

Transcatheter aortic valve implantation with a novel pre-packaged self-expandable dry-tissue transcatheter aortic valve: a case report

John Jose ^{1*}, Paul V. George¹, Krishnaprasath V.¹, and Raj Sahajanandan ²

¹Department of Cardiology, Cardiac valve and structural heart disease clinic, Cardiology unit-2, Christian Medical College Hospital Vellore, Ida, Scudder Road, Vellore 620004, Tamil Nadu, India; and ²Department of Anaesthesia, Christian Medical College Hospital Vellore, Ida, Scudder Road, Vellore 620004, Tamil Nadu, India

Received 27 August 2020; first decision 21 September 2020; accepted 2 December 2020

Background

Current commercially available transcatheter aortic valves are stored separately in a glutaraldehyde solution and mounted onto the delivery system by a technical expert during the transcatheter aortic valve implantation (TAVI) procedure. A pre-mounted dry-tissue valve that is crimped on a ready-to-use delivery system could simplify the procedure. The Vienna self-expanding transcatheter valve (P&F, GmbH, Wessling, Germany) is a novel ready-to-use pre-mounted dry-tissue transcatheter aortic valve. There are no prior reports on the efficacy of this valve system.

Case summary

Here, we report our experience of an implantation of a novel ready-to-use dry-tissue Vienna transcatheter aortic valve in a 72-year-old male with symptomatic severe aortic stenosis and severe left ventricular systolic dysfunction. He had presented with heart failure [N-terminal pro-brain natriuretic peptide (NT-proBNP) level at the admission of 10 600 pg/mL], New York Heart Association Class-3, and recurrent syncope. A 26 mm Vienna valve was successfully implanted via the transfemoral route under conscious sedation. There were no complications. The patient was discharged in a stable condition on the third post-procedure day. At 1-year follow-up, the valve is functioning well with no evidence of structural degeneration (mean gradient 9 mmHg, no valvular regurgitation). Currently, he is asymptomatic with normal left ventricular systolic function on echocardiography (NT-proBNP 57 pg/mL).

Discussion

To our knowledge, this is the first case of TAVI performed with the dry-tissue pre-mounted VIENNA valve. Our case highlights the feasibility and short-term efficacy of the VIENNA valve. Further safety and durability need to be addressed by a multicentre trial.

Keywords

Aortic stenosis • Transcatheter aortic valve implantation • Dry-tissue transcatheter aortic valve • Vienna valve • Self-expanding valve • Case report

Learning points

- A pre-mounted dry tissue valve that is crimped on a ready-to-use delivery system represents an attractive option to simplify the transcatheter aortic valve implantation (TAVI) procedure.
- We report the first case of TAVI performed with the dry-tissue pre-mounted VIENNA valve.
- Favourable outcomes were observed post-procedure and at 1-year follow-up in our patient. Further safety and efficacy need to be addressed by a multi-centre trial.

* Corresponding author. Tel: +91-9843593721, Email: drjohnjose@gmail.com

Handling Editor: Luigi Biasco

Peer-reviewers: Ali Nazmi Calik and Erik Holy

Compliance Editor: Reshma Amin

Supplementary Material Editor: Aiste Monika Jakstaite

© The Author(s) 2020. Published by Oxford University Press on behalf of the European Society of Cardiology.

This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (<http://creativecommons.org/licenses/by-nc/4.0/>), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited. For commercial re-use, please contact journals.permissions@oup.com

Introduction

Transcatheter aortic valve implantation (TAVI) has become the standard of care for the treatment of symptomatic severe aortic stenosis (AS) in elderly patients who are at intermediate or higher surgical risk.¹ Recent trials suggest comparability or even superiority of TAVI over surgical aortic valve replacement even in low surgical-risk population.^{2,3} Procedural simplification and improving durability are key targets while considering further expansion of TAVI to low-risk and younger age groups. Current transcatheter valves need to be stored 'wet' in glutaraldehyde solution (may affect durability) and require tedious intraprocedural cleaning and assembly by an on-site technical expert. The Vienna self-expandable transcatheter valve (P&F, GmbH Wessling, Germany) is a novel ready-to-use pre-mounted self-expandable dry-tissue transcatheter aortic valve that can simplify TAVI procedure (Figure 1). No prior reports exist on the efficacy of this valve system. Here, we report the first case of TAVI performed with the Vienna valve.

Timeline

2006	Percutaneous coronary intervention with stenting of the right coronary artery
2015	Percutaneous coronary intervention with stenting of the left coronary artery
22 July 2019	Patient presented with heart failure and syncope. He was diagnosed to have severe aortic stenosis (mean gradient ~58 mmHg) with severe left ventricular systolic dysfunction. N-terminal pro-brain natriuretic peptide (NT-proBNP) level at admission was 10 600 pg/mL.
24 July 2019	Coronary angiogram plus right and left heart catheterization study-patent coronary stents, severe aortic stenosis and severe pulmonary arterial hypertension.
2 August 2019	Transcatheter aortic valve implantation (TAVI) was successfully performed by the transfemoral route under conscious-sedation using a novel pre-packaged self-expandable dry-tissue 26 mm Vienna valve.
5 August 2019	Patient discharged.
2 September 2019	At 1-month follow-up, he has significant improvement of his symptoms and in New York Heart Association (NYHA) functional Class I.
3 February 2020	At 6-month follow-up, he is doing well, in NYHA functional Class I. Left ventricular systolic function is normal.
20 August 2020	At 1-year follow-up, he is asymptomatic and in NYHA functional Class I. Left ventricular systolic function is normal. NT-proBNP level is 57 pg/mL. The mean gradient across the valve is 9 mmHg.

Case presentation

A 72-year-old male presented with dyspnoea on exertion of 1-year duration with worsening in the 2 weeks prior to presentation. He had progressed from New York Heart Association (NYHA) Functional Classification Class-II symptoms at baseline to NYHA Class III at the time of admission. He also had effort angina, Canadian Cardiovascular Society Grade III, and recurrent episodes of syncope in the past 2 weeks. His past medical history included hypertension and prior percutaneous coronary intervention with stenting of the right coronary artery (RCA) in 2006 and left anterior descending artery (LAD) in 2015. He was a reformed smoker. He was on dual anti-platelets, atorvastatin, ranolazine, trimetazidine, and long-acting nitrates at the time of admission. At admission, his blood pressure was 90/60 mmHg. He had bilateral crackles in the lung bases and clinical findings of severe AS. N-terminal pro-brain natriuretic peptide (NT-proBNP) level at admission was 10 600 pg/mL (normal level: less than 125 pg/mL). Echocardiogram revealed a trileaflet aortic valve with a valve area of 0.5 cm², a mean pressure gradient across the aortic valve of 58 mmHg (severe AS), and severe left ventricular systolic dysfunction with an ejection fraction of 30% (Figure 2). After initial management with aggressive diuretics, he underwent coronary angiography that revealed patent stents in LAD and RCA. Left heart catheterization showed a peak-peak and mean aortic valve gradient of 154 mmHg and 97 mmHg, respectively (Figure 2). Left ventricular end-diastolic pressure was elevated at 45 mmHg. Right heart catheterization was also performed. The systolic and mean pulmonary artery pressures were 50 mmHg and 36 mmHg, respectively. In view of co-morbidities and surgical risk, he was deemed a candidate for TAVI. The chest computerized tomography (CT) showed a severely calcified aortic valve with an aortic annulus perimeter of 68.4 mm (perimeter derived diameter 21.8 mm) and an annulus area of 353.2 mm². The distance of the left and right coronary artery ostia to the aortic annulus plane was 13 mm and 10.6 mm, respectively. No peripheral artery disease was visualized on CT or femoral angiography. Baseline electrocardiography showed sinus tachycardia, left ventricular hypertrophy with strain pattern, and absence of any conduction blocks (Figure 2).

Procedure details

After obtaining informed consent and regulatory body approval, the procedure was performed via transfemoral access under conscious sedation (Figure 3, Video). Through the right radial arterial access, using a 6-Fr Judkins-right guide catheter, RCA was wired with a 0.014" coronary guidewire wire and retained until post valve deployment aortogram. Two proglides (Abbott Vascular Devices, CA, USA) and a 22-Fr sheath were used for the procedure. Pre-dilatation was done with a 18 mm × 4 cm Z Med-II balloon (NuMED, Inc., Denton, Texas, USA). A 26 mm VIENNA valve that was ready for use immediately upon package removal and purging of the delivery system of air, was taken over the pre-shaped Amplatz superstiff (Boston Scientific Corporation, Boston, MA, USA) guidewire placed in the left ventricular cavity (Figure 3). The techniques of valve placement and deployment were like routine TAVI procedures with existing self-expanding valves. At the initial stages of valve deployment, a

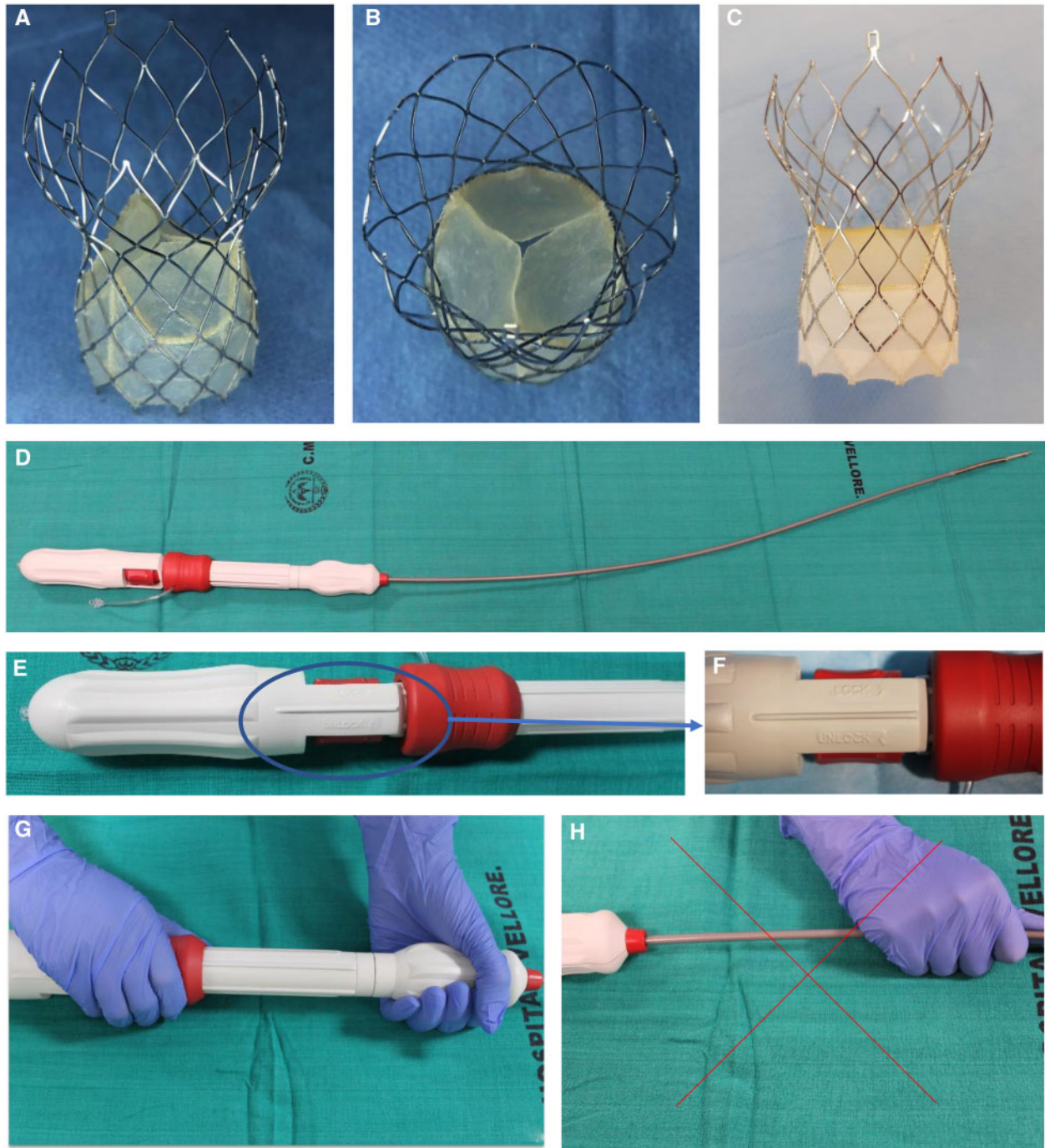


Figure 1 The Vienna valve-novel ready-to-use pre-mounted self-expandable dry-tissue transcatheter aortic valve. (A) and (B) the Vienna valve; (C) a newer version of Vienna valve featuring an outer sealing skirt currently under development; (D) delivery system of the Vienna valve; (E) and (F) Handle of the delivery system showing the 'lock' and 'unlock' feature; (G) Deployment of the valve by rotating the red knob; (H) during deployment, avoid handling the outer catheter sheath.

very slow and controlled release was done to allow full hydration and early functioning of the dry-tissue leaflets. The valve position was monitored under fluoroscopy throughout the deployment. Rapid pacing was not performed during valve deployment although a transvenous temporary pacing wire was positioned in the right ventricle

for back-up pacing if required. The mean aortic valve gradient after TAVI decreased to 4 mmHg. The final aortogram showed evidence of mild paravalvular aortic regurgitation; this finding was confirmed by echocardiography. An echocardiogram done a day later showed significant improvement of his left ventricular ejection fraction and a

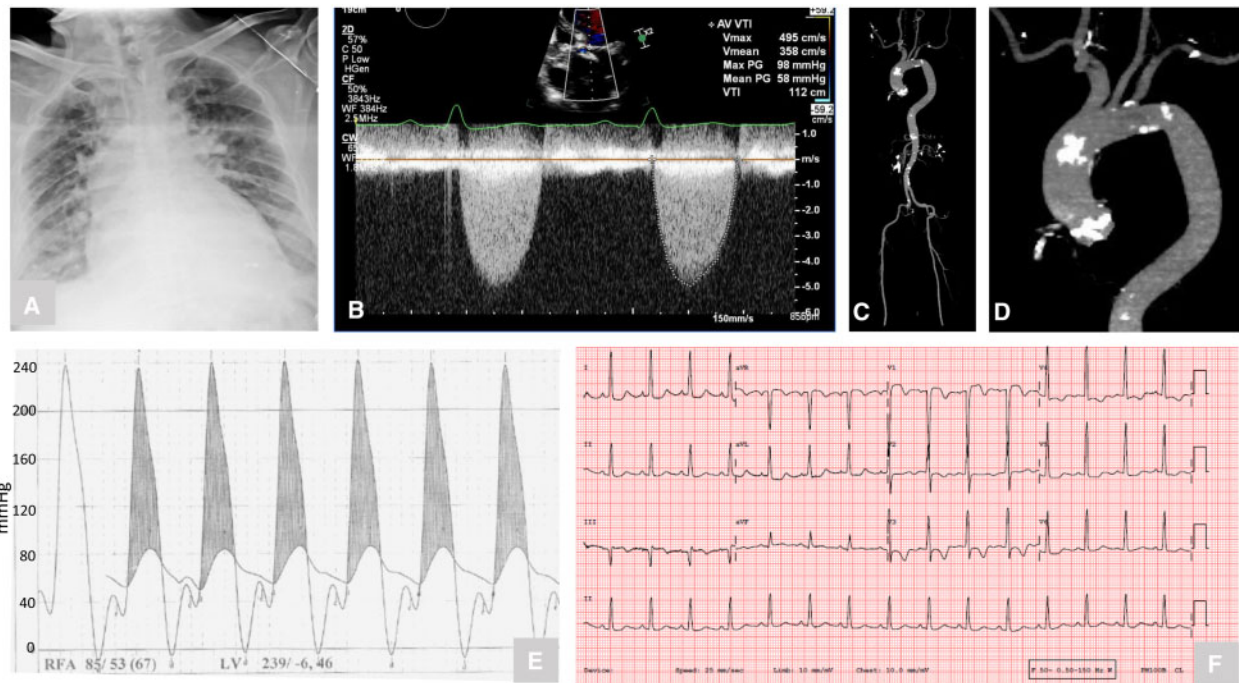


Figure 2 Pre-procedural evaluation (A) Chest radiograph showing cardiomegaly and pulmonary venous congestion; (B) continuous-wave Doppler echocardiography; (C) multidetector coronary computed tomography (MDCT) angiography of aorta and access vessels; (D) severe calcification of the aortic root on multidetector coronary computed tomography; (E) left ventricular and femoral arterial pressure tracing. Shaded area represents mean gradient (97 mmHg). Baseline left ventricular end-diastolic pressure was 45 mmHg. (F) Pre-procedure electrocardiography.

mean transvalvular gradient of 10 mmHg. There were no adverse events including heart block requiring a permanent pacemaker, stroke, or Valve Academic Research Consortium (VARC-II) defined bleeding or major vascular complication. The patient was discharged on the third post-operative day. At a 6-month follow-up, he reported a marked improvement in functional status to NYHA Class 1 (NT-proBNP-127 pg/mL). The echocardiographic assessment showed a left ventricular ejection fraction of 55%, a mean pressure gradient of 11 mmHg across the aortic valve, and mild paravalvular regurgitation. At 1-year follow-up, he was asymptomatic (NT-proBNP-57 pg/mL). No adverse cardiovascular events occurred during follow-up. Echocardiography at 1-year follow-up showed a mean pressure gradient of 9 mmHg across the aortic valve and mild paravalvular regurgitation. A surveillance CT scan at 1-year follow-up showed no evidence of structural degeneration (Figure 4).

Discussion

To the best of our knowledge, this is the first report of TAVI with the Vienna valve—a ready-to-use pre-mounted dry-tissue transcatheter aortic valve. The VIENNA valve has a self-expanding nitinol frame with leaflets made of thin bovine dry pericardial tissue in a supra-annular valve design and constrained within the delivery system. The device can be easily transported and stored locally. The valve is manufactured in sizes of 23 (for aortic annulus diameter 17–21 mm), 26

(annulus diameter 21–23 mm), 29 (annulus diameter 23–26 mm), and 31 mm (annulus diameter 26–29 mm). The sizing is based on perimeter derived aortic annulus diameter by CT. The delivery system has a knob with a lock system for slow and quick release. The techniques of valve advancement and deployment are not different from current commercially available self-expanding valves.

Previous experience with dry tissue transcatheter valve technology is limited to a single report of Venibri valve (a trileaflet porcine valve) implantation in an elderly patient with severe aortic stenosis.⁴ Unlike the Venibri valve, the Vienna valve does not have radiopaque markers to assist deployment. For an optimal implant depth, the device may be positioned and deployed such that the middle of the first diamond cell at its inflow portion corresponds to the aortic annulus plane in a co-planar view obtained from CT analysis. We observed good trackability and pushability of the Vienna device during advancement through the iliofemoral system. Our patient had a relatively steep aortic arch, and considerable but measured force was needed to negotiate the arch. Very slow deployment is desired once the optimal catheter position is obtained, to facilitate hydration of the valve leaflets. During release, it is essential to use only the handle of the delivery system and not the outer catheter sheath. Handling the outer catheter sheath during deployment could impede valve release. Our patient did not experience any conduction blocks. We did not post-dilate the valve since the paravalvular regurgitation was mild and there was no significant residual gradient. The device is retrievable and repositionable as per the manufacturer. In our case, we could

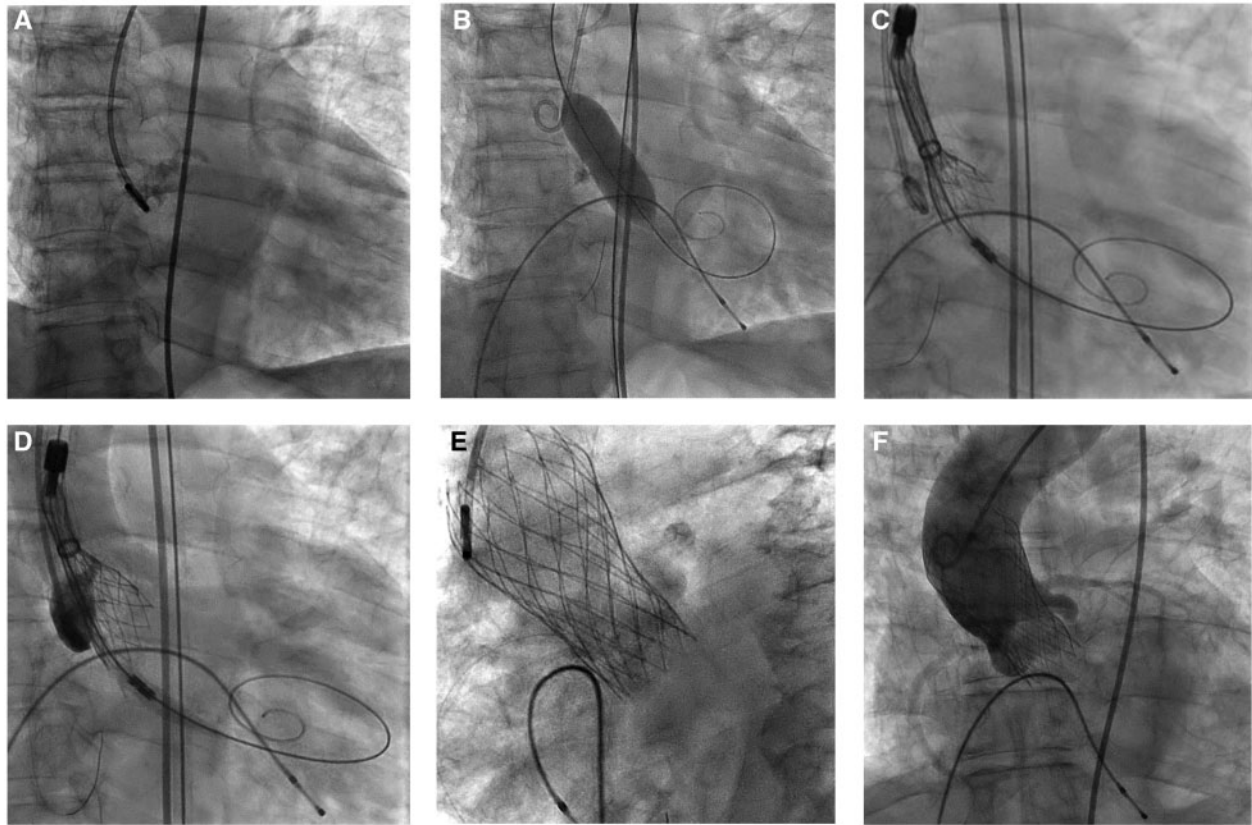
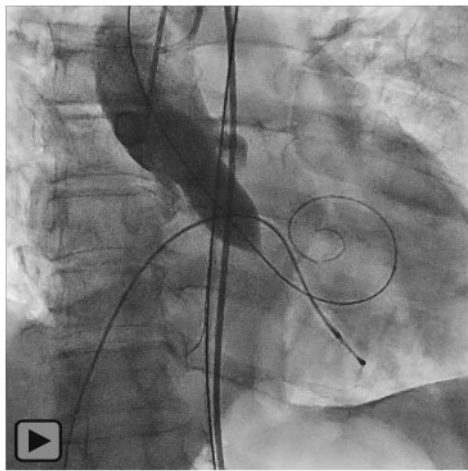


Figure 3 Transcatheter aortic valve implantation procedure. (A) Severe aortic root calcification seen on fluoroscopy; (B) pre-dilatation (C) and (D) unsheathing of the valve (E) Fluoroscopy of the valve post deployment (F) Aortography showing mild paravalvular regurgitation.



Video Transcatheter aortic valve implantation procedure.

implant the device on the first attempt without the need for recapture or retrieval.

As mentioned earlier, the use of an off-the-shelf, ready-to-use dry tissue transcatheter valve offers several advantages over current

devices: (i) the device can be easily shipped and stored at the point-of-use without the need for a valve assembly expert to be present during the procedure. This means reduced costs, improved accessibility, and popularization of the procedure, especially in resource-limited regions. (ii) In situations where haemodynamic instability warrants a quick TAVI procedure, the availability of a pre-packed sterile transcatheter valve without the need for intraprocedural valve preparation or assembly could be potentially lifesaving. (iii) Dry tissue technology avoids the need for glutaraldehyde storage and its potential effects. The drawbacks of the current version of the Vienna valve include the lack of an additional outer skirt or wrap that could improve valve-sealing and the large profile of the delivery system. A newer iteration featuring an outer sealing skirt and low-profile delivery (16/18-Fr) is under development. While we need to wait longer for ascertaining the durability of the dry-tissue technology, the 1-year follow-up results of our patient are certainly encouraging.

Conclusion

In conclusion, our report suggests the feasibility and short-term efficacy of the dry-tissue pre-mounted VIENNA valve. Further safety and long-term efficacy need to be addressed by a multi-centre trial.

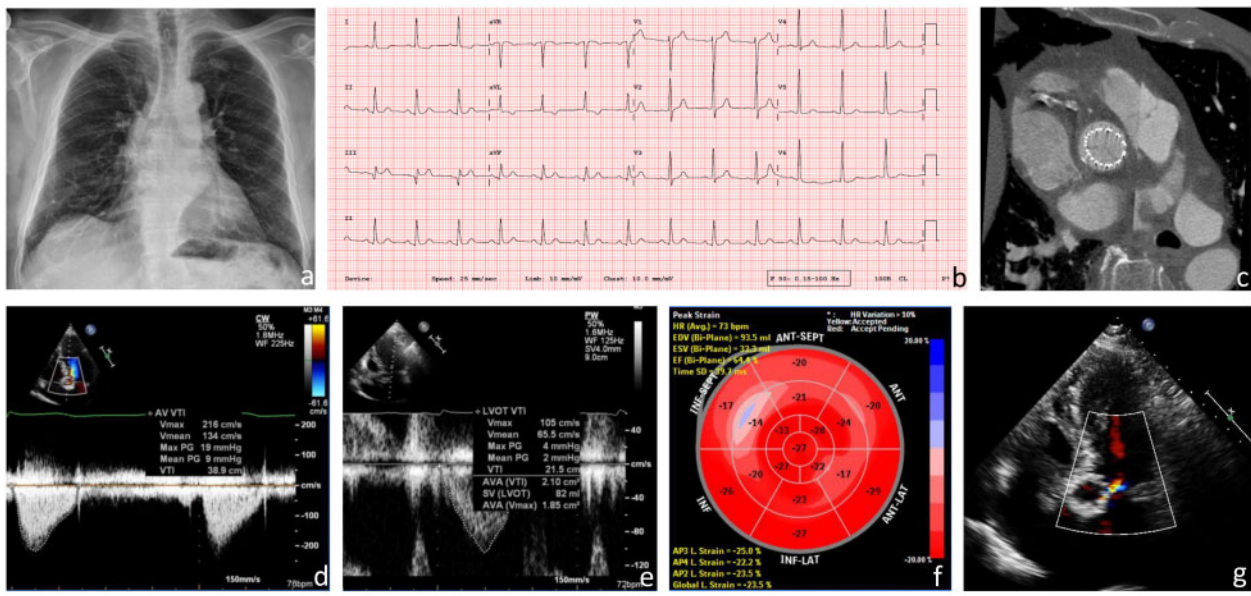


Figure 4 One-year follow-up evaluation. (A) Chest radiograph, (B) electrocardiogram, (C) well-expanded valve with no evidence of thrombosis or degeneration on computed tomography, (D) continuous-wave Doppler echocardiography (mean gradient of 9 mmHg), (E) aortic valve area of 2.1 cm² on continuity equation, (F) Bull's eye plot showing peak systolic strain and normal left ventricular function pattern, and (G) mild paravalvular leak on colour flow imaging.

Lead author biography



John Jose obtained a post graduate degree in Cardiology from Christian Medical College hospital, Vellore in 2011. He won the European Association of Percutaneous Cardiovascular Interventions (EAPCI) interventional Cardiology fellowship training grant award for the year-2015 which he completed at Bad Segeberg, Germany under the mentorship of Dr Mohamed Abdel-Wahab. In 2016, he started the TAVI program at Christian Medical College hospital. He has made numerous presentations as well

as authored several articles on TAVI in national and international journals. Currently, he works as professor of Cardiology and leads the structural and valvular heart disease program, Cardiology Unit 2 at Christian Medical College hospital Vellore.

Supplementary material

Supplementary material is available at *European Heart Journal - Case Reports* online.

Slide sets: A fully edited slide set detailing this case and suitable for local presentation is available online as [Supplementary data](#).

Consent: The authors confirm that written consent for submission and publication of this case report including images and associated text has been obtained from the patient in line with COPE guidance.

Funding: none declared

Conflict of interest: All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation. There are no conflicts of interest pertaining to this case report.

Acknowledgements

We sincerely thank Dr Kirubakaran D (Anaesthesia department) for support during the TAVI procedure. We would also like to acknowledge contribution of Dr Jesu Krupa (Cardiology department), Dr Elizabeth Joseph and Dr Aparna Irodi (Radiology department) in performing imaging assessments of the patient.

References

- Baumgartner H, Falk V, Bax JJ, De Bonis M, Hamm C, Holm PJ, et al. ESC Scientific Document Group. 2017 ESC/EACTS Guidelines for the management of valvular heart disease. *Eur Heart J* 2017;**38**:2739–2791.
- Popma JJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada H, O'Hair D et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med* 2019;**380**:1706–1715.
- Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med* 2019;**380**:1695–1705.
- Feng Y, Zhao ZG, Baccaro J, Zeng MF, Fish RD, Chen M. First-in-man implantation of a pre-packaged self-expandable dry-tissue transcatheter aortic valve. *Eur Heart J* 2018;**39**:713–713.