



## Case Series

# VERSATILITY OF THE ACCURA BALLOON FOR PULMONARY VALVOTOMY ACROSS THE AGE SPECTRUM: A FIVE-PATIENT EXPERIENCE: A CASE SERIES

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### ABSTRACT

**Background:** Severe valvular pulmonary stenosis (PS) presenting beyond childhood is uncommon and technically challenging due to large annular dimensions, dysplastic or calcified leaflets, and suboptimal performance of conventional low-pressure balloons. The Accura balloon—originally designed for percutaneous mitral commissurotomy—offers high-pressure inflation, predictable waist formation, and enhanced stability, which may be advantageous in such anatomies.

**Materials and Methods:** We report **five cases** of severe valvular PS across a wide age spectrum: an adult with a large annulus,<sup>[1]</sup> an elderly patient with calcified PS, right ventricular (RV) dysfunction and secundum atrial septal defect (ASD),<sup>[2]</sup> a low-weight child with combined PS and ASD,<sup>[3]</sup> a young female with severe PS and large ASD undergoing BPV followed by device closure<sup>4</sup>, and a young adult with large-annulus PS<sup>5</sup>. In all cases, conventional balloons were ineffective or unsuitable, and balloon pulmonary valvotomy (BPV) was performed using the Accura balloon.

**Results:** In all five cases,<sup>[1-5]</sup> Accura balloon valvotomy achieved clear waist formation with complete disappearance at peak inflation, resulting in significant reduction of transvalvular gradients and stable hemodynamics without major complications. The balloon was effective in large annuli (24–25 mm), fibrotic or calcified valves, and complex scenarios including staged and combined BPV with ASD closure.

**Conclusion:** The Accura balloon is a feasible, safe, and effective option for BPV in resistant, large-annulus, calcified, or complex pulmonary valve anatomy across age groups,<sup>[1-5]</sup> serving as a valuable bailout and selective primary device when conventional balloons fail.

**Keywords:** Accura balloon, balloon pulmonary valvotomy, pulmonary valve stenosis, transcatheter intervention, congenital heart disease.

## INTRODUCTION

Balloon pulmonary valvotomy (BPV) is the treatment of choice for severe valvular pulmonary stenosis. Standard balloons (Tyshak, Z-Med, Mammoth) perform reliably in children and young adults; however, technical limitations arise in

patients with large annuli, dysplastic valves, or calcific leaflets—conditions common in adults and elderly individuals. The Accura balloon, though designed for percutaneous mitral commissurotomy, provides high-pressure inflation, large sizes, controlled waist formation, and enhanced stability, making it a valuable rescue or primary tool in PS

with unfavourable anatomy. This case series highlights three successful uses of the Accura balloon after failure or limitation of conventional devices.

**Case 1: Severe Valvular PS with large annulus in an adult:** A 42-year-old male presented with exertional dyspnea (NYHA III). Echocardiography shown severe valvular PS (peak gradient 110 mmHg), calcified thick leaflets, annulus 24–25 mm. Procedure done under local anaesthesia, RFV access was established. Conventional balloon attempt with Tyshak II 20 × 40 mm and 22 × 40 mm produced inadequate waist formation. An Accura 26-mm balloon was advanced over a 0.035" extra-support wire. Stylet removed as per Accura protocol. Inflation produced a clear waist which disappeared at peak pressure. Post-BPV gradient reduced dramatically. No complications.

**Case 2: 71-Year-Old Male with Severe PS, Calcified Valve, ASD, RV Dysfunction:** This patient presented with exertional dyspnea and atrial fibrillation. Investigations shown AF on ECG and echocardiography shown dilated RA/RV, calcified pulmonary valve with severe PS and mild AS/MR/AR, moderate TR, and secundum ASD 2 cm. Peak gradient across pulmonary valve was 72 mmHg (velocity 3.8 m/s). Cardiac CT shown left PA aneurysm 5.8 cm; calcified pulmonary valve. Severe PH was attributed to valvular PS with left-to-right shunt across ASD. RV systolic dysfunction was present. The patient was started on optimal medical therapy (ACE inhibitor + diuretics) after BPV and advised for elective ASD closure after RV recovery due to the risk of acute RV failure.

Procedure done from Right femoral venous access (7F). A Mammoth 20 × 40 mm balloon got ruptured at 6 atm with no gradient reduction. A 26-mm Accura balloon was positioned; two inflations achieved complete waist formation and disappearance. RV pressure fell significantly. Patient remained stable and was discharged on medical therapy with follow-up ASD closure as planned.

**Case 3: Severe Pulmonary Stenosis with Large Ostium Secundum ASD in a 13-kg Child:** A 3.5-year-old girl (13 kg) had an 18-mm secundum ASD and severe valvar PS with a peak gradient of 74 mmHg. She had progressive right-sided dilation and mild PAH. Procedure done under general anaesthesia, RFV and LFA access were obtained through 5F sheaths. A 5F MPA catheter was advanced sequentially into the left pulmonary artery. An Amplatz superstiff wire was positioned, and an 18×40-mm Maxi LD balloon was used for initial BPV, showing minimal gradient reduction. A 20-mm Accura balloon was then introduced and inflated, producing effective commissural splitting with gradient reduction to 23 mmHg. There was no pulmonary regurgitation, perforation, effusion, or arrhythmia.

BPV was followed by ASD closure, ASD sizing confirmed an 18-mm stretched diameter. A 22-mm

Lifetech ASD device was deployed under LAO/cranial fluoroscopic view and echocardiographic guidance. Position was stable with no residual shunt.

The child was extubated, transferred to ICU, and discharged with in a stable condition. This case highlights simultaneous BPV and ASD closure in a low-weight child—a rarely reported combination.

**Case 4: Severe Pulmonary Stenosis With Large Secundum ASD in a Young Female.**<sup>[4]</sup>

A 20-year-old female presented with dyspnea on exertion for 2 months. ECG showed right bundle branch block (RBBB). 2D Echocardiography revealed:

- Large secundum ASD (~34 mm) with left-to-right shunt
- Severe valvular pulmonary stenosis (peak gradient 91 mmHg)
- Dilated right atrium and right ventricle
- Moderate tricuspid regurgitation

BPV was performed under local anaesthesia via right femoral venous access (7F sheath). RV angiography was performed, and the pulmonary valve annulus measured to 24 mm.

A 24-mm Accura balloon was positioned across the pulmonary valve and inflated-deflated quickly, achieving complete waist formation and disappearance.

Pressure gradient across pulmonary valve reduced significantly.

Subsequently, ASD device closure was performed under ICE guidance using a 40-mm Lifetech device, with no residual shunt.

**Case 5: Severe Pulmonary Stenosis With Large Annulus in a Young Adult.**<sup>[5]</sup>

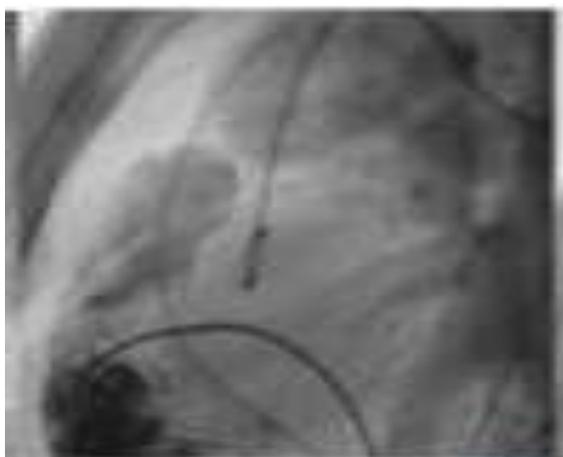
A 30-year-old patient presented with exertional dyspnea and was diagnosed with severe valvular pulmonary stenosis.

- Pulmonary valve annulus: 25 mm
- Peak Doppler gradient: 82 mmHg

BPV was performed using a 26-mm Accura balloon, resulting in effective commissurotomy with complete waist resolution. [Figure 6]

Post-procedure echocardiography demonstrated reduction of the peak gradient to 23 mmHg, with no procedural or post-procedural complications.

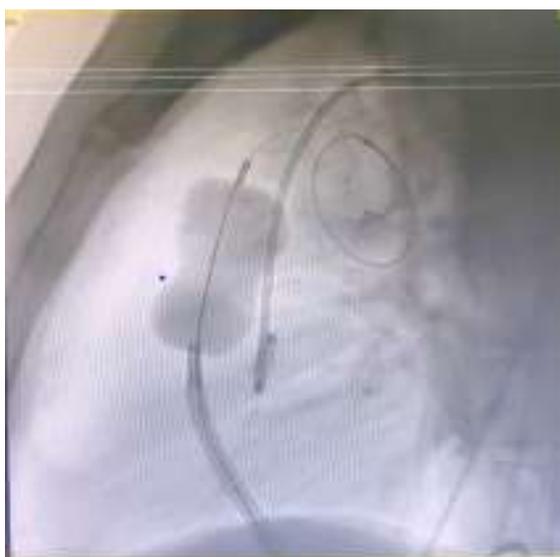
Image 1: Showing RV angiogram in LAO 90° projection



**Image 2: Showing inadequate dilatation of pulmonary valve by Tyshak II balloon**



**Image 3: Showing Accura balloon with waist formation across the pulmonary valve**



**Image 4: Showing Accura balloon with waist disappearance across the pulmonary valve**

## DISCUSSION

Severe valvular pulmonary stenosis (PS) presenting in adulthood or advanced age remains uncommon but technically challenging. The interplay of large annular dimensions, leaflet fibrosis, dysplastic morphology, and progressive calcification often renders standard low-pressure balloons insufficient for commissural splitting. Across both adult and pediatric PS literature, the predictors of a suboptimal balloon pulmonary valvotomy (BPV) remain consistent: low balloon-to-annulus ratio (BAR) leaflet rigidity, asymmetric fusion, and unfavourable right ventricular outflow tract (RVOT) geometry. In this context, the Accura balloon—though originally designed for percutaneous mitral commissurotomy—offers structural and biomechanical properties that directly address these limitations

Why Standard Balloons Fail in Adult and Elderly PS

1. **Inadequate Balloon-to-Annulus Ratio** Adult pulmonary annuli frequently measure 24–28 mm, surpassing the upper limits of standard balloons such as Tyshak or Maxi-LD, which often max out at 20–22 mm. A BAR <1.2 has repeatedly correlated with incomplete commissural disruption and persistent gradients (Kan et al.<sup>[1]</sup>). In Case 1 and Case 2, this mismatch was a major contributor to balloon rupture or inadequate dilation.
2. **Leaflet Rigidity: Fibrosis, Calcification, Dysplasia** Fibrotic and calcified pulmonary valves require substantially higher radial force for commissural splitting. Elderly patients exhibit progressive leaflet mineralization and reduced compliance, explaining why low-pressure balloons (Tyshak rated at ~2–3 atm) often fail to generate the required force. In Case 2, the Mammoth balloon ruptured at only 6 atm, highlighting insufficient burst tolerance.
3. **Geometric Instability and Slippage:** Adults have larger and more remodelled RVOT anatomies, leading to axial misalignment during balloon inflation. Standard balloons—completely compliant, thin-walled, and smooth—tend to slip out or migrate, especially during early inflation. This is a well-documented mechanism in adult BPV failure (Al-Hijji et al.<sup>[5]</sup>)
4. **Limited Ability to Treat Calcified Valves** Calcification drastically increases the commissural opening pressure. The predictable waist formation and controlled stepwise expansion of high-pressure balloons is more effective than the abrupt expansion of compliant devices.

### Biomechanical Advantages of the Accura Balloon:

The Accura balloon incorporates a multilayer, composite design optimized for controlled commissurotomy. Its key features directly address

the biomechanical limitations of conventional balloons:

1. High Burst Pressure (4–5 atm) Compared with the Tyshak’s lower burst threshold (~2–3 atm), the Accura tolerates higher pressures safely, enabling effective dilation of fibrotic or calcified adult valves. Sofi et al. demonstrated effective splitting without rupture in 43 adult patients (18–41 years).<sup>[2]</sup>
2. Predictable, Symmetric Waist Formation The hallmark of a successful commissurotomy is the progressive disappearance of the balloon waist during stepwise inflation. Accura balloons maintain a stable waist even in heavily calcified valves, as illustrated in Case 2, where clear waist formation and resolution were seen despite annular calcification.
3. Superior Stability and Reduced Slippage The balloon’s textured, double-layer surface and higher wall tension reduce migration. This stability is particularly important in tortuous RVOT geometries and in the elderly, where fluoroscopic landmarks may be distorted by post-stenotic dilatation.
4. Balloon Sizes Up to 30 mm Accura offers large diameters suitable for adult annuli—something conventional pediatric designed balloons cannot. This makes Accura the only reliable option when annuli approach 28–30 mm.
5. Compatibility with Standard Wires Unlike Inoue balloons, which require special guidewire systems and learning curves, Accura balloons track over standard 0.035” wires with minimal preparatory steps, simplifying use in unstable patients or resource-limited environments.
6. Utility as a Bailout Device Both cases in this series required the Accura only after failure of standard balloons, consistent with the recommendations of Adhikari et al,<sup>[4]</sup> who demonstrated Accura’s role as an effective bailout strategy when conventional balloons fail.

### Case-Specific Physiologic Implications

**Case 1 (42 years):** Fibrotic Valve, Large Annulus The annulus measured 24 mm, and the Tyshak

25×60 mm balloon ruptured early due to high leaflet resistance. Switching to the 28-mm Accura allowed successful high-pressure commissurotomy with predictable waist resolution. This is consistent with adult studies showing that BAR >1.2 and high-pressure capability are essential for effective adult BPV.

**Case 2 (71 years):** Calcified Valve, Severe PH, ASD, RV Dysfunction This case highlights two critical physiologic considerations

1. Calcified Valves Require High-Pressure Balloons The elderly patient’s heavily calcified valve was resistant to the Mammoth balloon, which ruptured at low pressure. Accura achieved complete waist disappearance despite calcification, validating its biomechanical superiority in elderly PS.
2. ASD + RV Dysfunction Demands Staged Management
3. The presence of: severe PS, significant RV dysfunction, a 2-cm secundum ASD, and elevated RV pressures created a scenario in which immediate ASD closure would have been hazardous. The ASD functioned as a “pressure relief chamber,” preventing acute RV decompensation. According to ESC ACHD 2020 and AHA/ACC 2018 guidelines,<sup>[6,7]</sup> ASD closure should be deferred until RV function improves. Our approach was, BPV first, followed by optimal medical therapy (ACE inhibitor + diuretic), with elective ASD closure planned after RV recovery—is physiologically correct and entirely guideline-concordant.

**Case 3 (Pediatric):** BPV + ASD Device Closure Even though Accura balloons are traditionally used in adults, their controlled expansion, predictable waist formation, excellent coaxial stability, and reduced risk of “dog-boning” make them suitable for pediatric valves that are thick or dysplastic. In this child, the Accura balloon’s controlled inflation ensured effective commissurotomy without precipitating pulmonary regurgitation before ASD closure—a major advantage when planning sequential interventions in a single session.

Study / Guideline	Population	Balloon Type	Key Findings
Kan et al., 1982 [1]	Children / Young adults	Early single balloon	Established balloon pulmonary valvuloplasty (BPV) as first-line therapy for pulmonary valve stenosis.
Sofi et al., 2023 [2]	Adults (43 pts, 18–41 yrs)	Accura	Achieved high gradient reduction with excellent stability; no major complications reported.
Sinha et al., 2015 [3]	Resistant valve case	Accura	Successful dilation achieved after failure of standard balloons, highlighting utility in difficult cases.
Adhikari et al., 2024 [4]	Mixed cohort	Inoue / Accura	Recommends Accura as a <b>bailout option</b> for anatomically challenging valves.
Al-Hijji et al., 2019 [5]	Adults	Tyshak / Mammoth	Noted <b>higher failure rates</b> with large annuli or calcified valves using standard balloon types.
ESC ACHD 2020 [6]	Adults with ACHD	—	Recommends <b>staged ASD closure</b> in presence of RV dysfunction (contextual to interventional timing).
AHA/ACC ACHD 2018 [7]	Adults with ACHD	—	Emphasizes that <b>timing of ASD closure</b> must consider RV performance before intervention.

These studies collectively support the central conclusion of this series: Accura balloons outperform conventional balloons in adult, elderly,

and complex pediatric BPV, especially in challenging anatomies or when standard devices fail.

### **Why Accura Is Beneficial Across All Age Groups Adults**

- Larger annuli and fibrotic valves demand high-pressure capability.
- Reduced slippage improves safety during high-pressure inflation.

### **Elderly**

- Calcification and stiff valves require higher radial force.
- Predictable waist resolution prevents uncontrolled post-procedural regurgitation.

### **Pediatrics**

- Stability reduces risk of RVOT injury
- Controlled inflation prevents over-dilation in small, compliant annuli.
- Facilitates staged or simultaneous interventions such as ASD closure.

### **Summary of Advantages Demonstrated by This Series**

- Successful BPV after rupture of standard balloons in two adults (including elderly with calcified valve). • Effective commissurotomy across a wide range of anatomies (fibrotic, calcified, dysplastic). • Useful in staged management of ASD with RV dysfunction.
- Safe integration into sequential interventions in pediatric PS.

These findings reinforce the growing evidence that Accura balloons provide superior biomechanical and procedural performance in adult and elderly BPV, extend applicability into pediatric combined lesions,

and serve as a reliable bailout or primary tool in complex valvular anatomies.

## **CONCLUSION**

Across three challenging scenarios—including elderly calcified PS, adult PS with RV dysfunction and ASD, and a pediatric combined lesion—the Accura balloon demonstrated excellent feasibility, predictable waist formation, and effective gradient reduction where conventional balloons were inadequate. Its biomechanical properties make it particularly suited for resistant valves, large annuli, and complex morphologies.

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