ESC European Society of Cardiology
European Heart Journal - Case Reports
doi:10.1093/ehjcr/ytab137

CASE REPORT
Congenital heart disease

A case report of open-aorta, direct transcatheter valve-in-valve implantation: an innovative approach to manage the hazard of coronary flow compromise in transcatheter aortic valve re-interventions

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Received 16 November 2020; first decision 7 December 2020; accepted 6 April 2021

Background Coronary flow compromise is a significant risk of transcatheter aortic valve therapy. Warranting preservation of coronary flow is even more challenging with transcatheter aortic valve re-intervention since the implantation of a transcatheter valve within a degenerated bioprosthetic or transcatheter valve increases significantly this hazard.

Case summary We present a case of heart failure secondary to transcatheter aortic valve degeneration requiring a transcatheter aortic valve re-intervention. Pre-operative imaging studies demonstrated a high risk for iatrogenic coronary flow impairment. The patient underwent a successful surgical removal of the prosthetic valve leaflets followed by direct transcatheter aortic valve implantation.

Conclusion We reviewed the literature on the approach to difficult coronaries in transcatheter aortic valve therapy, and we describe an innovative hybrid approach that may represent a viable alternative in cases where catheter techniques of coronary flow preservation are not applicable.

Keywords Case report • Transcatheter aortic valve re-intervention • Coronary flow compromise • Direct transcatheter aortic valve deployment

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Handling Editor: Dimitrios A Vrachatis
Peer-reviewers: Roberto Lorusso; Andreas Mitsis; Callum Little
Compliance Editor: Alexander Tindale
Supplementary Editor: Elhosseyn Guella
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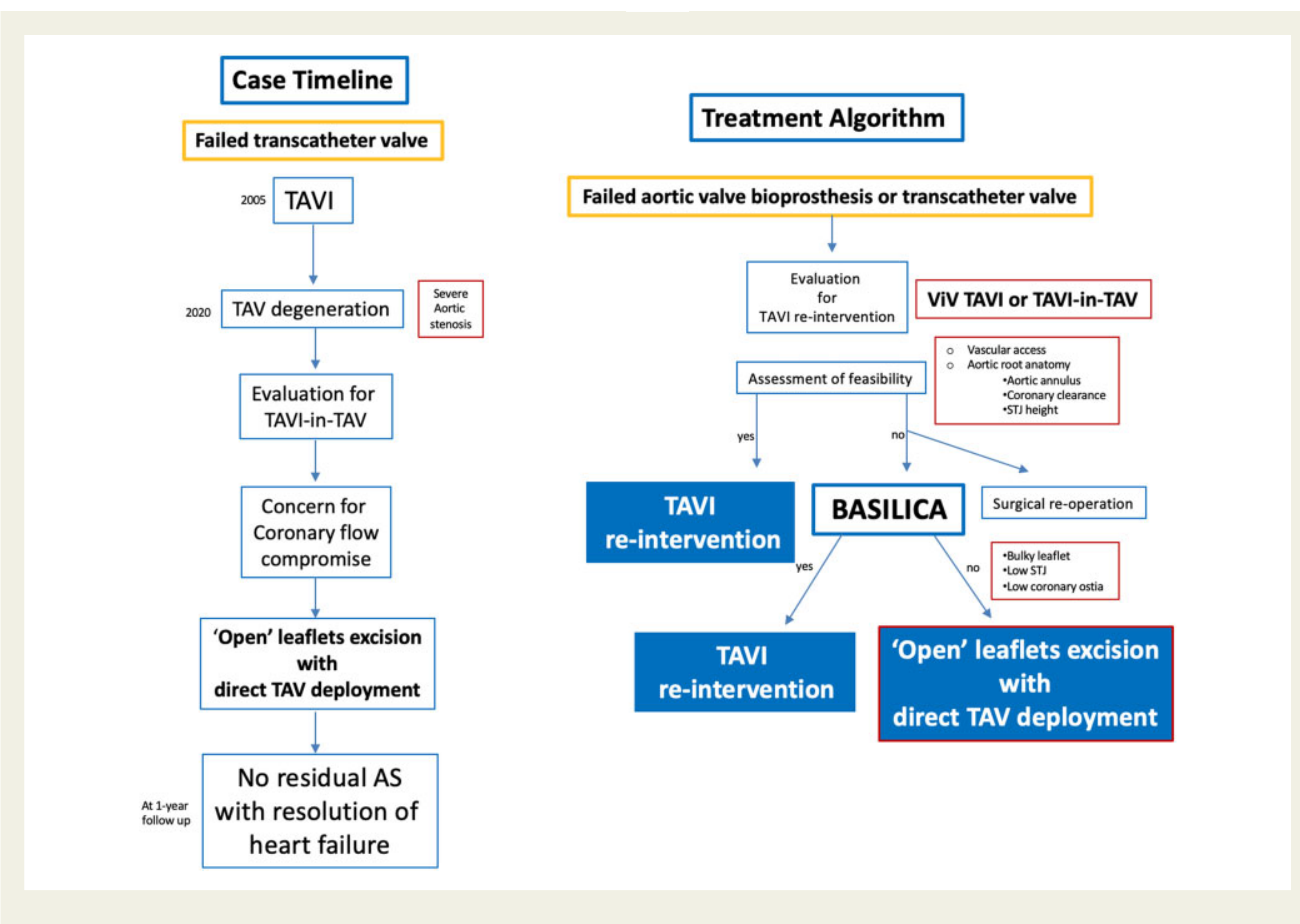
Learning points

- Transcatheter aortic valve re-interventions are faced by a significant risk of coronary flow compromise.
- The BASILICA procedure is a transcatheter intervention designed to produce a laceration of a native or bioprosthetic valve leaflet in cases where the transcatheter aortic valve re-intervention expose to the risk of coronary flow compromise.
- We report an innovative minimally invasive hybrid approach of 'open' prosthetic-valve leaflets excision with direct transcatheter aortic valve deployment in a case where catheter techniques of coronary preservation were not applicable.
- This approach reduces the operative risk and the incidence of perioperative complications simplifying the surgical intervention by avoiding the need to remove the transcatheter prosthesis stent and allowing an easier valve replacement by a direct deployment as compared to the standard surgical aortic valve replacement.

Introduction

Transcatheter valve therapy has changed the paradigm of management of patients affected by aortic valve stenosis, becoming a valid alternative to the traditional surgical aortic valve replacement.[1,2] Transcatheter aortic valves have also been broadly used to replace the function of a failed surgically implanted aortic bioprosthetic valve (ViV-TAVI) with the main objective of reducing the significant morbidity and mortality of a surgical reoperation.[2–9] Similarly, repeating a transcatheter aortic valve implantation (TAVI-in-TAV) is accomplished in the acute setting to repair the intraprocedural malfunction of a deployed transcatheter prosthesis or rather in patients with long-term degeneration of a previously implanted transcatheter valve.[3,4,10,11] Coronary flow compromise is the main concern for the feasibility of transcatheter aortic valve implantation (TAVI), and careful patient selection is a key factor to the applicability of this therapy.[12,13] This issue is even more compelling with TAVI re-interventions.[3–11] Nonetheless, predicting coronary flow compromise and implementing measures to prevent its occurrence is a challenging endeavour. The BASILICA procedure (Bioprosthetic or native Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery obstruction) is a transcatheter intervention aimed at splitting the leaflets of a native or bioprosthetic aortic valve in cases at risk for TAVI-induced coronary obstruction.[13,14] We present a novel technique of 'hybrid' TAVI-in-TAV with the direct deployment of the transcatheter valve through an open surgical approach. The procedure was combined with surgical removal of the leaflets of a previously implanted transcatheter valve. Informed consent for the publication of this manuscript was obtained from the patient.

Timeline



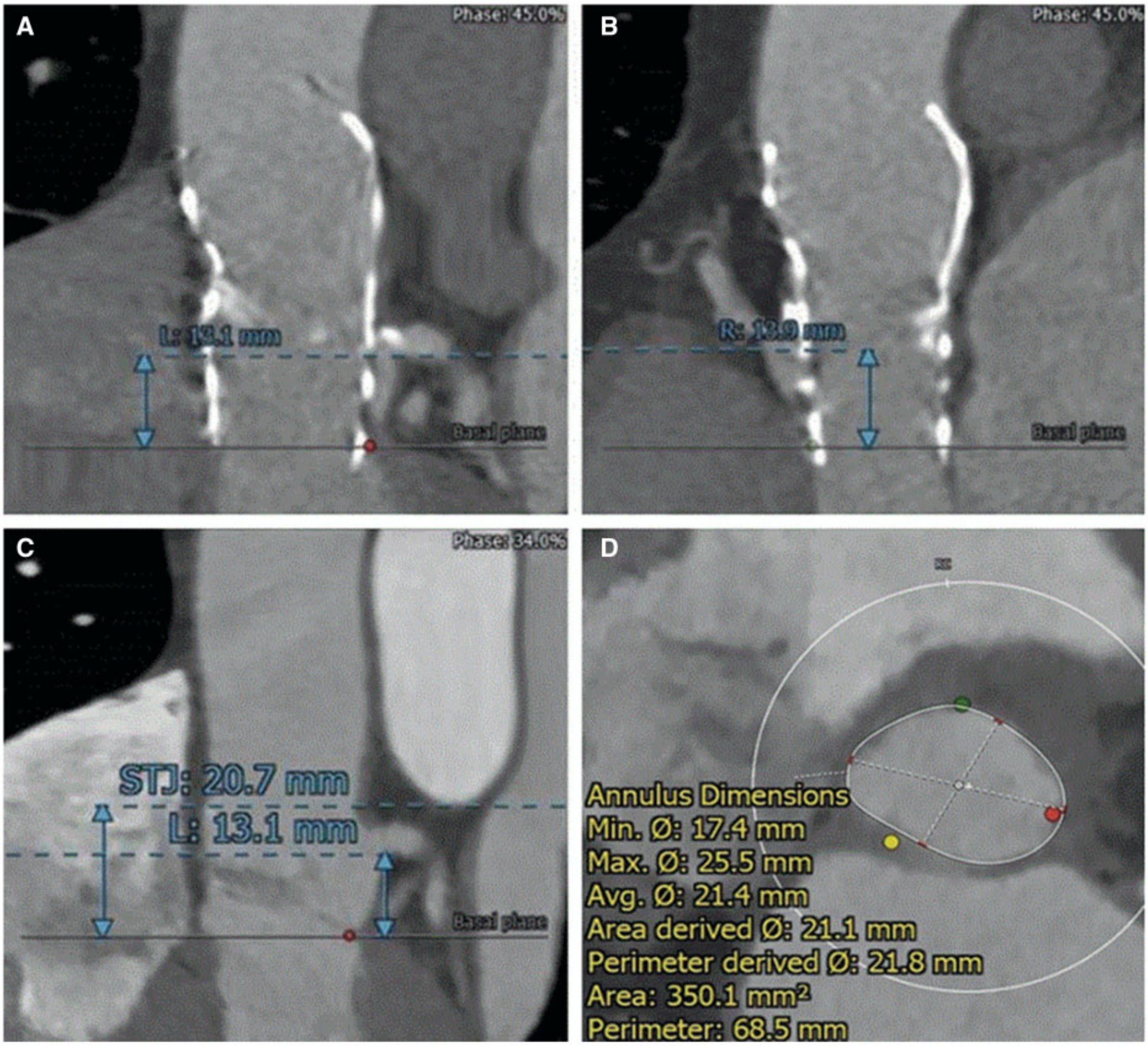


Figure 1 Computed tomography scan reconstructions showing height of coronary ostia and sino-tubular junction (STJ), and the aortic valve annular dimension.

Case presentation

A 72-year-old female who had a history of TAVI with a 25 mm CoreValve Evolut (Medtronic Inc., Minneapolis MN, USA) performed in 2015 at a different institution, presented with symptoms of severe dyspnoea and fatigue. She had a history of rapidly deteriorating heart failure for the past 2 months with recurrent hospitalizations for respiratory distress associated with bilateral pleural effusions requiring repeated thoracenteses. She had multiple comorbidities, including advanced scleroderma, complicated by moderate restrictive lung disease and severe peripheral vascular disease, and severe autoimmune hepatitis associated with mild baseline elevation of the liver function tests.

Transoesophageal echocardiogram (TOE) revealed depressed left ventricular function with ejection function of 35%, mild pulmonary hypertension, mild to moderate mitral stenosis and severe prosthetic aortic valve stenosis, with an orifice valve area of 0.46 cm^2, a mean pressure gradient of 60.3 mmHg and a peak velocity of 4.7 m/s. Computed tomography study scan in preparation of a TAVI-in-TAV raised concerns for bilateral coronary artery flow compromise (*Figure 1*). The case was discussed with a heart team comprised of national and international experts to establish candidacy for the BASILICA procedure. There was consensus that the unknown annular orientation of the existing valve leaflets rendered the BASILICA procedure unviable. Therefore, we opted for an 'open' approach of surgical excision of the prosthetic aortic valve leaflets followed by a direct TAVI-in-TAV deployment.

The procedure was performed through an upper midline hemisternotomy. Cardiopulmonary bypass was established with cut-down cannulation of the right femoral vessels. The aorta was opened transversally above the distal edge of the CoreValve Evolut stent, which was easily palpable through the aortic wall.[15,16] The prosthetic

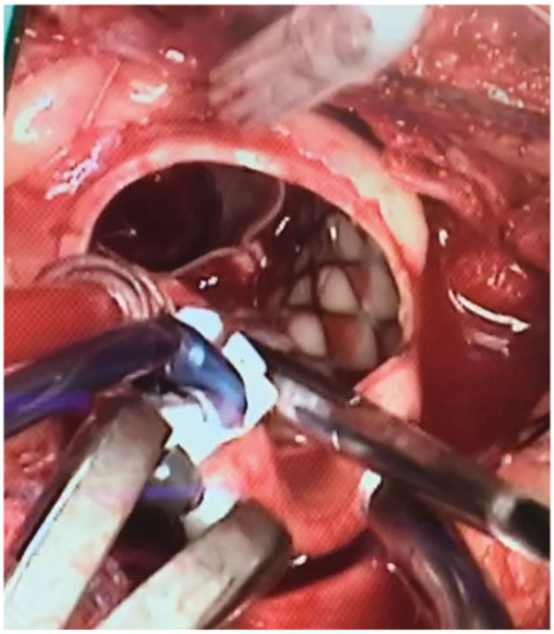


Figure 2 Intraoperative image with direct assessment of patency of left main (LM) coronary artery: right angle clamp is used to probe patency of left main coronary ostium.

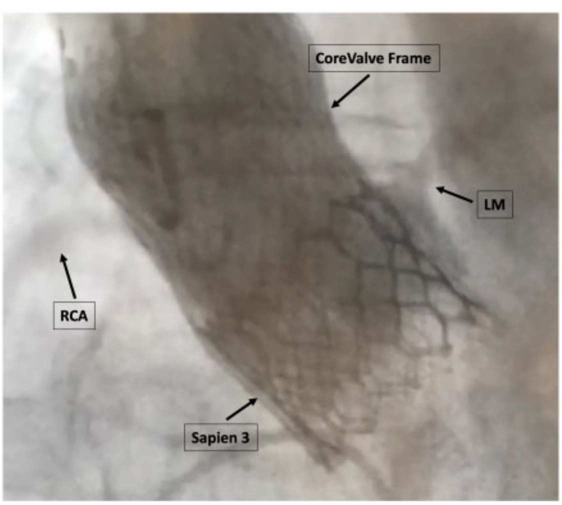


Figure 3 Post-procedure aortogram. LM, left main; RCA, right coronary artery.

valve leaflets, which were diffusely thickened and severely calcified, were excised under direct visualization, leaving in place the prosthetic Nitinol valve frame (*Figure 2*). A 23 mm Sapien 3 (Edwards Lifesciences Corp, Irvine, CA, USA) was deployed under direct vision warranting control of patency and unobstructed blood flow access to the coronary ostia. Post-procedure aortogram confirmed correct valve positioning and preservation of coronary flow (*Figure 3*). Cardiopulmonary bypass time was 28 min and cross-clamp time was

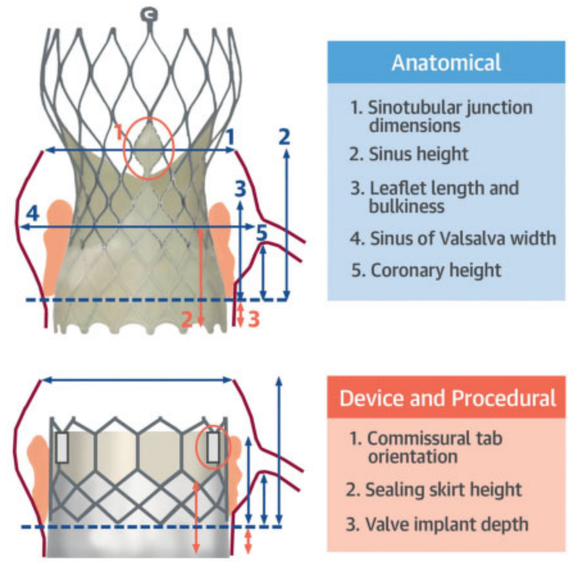


Figure 4 Factors impacting on risk of coronary flow compromise after TAVR (modified with permission from Yudi et al.).[17]

20 min. Intraoperative TOE showed the adequate function of the newly deployed aortic valve prosthesis with absence of any paravalvular leak.

The patient recovered remarkably and was eventually discharged to cardiac rehabilitation on post-operative Day 5. She currently remains symptom-free at a 12-month follow-up. An 11-month follow-up transthoracic echocardiogram showed improved left ventricular function with ejection fraction of 50% and a transvalvular mean gradient of 11 mmHg.

Discussion

Coronary ostia obstruction is a significant concern in transcatheter aortic valve re-interventions. Studies have shown a threefold increased risk of coronary obstruction as compared to the initial TAVI.[3,4,10,11] This occurrence depends on specific factors related to patients' anatomy, such as a low position of the coronary ostia or small coronary sinuses, but also on procedural factors, such as a high deployment, oversizing or malpositioning of the transcatheter prosthesis (*Figure 4*).[4,17] Coronary occlusion and flow compromise can be prevented with pre-wiring of the coronaries and subsequent coronary stenting as needed, although this approach may not be helpful in cases with potential risk of sinus sequestration.[12,13] The BASILICA procedure was designed with the specific objective of reducing the risk of coronary blood-flow compromise with transcatheter valve implantation.[13,14] In a study of the feasibility of repeat TAVI after Sapien 3 implantation, by Tang and co-authors, it was determined that TAVI-in-TAV may not be feasible in more than 20% of Sapien 3 TAVI procedures and in more than 50% among patients with sinus height inferior to the height of the transcatheter valve prosthesis.[17] The baseline incidence of coronary obstruction after transcatheter aortic valve replacement is 0.7%, with a 30-day mortality of 41%, but rises from 2.3

Table 1 Mechanisms and contributors to transcatheter aortic valve replacement-induced ostial coronary artery obstruction (modified with permission from Lederman *et al.*)[13]

Mechanism	Description	Amenable to BASILICA
'Deficient sinus'	Direct coronary obstruction by leaflet when the sinus of valsalva is obliterated or effaced.	Yes
'Sequestered sinus'	Indirect coronary obstruction; leaflet blocks the entire sinus of valsalva. Rare in native aortic valve disease.	Yes
Mass effect	Obstruction of coronary ostium by a leaflet mass, typically calcific nodule. Extrinsic compression by aortic haematoma intramural or extramural	No
TAVR skirt and commissure	Obstruction from fabric skirt or commissural posts on implanted TAVR device.	No
Embolization	Dislodgement of thrombotic or degenerative material.	No
Stent deformation and thrombosis	'Snorkel' coronary stents implanted to prevent or treat ostial coronary obstruction are subject to extrinsic compression and abnormal flow conditions.	No

BASILICA, bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction during TAVR; TAVR, transcatheter aortic valve replacement.

to 3.5% for ViV-TAVI.[4,11,17–24] Risk of coronary flow compromise is highest in the female gender, coronary ostial height below 10 mm, sinus of Valsalva width below 30 mm and with virtual valve-to-coronary distance of less than 4 mm.[13,20–25] Lederman *et al.*[13] described five mechanisms of TAVI-induced coronary obstruction (*Table 1*). BASILICA would apply to cases of initial TAVI, ViV-TAVI, or TAVI-in-TAV, when performing the transcatheter procedure would expose to the risk of coronary flow compromise. The BASILICA trial had a high procedural success of 95% with a very low mortality.[24] Nonetheless, it is not unusual to encounter conditions under which the BASILICA procedure would not be feasible, such as in cases with bulky and calcified native or prosthetic valve leaflets (*Table 1*).[13,24,25] In the case presented, we opted for the innovative combination of an open-aorta approach with surgical excision of the transcatheter valve leaflets, followed by transcatheter deployment of a balloon-expandable prosthesis under direct visualization, since performing the BASILICA procedure was not considered a viable option. In this case, the redo operation of surgical replacement of the CoreValve prosthesis would have required the complete extraction of the Nitinol valve frame, followed by a surgical aortic valve replacement. The potential complications of this procedure are significant, with risks of damage to the aorta or the coronary ostia and with a significant perioperative risk of surgical complications and stroke.[14,15] In our evaluation, the hybrid approach selected would have reduced the risk of intra and peri-operative complications, particularly avoiding the technical challenge of removing the stent of the previously implanted transcatheter prosthesis and also simplifying the aortic valve replacement with a direct deployment vs. a surgical implantation. Although more invasive than the traditional transcatheter approach, this hybrid strategy can be the only suitable alternative in those high-risk cases for which TAVI-in-TAV or ViV-TAVI cannot be safely performed because of the risk of coronary flow compromise. The use of this technique could also be hypothesized for cases of native aortic valve stenosis with risk of coronary flow compromise for which BASILICA would not be feasible or would rather be too risky. Its main contraindication would be the presence of a 'porcelain' aorta which would limit the surgeon's ability to cross-clamp the aorta without facing a high risk of stroke, distal embolization, or damage to the aortic wall.

In summary, TAVI-in-TAV or ViV-TAVI may not be feasible in a significant number of patients because of the hazard of coronary flow compromise. We report an innovative hybrid technique of 'open' surgical removal of the transcatheter prosthesis's leaflets followed by direct transcatheter aortic valve deployment with a minimally invasive approach in a case where the BASILICA procedure was not a suitable option. The approach presented has the substantial advantage of reducing the technical difficulty of the surgical intervention and may significantly decrease the occurrence of perioperative complications by avoiding the need to remove the previously implanted transcatheter prosthesis stent or the mechanical structure of a bioprosthetic valve, also simplifying the aortic valve replacement compared to the standard operative technique. Ultimately, this approach would add to the surgical armamentarium expanding the applicability of TAVI re-interventions to those cases that due to any possible constraint would not be suitable to transcatheter therapy, allowing to select a less invasive and less risky procedure as compared to a reoperation of transcatheter or bioprosthetic aortic valve explantation with a surgical aortic valve replacement.

Lead author biography

Dr Calcaterra main clinical interests are aortic diseases, off-pump coronary artery revascularization, minimally invasive cardiac valve surgery, structural valve therapy, and ECMO. His main research interests are centred on the study of aortic dissection, blood conservation, and public health with specific focus on quality improvement and assessment.

Supplementary material

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

Acknowledgements

The authors would like to thank Elyce Kwasman, MSN, ACNP for the kind collaboration on the preparation of this manuscript.

Slide sets: A fully edited slide set detailing these cases 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 guidelines.

Conflict of interest: None declared.

Funding: None declared.

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