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# Safety and Feasibility of Transcatheter Aortic Valve Replacement in COVID-19 Patients: A Case Series

Enrico Giacomin [a,b,*], Alberto Barioli [a], Luca Favero [a], Davide Lanzellotti [a], Diego Calzolari [a], Alessandro Daniotti [a], Carlo Cernetti [a]

[a] Cardiology Unit, Cardio-Neuro-Vascular Department, Ca' Foncello Hospital Azienda N 2 Marca Trevigiana, Treviso, Italy
[b] Department of Cardiac, Vascular, Thoracic Sciences and Public Health, University of Padua, Italy

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ABSTRACT

In 2020, the coronavirus disease 2019 (COVID-19) pandemic has led to a decrease in interventional treatment for structural heart disease worldwide. In this context, the management of patients with symptomatic severe aortic stenosis (AS) or bioprosthetic valve dysfunction (BVD) represents a clinical challenge, as a delay in aortic valve replacement procedures may increase short-term morbidity and mortality. We report four cases of TAVR performed in patients with Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection. All of them were discharged in good clinical conditions and no adverse events were reported at 30 days follow-up. Our experience suggests that in selected patients with mild SARS-CoV-2 infection and symptomatic native AS or BVD, TAVR has a favorable short-term outcome.



## 1. Introduction

The coronavirus disease 2019 (COVID-19) pandemic caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) virus has led to a very significant decrease in healthcare activity in interventional cardiology units worldwide (1). In Italy, one of the European countries hit hardest by COVID-19, a 70% drop in transcatheter aortic valve replacement (TAVR) procedures was observed [2]. However, it is known that patients with symptomatic severe aortic stenosis (AS) or bioprosthetic aortic valve dysfunction (BVD) are at high risk of severe adverse events, and treatment delays may result in increased short-term morbidity and mortality [3,4].

We report four cases of patients with mild SARS-CoV-2 infection and symptomatic severe AS or BVD, who have undergone successful TAVR in our Institution in the North-East of Italy.

## 2. Case series

Four patients with mild SARS-CoV-2 infection and severe symptomatic AS or BVD were admitted to our Cardiology Department for heart failure (HF) between November and December 2020. All patients were tested at admission for SARS-CoV-2 infection with rapid antigen tests. In patients with high clinical suspicion of COVID-19, but who tested negative on initial assessment, results were confirmed by reverse transcription polymerase chain reaction (RT-PCR) performed on a nasopharyngeal specimen. Additional tests were repeated during hospitalization in patients with clinical suspicion of infection and at discharge in all patients. According to previous reports [5], SARS-CoV-2 infection was classified as follows: mild (non-pneumonia and mild pneumonia), severe (dyspnea, respiratory frequency above 30/min, blood oxygen saturation <93%, partial pressure of arterial oxygen to fraction of inspired oxygen ratio <300, lung infiltrates >50% within 24 to 48 h), and critical (respiratory failure, septic shock, multiple organ dysfunction or failure).

After CT-scan assessment of aortic root anatomy, native valve disease or prosthetic valve dysfunction, and coronary and ilio-femoral arteries, all patients were allocated to TAVR by the local Heart Team. Baseline clinical and procedural characteristics are reported in Tables 1 and 2, respectively.

All procedures were performed following the recommendations of the Italian Society of Interventional Cardiology (GISE) for the treatment of Covid-19 patients [6]. As a matter of fact, all the staff wore the recommended personal protective equipment (PPE) (i.e. disposable gown, disposable N95 or FFP2 respirator, hair cover, shoe cover, googles or face shield, double pair of gloves). According to our hospital protocol, all the staff was tested for SARS-CoV2 infection immediately at the onset of fever or respiratory symptoms or every two weeks if asymptomatic. Terminal disinfection of the procedure room at the end of each procedure was performed as per hospital protocol. The average

* Corresponding author at: Cardiology Unit, Cardio-Neuro-Vascular Department, Azienda ULSS n. 2 Marca Trevigiana, Via Sant'Ambrogio, 37, 31100 Treviso, Italy.
*E-mail address:* enrico.giacomin@aopd.veneto.it (E. Giacomin).

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**Table 1**
Baseline characteristics.

| | Patient 1 | Patient 2 | Patient 3 | Patient 4 |
|---|---|---|---|---|
| Sex | Male | Female | Male | Female |
| Age (years) | 85 | 81 | 82 | 69 |
| Aortic valve disease | Severe AR in bioprosthetic valve | Severe AS | Severe AR in bioprosthetic valve | Severe AS |
| Type of Heart Failure | Wet and warm | Wet and warm | Wet and warm | Wet and warm |
| NYHA class at admission | III | III | III | IV |
| Covid-19 positive interval | 6th day-26th day | 1st day-36th day | 21st day-39th day | 3rd day-32nd day |
| EKG at admission | AF, 70 bpm, RBBB + LAFB | AF, 81 bpm | AF, 73 bpm | SR, 66 bpm, LV hypertrophy |
| Echo at admission | | | | |
| LVEF (%) | 44 | 67 | 66 | 62 |
| Stroke volume index (ml/m$^2$) | 41 | 25 | 57 | N/A |
| Max/mean Aortic gradient (mmHg) | 49/21 | 54/31 | 55/30 | 80/48 |
| Aortic valve area (cm$^2$) | >1 | 0.7 | >1 | 0.9 |
| Aortic regurgitation grade | Severe | Mild | Severe | Mild |
| Blood test at admission | | | | |
| Hemoglobin (g/l) | 141 | 144 | 141 | 99 |
| Creatinine (umol/l) | 100 | 193 | 120 | 1100 |
| eGFR (ml/min/1.73m$^2$) | 58 | 24 | 48 | 3 |

AR: aortic regurgitation; AS aortic stenosis; LVEF: left ventricular ejection fraction; eGFR: estimated glomerular filtration rate; RBBB: right bundle branch block; LAFB: left anterior fascicular block; AF: atrial fibrillation; SR: sinus rhythm.

time in cath-lab was 102.5 min and 40 extra minutes for cleaning were needed after each procedure. No case of infection was reported in the personnel involved in the procedures.

## 3. Case 1

The first patient was an 85-year-old man with history of permanent atrial fibrillation (AF) and previous ischemic stroke. In 2006 the patient underwent surgical aortic valve replacement (SAVR) with a 25 mm Hancock II bioprosthetic valve (Medtronic, Dublin, Ireland) for severe aortic regurgitation and ascending aorta replacement (Bentall procedure) for ascending aortic aneurysm. Subsequent follow-up reported normal left ventricle ejection fraction (LVEF) and no significant BVD. In November 2020, the patient was admitted to our hospital for congestive HF (NYHA class III). Transthoracic and transesophageal echocardiography revealed a moderate reduction of LVEF (45%), moderate-to-severe mitral regurgitation, and BVD with severe intraprosthesis regurgitation. On day 6 since admission, the patient developed cough and worsening dyspnea and tested positive for COVID-19. The course of the infection was favorable, with no signs of respiratory failure. CT-scan assessment for procedural planning of TAVR showed diffuse bronchial wall thickening as well as parenchymal consolidation of the left upper lobe (Fig. 1). On day 20, TAVR-in-SAVR with a 26 mm Medtronic Corevalve Evolut R valve was performed. The postoperative course was uneventful. The patient was discharged on day 25 in good condition with a negative COVID-19 test result.

## 4. Case 2

The second patient was an 81-year-old woman with known paradoxical low-flow low-gradient severe AS and a history of paroxysmal AF, previous carotid artery endarterectomy, severe chronic kidney disease and intestinal angiodysplasia. In November 2020, the patient was admitted to the Emergency Department with cough, fever and symptoms of congestive HF (NYHA class III). The patient tested positive for COVID-19 and was admitted to the Infectious Disease Department of our hospital. After 23 days of hospitalization, the patient was transferred to our Cardiology Department. The Heart Team decision was to proceed with percutaneous intervention, so the patient underwent TAVR with a 26 mm Edwards Sapien 3 valve (Edwards Lifesciences Corp. Irvine, CA, USA) without complications. On the second postoperative day, advanced atrio-ventricular block was detected so the patient underwent pacemaker implantation. The patient was still positive to COVID-19 test when discharged on day 36, although asymptomatic.

## 5. Case 3

The third patient was an 82-year-old man with history of paroxysmal AF. In 2017 the patient underwent SAVR with a 25 mm Medtronic Hancock II bioprosthetic valve for severe AS. One year later the patient was hospitalized for bacterial endocarditis of the bioprosthetic aortic valve due to Streptococcus Salivarius. At that time, there was no indication for redo SAVR, so the patient was medically managed. In October 2020, the patient was admitted to our Cardiology Unit for congestive

**Table 2**
Procedural data.

| | Patient 1 | Patient 2 | Patient 3 | Patient 4 |
|---|---|---|---|---|
| TAVR type | Corevalve Evolut R | Sapien 3 | Corevalve Evolut R | Sapien 3 |
| TAVR size (mm) | 26 | 26 | 26 | 23 |
| Principal arterial access | Right common femoral | Right common femoral | Right common femoral | Right common femoral |
| Secondary arterial access | Left radial | Left radial | Left radial | Left common femoral |
| Time in Cath lab (min) | 110 | 80 | 90 | 130 |
| Vascular complication | None | None | None | Left common femoral artery pseudoaneurysm |
| Post procedural AV block | None | Advanced AV block | None | None |
| Post-TAVR trans-aortic mean gradient (TTE, mmHg) | 13 | 11 | 13 | 15 |
| Post-TAVR aortic regurgitation | Trivial | Trivial | Trivial | Trivial |
| NYHA class at discharge | I | I | I | I |
| Event at 30 days from discharge | None | None | None | None |

TAVR: transcatheter aortic valve replacement; AV: atrioventricular; TTE: trans-thoracic echocardiography.

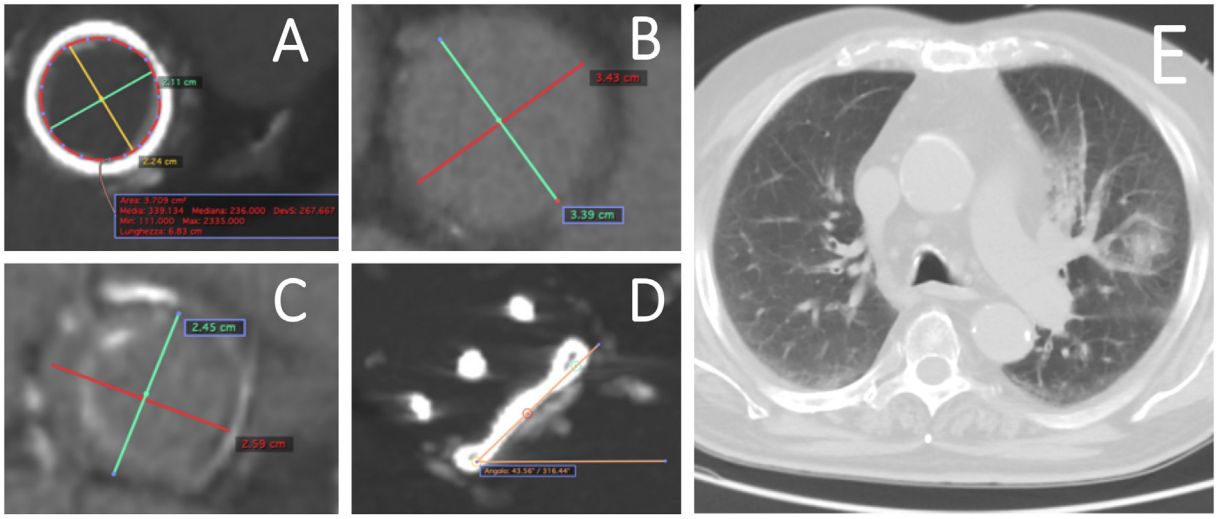


**Fig. 1.** CT-scan assessment for procedural planning of TAVR in a patient with BVD. A–D EKG-synchronized acquisition assessing bioprosthetic valve and ascending aorta dimensions (A annulus, B sino-tubular junction, C left ventricular outflow tract, D aorto-ventricular plane). E. Thoracic CT-scan showing diffuse bronchial wall thickening as well as parenchymal consolidation of the left upper lobe. CT: computed tomography. TAVR: transcatheter aortic valve replacement. BVD: bioprosthetic valve dysfunction.

HF caused by worsening of BVD with severe aortic regurgitation (NYHA class III). No clinical nor laboratory signs of recurrent bacterial endocarditis were found. On day 21 since admission, the patient developed cough and tested positive for COVID-19. The course of the infection was favorable, with no signs of respiratory failure. On day 35, TAVR-in-SAVR with a 26 mm Medtronic Corevalve Evolut R valve was performed. The patient tested negative for COVID-19 on day 39 and was subsequently discharged after another brief and uneventful hospitalization.

## 6. Case 4

The fourth patient was a 69-year-old woman with known severe AS, paroxysmal AF, end-stage kidney disease on dialysis treatment and thyroid goiter with indication for thyroidectomy. In November 2020, the patient was admitted to another hospital for HF (NYHA class IV), testing negative for COVID-19, and was then referred to our Cardiology Department for intervention. At admission, COVID-19 test was repeated and resulted positive. As respiratory symptoms were judged mainly related to the AS, the Heart Team decision was to proceed with TAVR. Intervention with a 23 mm Edwards Sapien 3 valve was then performed on day 5. Post-operative course passed without major TAVR-related complications. On day 9, the patient developed bilateral pneumonia and was treated with corticosteroids, ceftriaxone and oxygen supplementation. In the following days, we assisted to a progressive improvement in symptoms and pulmonary exchanges, so the patient was discharged in good condition on day 39, with positive COVID-19 test result but in the absence of respiratory symptoms.

## 7. Discussion

The COVID-19 pandemic has led to an increase in mortality directly, due to complications related to the infection, and indirectly, due to the saturation of hospital resources with consequent delay in the diagnosis and treatment of serious non-COVID-19 diseases, in particular cardiovascular and neoplastic ones [8]. As a matter of fact, COVID-19 pandemic has caused an important volume reduction in elective structural heart disease intervention that has led to treatment delays [1,2]. Deferment of TAVR for symptomatic severe AS or BVD is associated with increased risk of adverse events, including sudden death [3,4]. Consequently, it appears mandatory for health care systems to develop strategies that allow the correct and timely treatment of symptomatic AS or BVD, even in the course of the COVID-19 pandemic. To this regard, during the coronavirus pandemic, an ACC position statement suggests to proceed with TAVR without delay in patients with severe heart failure symptoms due to aortic stenosis [8]. Some authors have even suggested to reconsider TAVR instead of SAVR in patients with severe symptomatic AS eligible to surgery, in an effort to save health care resources by shortening the permanence of patients in the Intensive Care Units [9–11]. To reduce even further health care resources consumption in pandemic times, Zouaghi et al. proposed a day-hospital approach for TAVR [12].

TAVR in COVID-19 patients has never been evaluated in large studies and only few case reports have been reported so far. Attisano et al. reported a balloon valvuloplasty strategy as a bridge to TAVR in an 86-year-old man with hemodynamic instability due to severe AS and suspected COVID-19 infection [13]. Similarly, Bauernschmit et al. described a case of a 57-year-old man with previous aortic root replacement, admitted to the Cardiology Department for acute HF due to severe aortic regurgitation and high clinical suspicion of COVID-19, despite multiple negative tests. The patient underwent successful TAVR-in-SAVR during hospitalization [14].

Italy has been among the European countries most impacted by the coronavirus outbreak and the coexistence of SARS-CoV-2 infection and symptomatic severe AS may not be rare. In this case series, we report four TAVR performed in patients with mild SARS-CoV-2 infection. All procedures were successful and only one patient required pacemaker implantation on the second postoperative day following detection of asymptomatic advanced AV block. Three patients needed neither admission in coronary intensive care unit nor specific treatment of COVID-19 infection, and were discharged on the fifth postoperative day. The fourth one developed Covid-19 pneumonia after TAVR, thus requiring corticosteroids and antibiotics administration and 20 additional days of stay in coronary intensive care unit. Thirty-day follow-up after discharge was uneventful for all patients.

The presence of HF due to severe AS or BVD could theoretically worsen respiratory symptoms of pulmonary SARS-CoV-2 infection. The hemodynamic improvement resulting from successful TAVR, mainly by decreasing left ventricle filling pressures, could promote pulmonary exchanges and reduce the risk of respiratory failure and need for intubation. All treated patients had mild COVID-19 infection, not significantly affecting prognosis so, delaying TAVR could have exposed patients to the complications of AS or BVD and could have complicated the course of the infection, likely resulting in longer hospital stays and

increased resource utilization. Conversely, in patients with severe forms of COVID-19, in whom prognosis depends on the infection, TAVR, even if effective, could be a futile and resources wasting procedure. We believe that pre-operative CT-scan, routinely performed before TAVR to assess valve anatomy or prosthetic valve dysfunction, could be a valuable tool also in excluding a severe COVID-19 pulmonary involvement, in order to guide the Heart Team decision.

To the best of our knowledge, this is the first case series of patients successfully treated with TAVR for severe AS or BVD and concomitant SARS-CoV-2 infection. Our experience suggests that, in appropriately selected patients with mild SARS-CoV-2 infection and symptomatic severe AS or BVD, a timely procedure of TAVR could be a safe and effective treatment. However, longer follow-up studies in a larger population are necessary to evaluate these preliminary results.

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## Declaration of competing interest

None.

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