Transvalvular Gradient (mmHg) | | Balloon Type, Size (mm) | Immediate Success, Hospital Complications/ Sequelae | Outcomes and Follow-Up |
|---|---|---|---|---|---|---|---|
| | | | Before PTTBV | After PTTBV | | | |
| Petrou E, et al.[14] (2014) | 73, M | 40 | 13 | 6 | Inoue, 15 | Yes, none | Patient died 2 yr later after long stay in intensive care unit with pulmonary hemorrhage |
| Reddy G, et al.[15] (2015) | 29, M | 2 | 16 | 12 | Nucleus-X, 25 | Yes, none | 6-wk follow-up with excellent results |
| Rana G, et al.[2] (2015) | 47, M | 9 | 9 | 4 | Tyshak, 25 | Yes, none | 1 yr without symptoms |
| Current case | 60, M | 32 | 6 | 4 | Tyshak, 25 | Yes, none | 6 mo without sequelae |
| Current case | 65, F | 10 | 8 | 8 | Tyshak, 25 | No, none | No reduction in gradient |

F = female; M = male; NA = not available; PTTBV = percutaneous transcatheter tricuspid balloon valvuloplasty

the PTTBV after removal of the multipurpose catheter (Fig. 1E). A 25-mm × 4-cm Tyshak-X™ Percutaneous Transluminal Valvuloplasty Catheter (NuMED Inc.; Hopkinton, NY) was used in all 3 patients (Fig. 1F).

### Literature Search

Two authors (GR and RM) undertook an electronic literature search using PubMed, Medline®, and Google Scholar for case reports of PTTBV, with search-term combinations that included tricuspid valve, valvuloplasty, valvotomy, balloon, prosthetic, bioprosthetic, transcatheter, and percutaneous. We excluded reports of PTTBV on native TVs. We imposed no date restrictions; only articles in English were reviewed. We identified 14 articles regarding intervention for degenerated bioprosthetic TVs, which had been published in journals from 1980 through 2014. We extracted data points from the published articles for patient demographics, indications, symptoms, pressures pre- and postvalvuloplasty, the binary acute success of the procedure, and long-term survival information if available. Table I shows our findings.[2-15]

## Discussion

Percutaneous transcatheter balloon valvuloplasty for bioprosthetic TV stenosis is not performed as often as it is in other bioprosthetic valves.[16] Herein we present reports of 3 cases performed at our hospital and a comprehensive compilation of previously reported cases of this procedure. Bioprosthetic valve dysfunction or obstruction usually results from leaflet calcification, thrombosis, pannus ingrowth, or vegetation. Balloon valvuloplasty works by tearing leaflets, fracturing calcium, and perforating cusps, as seen in vitro, in studies performed on valves in the mitral position.[17] Our findings suggest that PTTBV might well be a viable procedure for the alleviation of bioprosthetic TV stenosis.

In our literature review, we identified 16 cases of PTTBV. The age of patients who underwent PTTBV ranged from 19 to 73 years (mean age, 48.2 ± 6.2 yr), with no reported difference in immediate outcomes for each tertile age group. There were mean pressure gradient improvements and symptomatic benefits in all the case reports identified in the available literature. The mean preprocedural pressure gradient was 12 mmHg. After PTTBV, the gradient improved to an average mean residual of 7 mmHg. All patients with successful reduction of transvalvular gradient also had immediate postprocedural symptomatic improvement. Although objective data quantifying the symptoms is not available in many of the case reports, most patients were reported to have presented with severe dyspnea, orthopnea, and pedal edema before intervention and to have experienced postprocedural improvement in those symptoms. For some patients the good effects lasted as long as 16 months,[8] whereas in others those effects lasted only a few months, necessitating a repeat PTTBV procedure or TV replacement. The only unsuccessful procedure was the one in our 3rd patient. There were no major procedure-related sequelae reported; 3 patients died of pre-existing severe comorbid conditions, including sepsis.[7,9,14]

A variety of interventional techniques were used in the cases identified in our literature review. Nine patients (47%) had single balloons, whereas 7 (37%) had double balloons.[6-8,10] In 2 cases (16%), sequential dilation with balloons of increasing sizes was performed.[11] Neither single- nor multiple-balloon techniques led to severe valvular regurgitation in the immediate postprocedural period. Long-term follow-up data, when available, did, however, identify cases of restenosis.[4,8] Wren

and Hunter[4] observed an immediate gradient reduction and clinical improvement in their 19-year-old patient, but also reported restenosis at 3 months that necessitated repeat valvuloplasty. This was followed by recurrence of symptoms and stenosis at 6 months, at which point no further valvuloplasty was attempted. The valve was eventually replaced surgically and was found to have calcific deposits on both atrial and ventricular surfaces.[4] On the other hand, Slama and colleagues[8] reported a similar acute symptomatic improvement after PTTBV, followed by recurrence of stenosis and symptoms, which was treated with valve replacement at 16 months; a pathologic study of the bioprosthetic valve showed predominantly fibrous and slightly calcific changes on the valve cusps. Of note, both groups[4,8] also reported a right atrial thrombus as a PTTBV sequela. The data regarding anticoagulation management are not available, but it can be hypothesized that increased stasis—caused by recurrent severe stenosis—leads to a prothrombotic state in the right atria of patients who might have sustained endothelial damage from instrumentation during the PTTBV procedure.

It is worth noting that there have been no randomized controlled trials to prove the efficacy of PTTBV. Although these case reports suggest that PTTBV for stenosis of bioprosthetic TVs is effective and is associated with low morbidity, isolated case reports almost certainly carry a degree of publication bias. It is conceivable that PTTBV has been performed in a multitude of patients who had less favorable results, reports of which were not presented or not accepted for publication. One of our 3 patients failed to gain hemodynamic or symptomatic benefit from the procedure. Further evidence is required before we can recommend PTTBV as a frontline therapy for such patients; in the meanwhile, surgical correction of stenosed bioprosthetic valves remains the preferred method of treatment. Finally, transcatheter implantation of a valve-in-valve for a failed tricuspid bioprosthesis—using either commercially available aortic transcatheter heart valves or dedicated devices[18,19]—might prove an appropriate option for highly selected patients.

## Conclusion

On the basis of our own experience and these supplemental case reports, we conclude that PTTBV is reasonable to consider as a bridge to eventual TV replacement in high-risk patients, with the aim of effecting symptomatic short-term improvement. In patients who are gravely ill with comorbidities, PTTBV can be used as a palliative option to relieve symptoms and obtain some hemodynamic stability. It may also be considered for use in patients at high risk of morbidity and death from repeat sternotomy, who can benefit from PTTBV in the short-to-medium term. Successful PTTBV often leads to significant transvalvular pressure gradient reduction and to acute decreases in right atrial pressure. As seen in most of these reports, a significant increase in tricuspid regurgitation is an uncommon result of PTTBV. Single-balloon dilations might be as effective as double-balloon dilations, with the advantage of procedural simplicity.

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