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First Dual-Center Clinical Experience With the Premounted Vienna Transcatheter Aortic Valve System: A Prospective Feasibility and Safety Study

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Research Article

Keywords: Vienna valve, TAVI, Self-expandable heart valve, Transcatheter aortic valve implantation, severe aortic stenosis

Posted Date: March 22nd, 2026

DOI: https://doi.org/10.21203/rs.3.rs-8854650/v1

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Additional Declarations: No competing interests reported.

Abstract

Background:

Transcatheter aortic valve implantation has become the preferred treatment for many patients with severe aortic stenosis. The Vienna valve is a next-generation, premounted self-expandable transcatheter heart valve designed to simplify procedural workflow and enhance deployment accuracy.

Objective:

To evaluate the feasibility, procedural safety, and early clinical and hemodynamic outcomes of the Vienna transcatheter aortic valve system in patients with severe symptomatic aortic stenosis.

Method:

This prospective, dual-center observational study enrolled 13 consecutive patients with severe symptomatic aortic stenosis who underwent transfemoral TAVI using the Vienna valve between February 2024 and July 2025. Clinical and echocardiographic assessments were performed at baseline, post-procedure, and during follow-up at 1 and 6 months. Primary endpoints were mortality, stroke, bleeding, pacemaker requirement, rehospitalization, and functional improvement. Outcomes were defined according to Valve Academic Research Consortium-3 criteria.

Result:

The mean patient age was 72 ± 9 years, and the mean EuroSCORE II was 6.7 ± 0.3%. Procedural success was achieved in 92.3% of cases. One intraprocedural cardiovascular death occurred due to valve infolding with cardiac tamponade. Mean transvalvular gradients decreased from 45.2 ± 19.0 mmHg at baseline to 11.7 ± 8.0 mmHg post-procedure and remained stable at 6 months. One patient (7.7%) required permanent pacemaker implantation during follow-up. No strokes, major bleeding events, or valve-related rehospitalizations were observed through 6 months.

Conclusion:

In this initial dual-center experience, the Vienna premounted self-expandable valve demonstrated encouraging feasibility, acceptable early safety, and sustained hemodynamic performance. Larger studies with longer follow-up are warranted to confirm long-term outcomes and durability.

Introduction

Aortic stenosis (AS) is the most prevalent valvular heart disease in developed countries and remains a major cause of cardiovascular morbidity and mortality. Its prevalence increases markedly with age, affecting approximately 1–2% of individuals aged ≥ 65 years and more than 12% of those aged ≥ 75 years (1, 2). As population aging continues, the number of patients requiring aortic valve intervention is expected to rise substantially (3).

Surgical aortic valve replacement (SAVR) has historically been the standard treatment for severe symptomatic AS. Over the past decade, however, transcatheter aortic valve implantation (TAVI) has transformed the management of this condition. Randomized trials across the surgical risk spectrum have demonstrated that transfemoral TAVI provides outcomes that are non-inferior, and in selected populations superior, to SAVR (4–6). Consequently, contemporary European and American guidelines now recommend TAVI as an alternative to surgery, with treatment selection guided by patient age, anatomical suitability, surgical risk, and patient preference (2, 7).

Despite these advances, current transcatheter heart valve platforms are associated with technical challenges, including manual valve loading, prolonged preparation time, and the risk of procedural complications such as paravalvular regurgitation and conduction disturbances. These limitations underscore the need for next-generation devices designed to simplify procedural workflow while maintaining safety and favorable hemodynamic performance.

The Vienna valve is a novel self-expanding, premounted transcatheter heart valve constructed on a nitinol frame with bovine pericardial leaflets. Its premounted configuration eliminates the need for intra-procedural crimping and aims to reduce operator-dependent variability. Early first-in-human experience has demonstrated high technical success and encouraging short-term outcomes .(8–10)

Building on these initial findings, the present prospective dual-center study aimed to evaluate the feasibility, procedural safety, and early clinical and hemodynamic performance of the Vienna valve in patients with severe symptomatic aortic stenosis treated in a real-world clinical setting.

Method

Study Design and Population:

This prospective, dual-center observational study included 13 consecutive patients with severe symptomatic aortic stenosis who underwent transfemoral TAVI using the Vienna self-expandable valve system between February 2024 and July 2025. Procedures were performed at Tehran Heart Center and Rajaie Cardiovascular Medical and Research Center.

Eligible patients were adults with symptomatic severe aortic stenosis, defined by transthoracic echocardiography as an aortic valve area ≤ 1.0 cm² or indexed area ≤ 0.6 cm²/m², in combination with a mean gradient > 40 mmHg or peak velocity > 4.0 m/s, in accordance with the 2021 ESC/EACTS guidelines (11).

Patients were considered candidates for TAVI if they were classified as intermediate or high surgical risk (EuroSCORE II ≥ 4%) or deemed unsuitable for surgery by the multidisciplinary Heart TeamFull inclusion and exclusion criteria are provided in the Supplementary Material.

Device description:

The Vienna self-expandable transcatheter aortic valve system (P + F Products & Features GmbH, Vienna, Austria) consists of a nitinol frame with three bovine pericardial leaflets and an external sealing skirt designed to reduce paravalvular regurgitation (Fig. 1)(9).

The valve is premounted on a 16-F delivery catheter compatible with a 20-F outer sheath and allows for resheathing and recapture prior to final deployment (Fig. 2) (9).

All procedures were performed via transfemoral access under fluoroscopic and echocardiographic guidance using local anesthesia and conscious sedation. Valve sizing and procedural planning were based on multidetector computed tomography. Unfractionated heparin was administered to maintain an activated clotting time > 250 seconds. Post-deployment balloon dilatation was performed at the operator's discretion. Procedural success and complications were defined according to Valve Academic Research Consortium-3 (VARC-3) criteria (12).

Follow-up and Endpoints

Baseline assessment included transthoracic echocardiography (TTE), computed tomography angiography (CTA), and electrocardiography (ECG). Immediate post-procedure TTE confirmed device positioning and absence of significant complications, including paravalvular leak, prosthesis malposition, or hemodynamic instability. Clinical and ECG monitoring continued during hospitalization. Follow-up at 1 and 6 months included clinical evaluation, ECG, and TTE, as recommended by VARC-3. Clinical outcomes were assessed using a standardized Major Adverse Cardiac Events (MACE) questionnaire (Supplementary Material).

Primary endpoints included all-cause and cardiovascular mortality, stroke, major bleeding, permanent pacemaker implantation, and rehospitalization for valve-related or heart failure causes. Secondary endpoints included echocardiographic valve performance and New York Heart Association (NYHA) functional class. All clinical events were adjudicated by the local Heart Team at each center according to VARC-3 definitions.

Statistical Analysis:

Continuous variables are presented as mean ± standard deviation, and categorical variables as counts and percentages. Given the exploratory nature of this feasibility study and the limited sample size, analyses were descriptive and no hypothesis-driven inferential statistical testing was performed.

Result

Baseline

Between February 2024 and July 2025, thirteen patients with severe symptomatic aortic stenosis underwent transfemoral TAVI using the Vienna valve. The mean age was 72 ± 9 years, and 46% of patients were male. Most patients were in NYHA functional class II (61.5%), while 38.5% were class III or IV (Table 1). The mean EuroSCORE II was 6.7 ± 0.3%, with the majority classified as intermediate surgical risk.

Table 1
Baseline Clinical and Demographic Characteristics

Patient ID	Gender, age	Body mass	Euro score	NYHA class	LVEF pre	DM history	CAD history	Prior PCI	Prior CABG	AF history	Cerebrovascular history	COPD history	TIA history	HTN
P1	Male 70	22	3.10%	class 2	55%	No	No	No	No	No	No	No	No	No
P2	Female 61	20	4.22%	class 2	60%	No	Yes	Yes	No	No	No	No	No	Yes
P3	Female 83	29.29	19.45%	class 2	50%	No	Yes	No	Yes	No	No	No	No	Yes
P4	Female 58	39.4	4.40%	class 3	55%	No	No	No	No	No	Yes	No	No	No
P5	Male 59	17.3	2.82%	class 2	60%	No	Yes	No	No	Yes	No	Yes	No	Yes
P6	Female 78	35	4.01%	class 2	55%	No	Yes	Yes	No	No	No	No	No	Yes
P7	Male 67	27	5.22%	class 3	25%	No	No	No	No	No	No	No	No	No
P8	Male 85	29	6.29%	class 2	45%	No	No	No	No	No	No	No	No	Yes
P9	Female 74	19	7.73%	class 3	25%	No	No	Yes	No	No	No	No	No	Yes
P10	Male 72	22	12.86%	class 3	NA	Yes	No	No	Yes	No	No	No	No	No
P11	Female 82	NA	4.43%	class 2	55%	NA	NA	NA	NA	NA	NA	NA	NA	NA
P12	Male 78	18	7.88%	class 4	55%	No	No	No	No	No	No	Yes	No	No
P13	Female 69	32.9	4.98%	class 2	60%	No	No	No	No	No	No	No	No	Yes

NA indicates data not available

Baseline ECG revealed left bundle branch block in 15% and right bundle branch block in 8% of patients. Bicuspid morphology was present in 31% of CTA. Baseline echocardiography demonstrated a mean aortic valve area of 0.84 ± 0.26 cm² and a mean transvalvular gradient of 45.2 ± 19.0 mmHg. Mean left ventricular ejection fraction was 49 ± 12%. Bicuspid valve morphology was present in 31% of patients on computed tomography. Baseline clinical and imaging characteristics are summarized in Table 1 and Supplementary Table S1.

Procedural and Early Safety Outcomes:

Procedural success was achieved in 12 of 13 patients (92.3%). Mean procedural time was 43.6 ± 5.5 minutes. One patient experienced valve infolding during the procedure, resulting in acute cardiac tamponade and intraprocedural cardiovascular death (Fig. 3). No other in-hospital strokes, major vascular complications, annular rupture, valve migration, or life-threatening bleeding events occurred (Table 2). Due to this intraprocedural mortality, 12 patients were available for 1-month follow-up. At 6 months, follow-up data were available for 11 patients, as one patient underwent TAVI less than two months before the end of the study period (Table S3, S4)

Table 2
Procedural and Clinical Outcomes

	Post-operative hospitalization (n = 13)	30-days (n = 12)	6 months (n = 11)
All-cause death	1 (7.7%)	0 (0%)	0 (0%)
Cardiovascular death	1 (7.7%)	0 (0%)	0 (0%)
Stroke	0 (0%)	0 (0%)	0 (0%)
Acute kidney injury	0 (0%)	0 (0%)	0 (0%)
Life-threatening bleeding	0 (0%)	0 (0%)	0 (0%)
Hospitalization for valve-related Symptoms of congestive heart failure	0 (0%)	0 (0%)	0 (0%)
Valve-related dysfunction requiring Repeat procedure	0 (0%)	0 (0%)	0 (0%)
Conduction disturbances requiring permanent pacemaker implantation*	0 (0%)	0 (0%)	1 (7%)

Data are displayed as n (%)
*A patient with treatment-resistant sinus bradycardia necessitating permanent pacemaker implantation.
†Given the periprocedural mortality, 12 patients got follow-up at one month, and one patient (P13) underwent TAVI two months ago; therefore, only one month follow up was performed for her.

One patient (7.%) developed symptomatic bradycardia requiring permanent pacemaker implantation during follow-up. No additional conduction disturbances, strokes, or valve-related rehospitalizations were observed through 6 months. Patient enrollment, procedural outcomes, and follow-up availability are summarized in the study flow diagram (Fig. 5)

Fluoroscopic imaging confirmed appropriate valve positioning and complete expansion in successfully treated patients (Fig. 4).

Hemodynamic and Echocardiographic Outcomes:

Mean transvalvular gradient decreased from 45.2 ± 19.0 mmHg at baseline to 11.7 ± 8.0 mmHg immediately post-procedure and remained stable at 6 months (11.9 ± 4.3 mmHg) (Fig. 6). Peak gradients demonstrated a similar sustained reduction. No patient developed moderate or severe paravalvular regurgitation during follow-up.

Functional status improved in surviving patients, with a reduction in NYHA functional class observed at both 1- and 6-month follow-up visits. Detailed echocardiographic and clinical outcomes are provided in Tables 2 and Supplementary Tables S2–S4.

Discussion

A. Key Findings and Study Context

The Vienna transcatheter aortic valve system is a novel premounted self-expanding valve utilizing dry-processed bovine pericardium and designed to simplify procedural workflow while maintaining contemporary safety and hemodynamic standards. First introduced in 2023, the device has previously demonstrated encouraging outcomes in first-in-human feasibility studies(13, 14).

The present prospective dual-center study represents an early multicenter, real-world experience evaluating the feasibility, procedural safety, and short-term performance of the Vienna valve following initial first-in-human investigation. In a cohort of patients with predominantly intermediate surgical risk, the device demonstrated high procedural success, favorable hemodynamic performance, and acceptable early safety through 6-month follow-up.

B. Eolution of Contemporary Transcatheter Aortic Valve Platforms

The evolution of transcatheter aortic valve implantation has been driven by ongoing efforts to reduce paravalvular regurgitation, minimize conduction disturbances, and optimize valve hemodynamics. Contemporary balloon-expandable valves (BEVs) and self-expanding valves (SEVs), such as the SAPIEN 3 and Evolut R/PRO platforms, have demonstrated comparable clinical outcomes across a wide range of patient risk profiles.

Large comparative analyses and meta-analyses have shown that SEVs generally provide lower transvalvular gradients and larger effective orifice areas, whereas BEVs are often associated with lower rates of paravalvular leak. Despite these differences, overall rates of mortality, stroke, major bleeding, and vascular complications are broadly similar between modern SEV and BEV platforms (15–17).

C. Workflow and Procedural Efficiency

The Vienna valve differs from many contemporary transcatheter heart valves by being premounted and utilizing dry-processed bovine pericardium, thereby eliminating the need for on-table crimping and reducing operator-dependent variability during valve preparation. In the present study, this premounted configuration translated into a streamlined procedural workflow, without device assembly–related complications. Similar workflow advantages were reported in the VIVA first-in-human feasibility study, which demonstrated high procedural success and absence of moderate or severe paravalvular regurgitation at 30 days (13).

Procedural efficiency varies across transcatheter valve platforms and centers. Published registry and real-world data report mean procedural times ranging from approximately 60 to 80 minutes for contemporary self-expanding and balloon-expandable valves, including Evolut R, CoreValve, and SAPIEN 3 systems. In our cohort, the mean procedural time was 43.6 ± 5.5 minutes, which compares favorably with these reports and suggests that the premounted design may contribute to shorter case durations (18–20)

D. Safety of Vienna valves:

In this real-world cohort, one intraprocedural death occurred due to valve infolding during resheathing, resulting in acute cardiac tamponade and refractory hemodynamic collapse. This event corresponded to an in-hospital cardiovascular mortality rate of 7.7% (1/13). Aside from this complication, no other in-hospital or 30-day major adverse cardiac events were observed.

At 6-month follow-up, one additional noncardiac death due to malignancy was recorded, resulting in a 6-month all-cause mortality rate of 7.7%. These outcomes are broadly consistent with early feasibility experiences involving novel transcatheter heart valves and fall within the wide range reported in higher-risk TAVI populations(21–23). The observed 6-month MACE rate of 15.3% compares favorably with the composite endpoint rates reported in landmark TAVI trials (24).

Notably, no strokes, major bleeding events, valve thrombosis, endocarditis, or valve-related rehospitalizations were observed during follow-up. These findings align with contemporary VARC-3–based analyses and reported safety benchmarks for established transcatheter valve platforms (25–27).

E. Conduction Disturbances and Safety Profile

Permanent pacemaker implantation remains a clinically relevant limitation of self-expanding valve technology. Historically, SEVs have been associated with higher rates of new pacemaker implantation compared with BEVs, with reported rates ranging from 17% to 25% for earlier-generation SEVs versus approximately 6% to 8% for BEVs.

In the present study, only one patient (7.7%) required permanent pacemaker implantation during follow-up. Although this rate is lower than many historical SEV reports, the small sample size precludes definitive conclusions. Nevertheless, these findings are consistent with a trend toward improved conduction outcomes observed with newer-generation self-expanding platforms. (20)

F. Valve Infolding and Procedural Complications

Valve infolding is an uncommon but increasingly recognized complication of self-expanding transcatheter valves and has been associated with severe annular or leaflet calcification, bicuspid valve anatomy, and interaction with stiff guidewires during repositioning attempts (28–30).

Previously published case series and registries have emphasized the importance of careful wire selection and cautious manipulation during resheathing maneuvers, particularly in anatomically challenging cases. The occurrence of this complication in the present study underscores the learning curve associated with novel transcatheter valve platforms and highlights the need for meticulous procedural technique (28, 31–33).

G. Hemodynamic Performance and Valve Function

Hemodynamic performance following Vienna valve implantation was favorable and sustained throughout follow-up. All surviving patients met VARC-3 criteria for device success, with post-procedural mean transvalvular gradients remaining below 20 mmHg and no occurrence of moderate or severe paravalvular regurgitation at 1- or 6-month follow-up (12).

Given the established association between residual paravalvular regurgitation and late mortality and reintervention, the absence of significant paravalvular leak in this cohort is clinically meaningful. This finding may reflect the valve's external sealing skirt and supra-annular frame design, which are intended to optimize annular sealing and valve hemodynamics (34, 35).

H. Early and Mid-Term Clinical Outcomes

Notably, no strokes, major bleeding events, valve thrombosis, endocarditis, or valve-related rehospitalizations were recorded during follow-up. These outcomes compare favorably with historical TAVI benchmarks and align with VARC-3–based analyses of contemporary transcatheter valve platforms (12, 25, 27, 36)

Survivors experienced improvement in functional status, as reflected by reductions in NYHA class, along with stable echocardiographic hemodynamics. Mean transvalvular gradients remained below 20 mmHg, and no new moderate or severe paravalvular regurgitation was observed through 6 months. These findings are concordant with the 6-month outcomes reported in the VIVA first-in-human study, although they should be interpreted cautiously given the limited sample size (13, 14).

i. Functional Status and Patient-Reported Improvement

Surviving patients experienced meaningful improvement in functional status, as reflected by reductions in NYHA functional class at both 1- and 6-month follow-up. Although formal quality-of-life instruments were not employed, these findings are consistent with symptomatic improvements reported in prior TAVI studies and reinforce the clinical benefit of effective relief of aortic stenosis (13, 14)

J. Study Limitation:

This study has several limitations. First, the sample size was small, reflecting the early feasibility nature of the investigation. Second, the absence of a comparator group limits direct comparisons with other commercially available transcatheter valves. Third, follow-up was limited to 6 months and does not permit assessment of long-term durability or late valve-related complications. Larger studies with extended follow-up and comparative designs are required to confirm these findings.

Conclusion

In this two-center study, we evaluated the initial safety and technical feasibility of the novel Vienna valve in thirteen high-surgical-risk patients with severe aortic stenosis. The Vienna premounted valve demonstrated encouraging feasibility, procedural safety, and hemodynamic durability at 6-month follow-up. While one intra-procedural mortality underscores the learning curve, overall outcomes suggest this platform may offer workflow and performance advantages in selected patients.

These early multicenter results are encouraging; however, larger comparative studies are needed to confirm performance and durability of the Vienna valve within the contemporary TAVI landscape.

Declarations

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors. The study was conducted using institutional resources only.

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to patient confidentiality and institutional data protection regulations but are available from the corresponding author on reasonable request.

Ethics Statement

This study was approved by the institutional ethics committees of Tehran Heart Center and Rajaie Cardiovascular Medical and Research Center (Ethics Code: IR.TUMS.THC.REC.1404.029). The study was conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from all participants prior to enrollment.

Competing interests

The authors declare that they have no competing interests.

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Figures

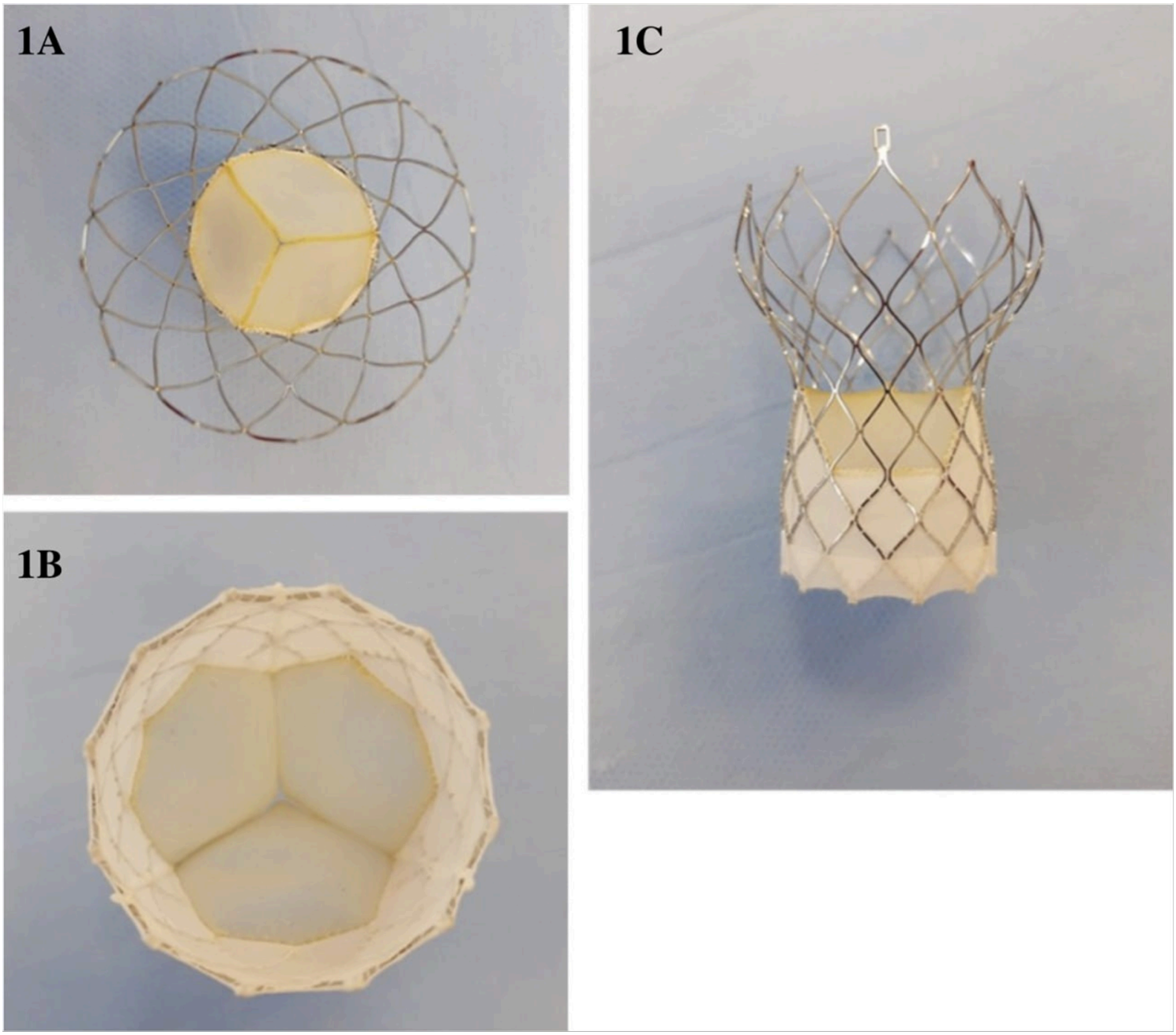


Figure 1

The Vienna self-expandable transcatheter aortic valve system. (A) Outflow view, (B) inflow view, and (C) lateral view demonstrating the nitinol frame and bovine pericardial leaflets.

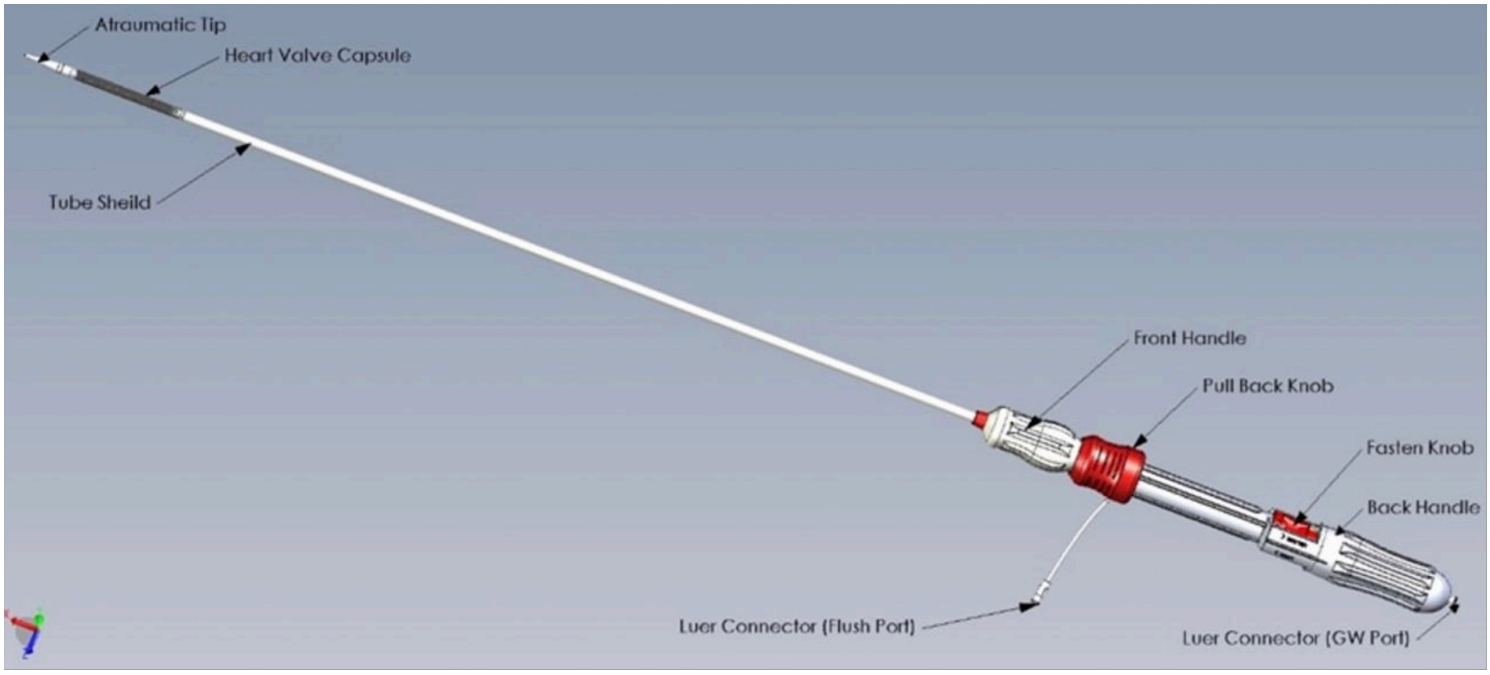


Figure 2

Delivery system of the Vienna transcatheter aortic valve, illustrating the premounted valve configuration and deployment mechanism.

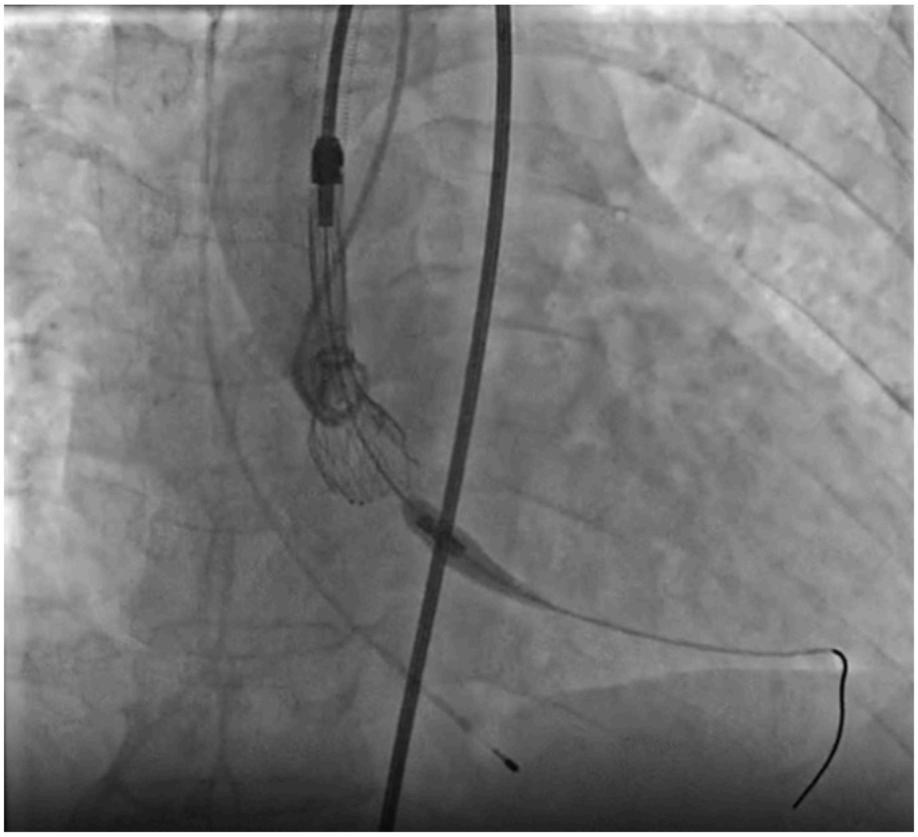


Figure 3

Intra-procedural valve infolding with incomplete expansion of the self-expandable transcatheter valve following resheathing, resulting in hemodynamic compromise.

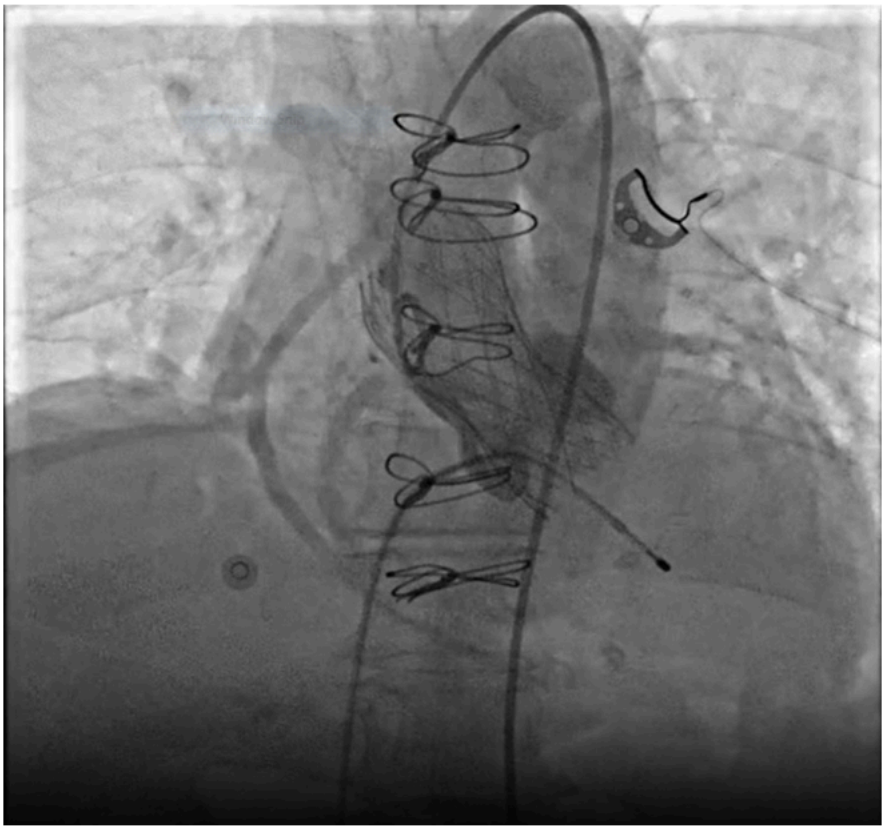


Figure 4

Representative fluoroscopic image demonstrating correct positioning and full expansion of the Vienna transcatheter aortic valve after deployment.

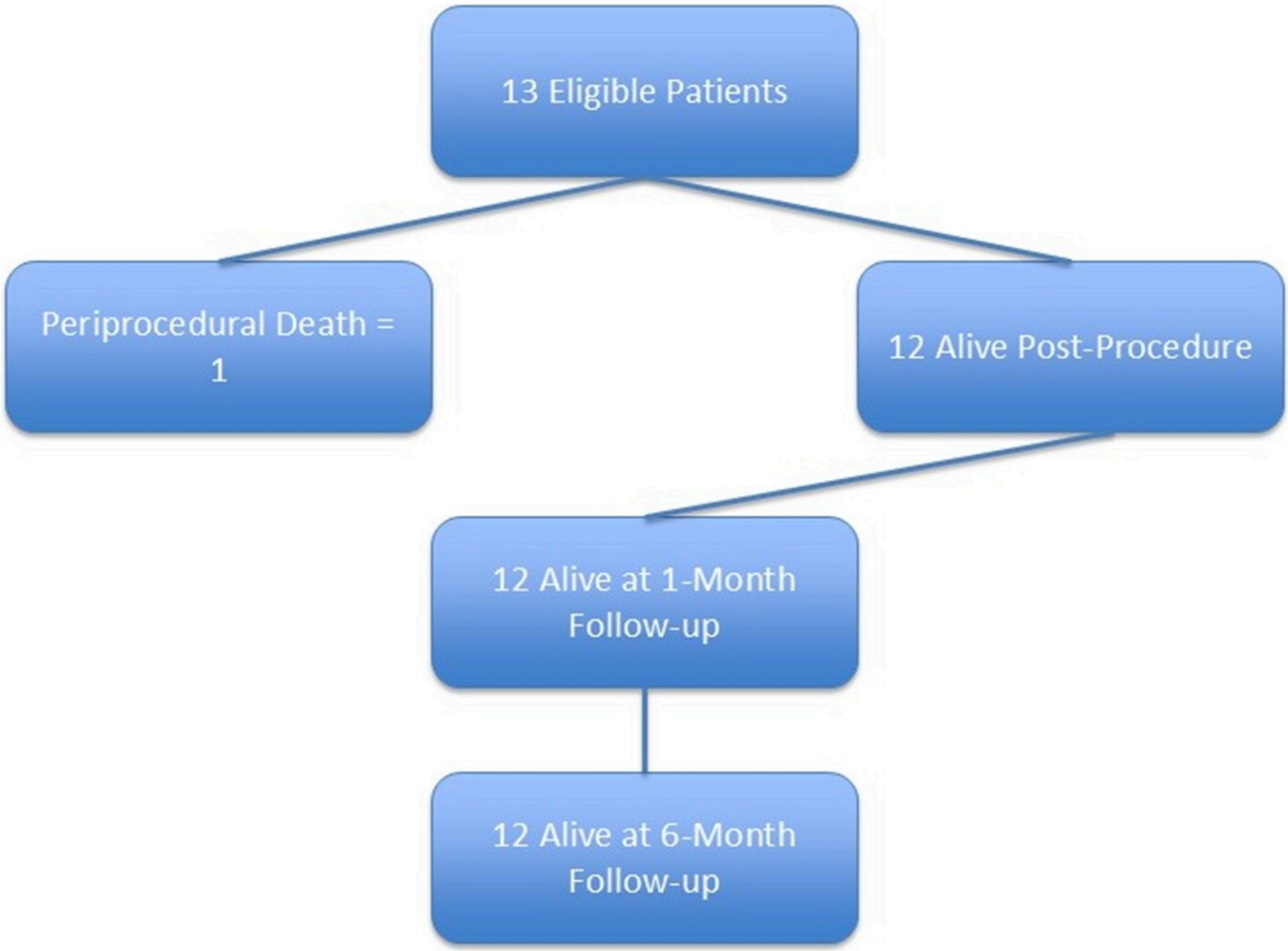


Figure 5

Study flow diagram illustrating patient enrollment and follow-up availability at post-procedure, 1-month, and 6-month assessments

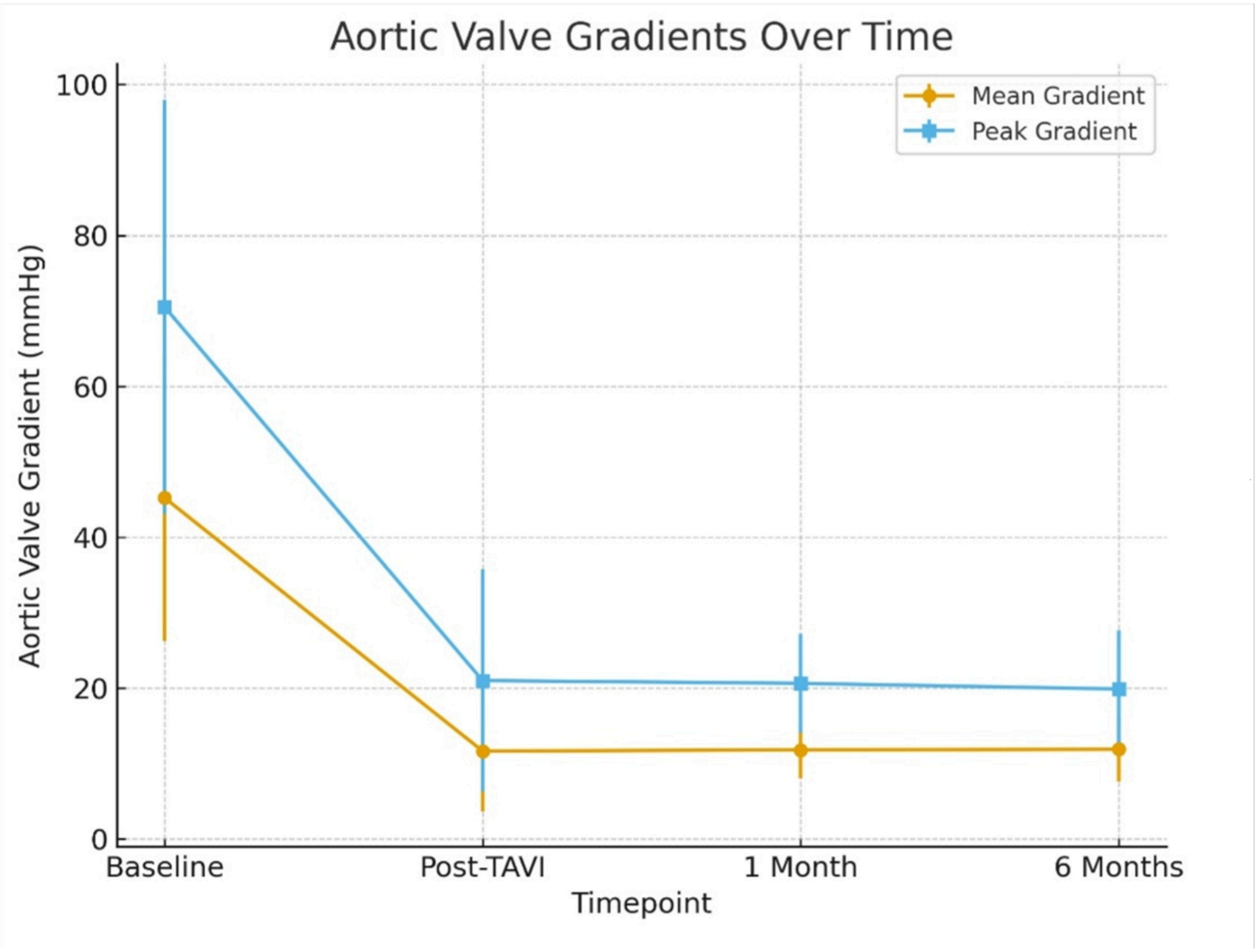


Figure 6

Changes in peak and mean transaortic valve gradients before TAVI, immediately post-procedure, and at 1- and 6-month follow-up.

Supplementary Files

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- Supplementary.docx