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Transcatheter aortic valve implantation (TAVI) outcomes during the coronavirus disease 2019 (COVID-19) pandemic have not been fully evaluated and some structural programs in the world have been suspended during this period. We sought to evaluate and compare clinical outcomes in patients undergoing TAVI in pandemic versus nonpandemic era. In a single center, we compared 198 TAVI patients performed during 2019 to 59 patients performed during the COVID-19 pandemic period (March 1st to June 30th, 2020). Primary outcome was procedural success according to VARC criteria and 30-day mortality rates. VARC-defined procedural success was high in both groups (93.3% vs 96.6%; p = 0.53). There were no differences in any vascular complications (26% vs 19%; p = 0.3), permanent pacemaker implantation (11.8% vs 15.3%; p = 0.63), and length of hospital stay (5.2 vs 4.2 days; p = 0.29). Thirty-day mortality was similar (3% vs 3.4%; p = 1.0). We had no documented COVID-19 disease in our patients during follow up. In conclusion, TAVI procedures can be performed effectively and safely during the COVID-19 pandemic, using a minimalist approach, early discharge, and by maintaining proper use of personal protective equipment.

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difference between groups was assessed using the student’s \( t \) test. For continuous variables not normally distributed were reported as median and interquartile range (IQR, 25th-75th percentiles) values, and significance was assessed using the Mann-Whitney U or Kruskal-Wallis tests. Categorical variables were presented in frequencies and percentages and significance was assessed using the chi-square test or Fisher’s exact test. Kaplan-Meier estimates of survival analysis were calculated. Differences among the groups were compared with the log-rank test. Statistical significance was accepted for a 2-sided \( p < 0.05 \). All data were initially entered into statistical program SPSS (version 25.0.0; IBM, Armonk, NY, USA) and R version 4.0.0 software (The R foundation).

**Results**

Of the 257 patients included in the present analysis, 59 (23%) underwent TAVI during the COVID 19 pandemic. This group was compared with the TAVI patients performed in 2019 (n = 198, 77%).

As shown in Table 1, baseline characteristics including age, gender, co-morbidities, and STS score were similar in both study groups. Patients in COVID-19 pandemic were using significantly more anticoagulant therapy at baseline.

Echocardiographic and tomographic characteristics previous TAVI of the participants are shown in Table 2 with no significant differences between the 2 groups. The vast majority of cases were done via femoral access. There were no differences in the type of access, type of valve, valve in valve procedures, and other technical issues during the procedure, such as balloon pre- and postdilation (Table 3).

Outcomes are presented in Table 4. In both groups there was a high TAVI device success. There were no differences in rates of any vascular complications, major or minor bleeding and permanent pacemaker implantation. Thirty-day mortality was similar (3% vs 3.4%; \( p = 0.26 \)) (Figure 1).

In the TAVI group performed during the COVID-19 pandemic, there was a tendency for a shorter length of hospital stay after the procedure (4.2 vs 5.2 days; \( p = 0.29 \)). None of the patients in the COVID-19 era were infected with the virus from the procedure to the latest follow-up day.

**Discussion**

This study shows that TAVI program could have been maintained despite the limitations and restrictions applied by the COVID-19 outbreak with excellent and comparable outcomes to a nonpandemic era.

The ACC/SCAI group proposed criteria for not delaying intervention in hospitalized patients with severe AS despite the outbreak including associated reduction in ejection fraction, presence of class III-IV congestive heart failure symptoms, or syncope secondary to AS. The document states that it would be reasonable to schedule TAVI for elective patients with severe to critical aortic stenosis and class III-IV CHF symptoms. In patients with mild symptoms decision should be made according to quantitative measures of valve severity that indicate a critically tight valve. For truly asymptomatic patients, it is reasonable to postpone TAVI for 3 months or until after hospital operations resume elective procedures. Close outpatient monitoring, possibly via telehealth, should continue for all patients with severe AS.

On February 21st, 2020, Israel confirmed the first case of COVID-19. In the following months, we saw an exponential increase in cases, reaching a peak during April 2020. Until the end of June, 25,244 confirmed cases were registered with 354 deaths. During this time, dynamic quarantines and total lockdown were carried out in the country. With widespread community transmission of COVID-19, the over arching goal was to minimize the risk of COVID-19 exposure and to preserve limited resources such as anesthesia care, ventilators, intensive care unit (ICU) beds, and PPE, making TAVI implants more difficult. In our

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**Table 1**

| Variable                                | All patients (N = 257) | Pre-COVID (N = 198) | COVID period (N = 59) | \( p \) Value |
|-----------------------------------------|------------------------|---------------------|-----------------------|--------------|
| Age (years ± SD)                        | 80.3 ± 9               | 80.2 ± 9.5          | 80.5 ± 6.9            | 0.82         |
| Men                                     | 127 (50%)              | 97 (49%)            | 30 (51%)              | 0.95         |
| Body mass index (Kg/m² ± SD)            | 28.1±5.3               | 28.4±5.7            | 27.3±3.7              | 0.16         |
| NYHA class III-IV                       | 121 (47%)              | 89 (45%)            | 32 (54%)              | 0.28         |
| STS score, (mean ± SD)                  | 3.1± 2.4               | 3.2± 2.4            | 2.1± 0.6              | 0.13         |
| Hypertension                            | 197 (77%)              | 151 (77%)           | 46 (78%)              | 0.97         |
| Diabetes mellitus                       | 97 (38%)               | 75 (38%)            | 22 (37%)              | 1            |
| Chronic obstructive pulmonary disease   | 17 (7%)                | 12 (6%)             | 5 (10%)               | 0.56         |
| Malignancy                              | 48 (19%)               | 33 (17%)            | 15 (25%)              | 0.19         |
| Cerebrovascular disease                 | 26 (10%)               | 21 (11%)            | 5 (9%)                | 0.77         |
| Atrial fibrillation                     | 66 (26%)               | 46 (24%)            | 20 (34%)              | 0.15         |
| Chronic renal failure                   | 83 (32%)               | 65 (33%)            | 18 (31%)              | 0.86         |
| Liver disease                           | 4 (2%)                 | 3 (2%)              | 1 (2%)                | 1            |
| Peripheral artery disease               | 12 (7%)                | 6 (5%)              | 6 (10%)               | 0.28         |
| Previous myocardial infarction          | 32 (21%)               | 20 (22%)            | 12 (20%)              | 0.84         |
| Previous revascularization (PCI or CABG)| 96 (37%)               | 79 (40%)            | 16 (27%)              | 0.09         |
| Anticoagulant therapy                   | 71 (28%)               | 47 (24%)            | 24 (41%)              | 0.01         |
| Baseline albumin (mg/dL ± SD)           | 3.97±1.78              | 3.98±2.03           | 3.97±0.32             | 0.98         |

CABG = Coronary artery bypass graft; PCI = Percutaneous Coronary Intervention; STS = Society of Thoracic Surgeons Score.
experience, we continued our regular TAVI program without a selection of priority cases. We have maintained our program focusing on early discharge and WHO’s recommendations for the rational use of PPE in health care. Close monitoring of symptoms after discharge was achieved via telehealth.

Patients with severe symptomatic AS have poor overall survival without definitive treatment. Outcome data from the PARTNER-1 cohort B trial showed 1-year all-cause mortality of 50.7% in the medical arm group. Even for asymptomatic patients, long-term survival is poor, with a mortality of 21.1% at 3 years from diagnosis.

Table 2
Echocardiographic and tomographic characteristics

| Variable                                      | All patients N = 257 | Pre-Covid19 N = 198 | Covid period N = 59 | p Value |
|-----------------------------------------------|----------------------|----------------------|---------------------|---------|
| **Echocardiography**                          |                      |                      |                     |         |
| Left ventricular ejection fraction (%, [IQR]) | 55% [50.65]          | 55% [50.60.7]        | 56% [50.65]         | 0.65    |
| Aortic valve area cm² ± SD                   | 0.74 ± 0.17          | 0.75 ± 0.17          | 0.71 ± 0.16         | 0.11    |
| Moderate or severe regurgitation              |                      |                      |                     |         |
| Aortic                                        | 24 (14%)             | 18 (15%)             | 6 (10%)             | 0.48    |
| Mitral                                        | 53 (21%)             | 40 (29%)             | 13 (22%)            | 0.38    |
| Tricuspid                                     | 50 (25%)             | 35 (25%)             | 15 (25%)            |         |
| **Computed tomography**                      |                      |                      |                     |         |
| Calcium score aortic valve (Agatstone Units ± SD) | 2842 ± 1496          | 2865± 1456           | 2785 ± 1603         | 0.73    |
| Systolic annular perimeter, (mm ± SD)        | 73.8 ± 7.8           | 74 ± 7.9             | 73.1 ± 7.8          | 0.48    |
| Systolic annular area (mm² ± SD)             | 408 ± 126            | 439 ± 94             | 430 ± 91            | 0.55    |

IQR: Inter-quartile range.

Table 3
Procedural details

| Variable                                      | All patients N = 257 | Pre-Covid19 N = 198 | Covid19 period N = 59 | p Value |
|-----------------------------------------------|----------------------|----------------------|-----------------------|---------|
| Femoral vascular access                       | 246 (96%)            | 186 (94%)            | 58 (98%)              | 0.30    |
| Balloon expandable valve                      | 92 (36%)             | 67 (34%)             | 24 (41%)              | 0.35    |
| Valve size (mean)                             |                      |                      |                       |         |
| 23                                            | 48 (19%)             | 38 (19%)             | 10 (17%)              | 0.16    |
| 26                                            | 80 (31%)             | 56 (28%)             | 24 (41%)              |         |
| 29                                            | 72 (28%)             | 58 (29%)             | 14 (24%)              |         |
| 34                                            | 28 (11%)             | 25 (12%)             | 3 (5%)                |         |
| Pre dilatation                                | 117 (46%)            | 91 (47%)             | 25 (42%)              | 0.65    |
| Post dilatation                               | 68 (27%)             | 54 (28%)             | 14 (24%)              | 0.61    |
| Valve in valve                                | 16 (6%)              | 14 (7%)              | 2 (3%)                | 0.37    |
| Moderate and severe paravalvular leak per angiography | 14 (5%)             | 12 (6%)              | 2 (3%)                | 0.74    |
| Numbers of staff TAVI operators               | 5                    | 5                    | 5                     | 1       |

Table 4
Outcomes

| Variable                                      | All patients (N= 257) | Pre-COVID 19 (N = 198) | COVID 19 period (N = 59) | p Value |
|-----------------------------------------------|-----------------------|------------------------|--------------------------|---------|
| TAVI device success VARC-2                    | 239 (93%)             | 182 (93%)              | 56 (97%)                 | 0.53    |
| Vascular complications (VARC-2)               | 61 (24%)              | 50 (26%)               | 11 (19%)                 | 0.3     |
| Minor                                         | 53 (21%)              | 42 (22%)               | 11 (19%)                 | 0.71    |
| Major                                         | 8 (3%)                | 8 (4%)                 | 0                       | 0.20    |
| Permanent pacemaker implantation              | 23 (9%)               | 14 (12%)               | 9 (15%)                  | 0.63    |
| Procedural bleeding (BARC)                    | 25 (10%)              | 20 (17%)               | 5 (9%)                   | 0.17    |
| Minor                                         | 18 (7%)               | 14 (12%)               | 4 (7%)                   | 0.43    |
| Major                                         | 7 (3%)                | 6 (5%)                 | 1 (2%)                   | 0.43    |
| New atrial fibrillation                       | 18 (10%)              | 14 (12%)               | 4 (7%)                   | 0.42    |
| Hospitalization days ± SD                     | 5.04 ± 6.9            | 5.2 ± 7.7              | 4.2 ± 2.9                | 0.29    |
| 30-day mortality                              | 8 (3%)                | 6 (3%)                 | 2 (3%)                   | 1       |

VARC-2 = Valve Academic Research Consortium-2; BARC = Bleeding Academic Research Consortium.
suggesting that all severe AS patients do poorly in the long term in the absence of intervention.

Sudden cardiac death can occur with asymptomatic severe AS (without intervention) at a rate of approximately 1 in a 100,13 and may occur without any prodromal symptoms. Should symptoms develop, clinical deterioration may progress rapidly, and the risk of sudden death can escalate if AS is managed conservatively (4% at 1 month, 12% at 6 months).14 In a recent study of AS patients with a high probability of LV decompensation, more than 50% were either dead or hospitalized with heart cardiac failure within 2 years.15

Timing of intervention is also crucial, as perioperative morbidity is markedly increased if advanced left ventricular systolic dysfunction occurs due to a delay in intervention.16,17 Registry data unsurprisingly revealed greater mortality during the preoperative period for patients with established heart failure and advanced myocardial scarring.18 There is an increasing awareness that aortic valve intervention is often performed too late, and several studies are examining the effects of earlier intervention in asymptomatic patients.19

It is important to focus on the concept of minimalist TAVI using local anesthesia with minimal sedation and supported by patient coaching and avoidance of invasive lines; and early recovery monitoring protocol with accelerated reconditioning and continuity/consistency of medical care. Accelerated mobilization and reconditioning are pivotal to avoiding a cascade of in-hospital adverse events in older patients, including loss of motor function and increased risk of falls.20 Similarly, the avoidance of hospitalization-related modifiable risk factors such as the use of general anesthesia and "deep" monitored anesthesia care, administration of opioids, urinary tract and other infections, immobility, deconditioning, and long length of stay may reduce the incidence of procedure-related delirium to its near elimination in the era of contemporary TAVI. We believe that this strategy is useful in these times of pandemic, where the patient’s exposure should be as low as possible, being the strategy that we use during the pandemic.

This is a retrospective, nonrandomized, nonblinded observational study, and therefore it is subjected to limitations inherent in this design. We hope that early experience from our center may prove useful for others adapting their practice in preparation for local COVID-19 surges.
In conclusion, experience from out single center study shows that TAVI procedures can be performed effectively and safely during the COVID-19 pandemic with a minimal-ist implant strategy, early discharge and WHO’s recommen-dations for the rational use of personal protective equipment. However, the decision to intervene in a patient needing a valve procedure will be determined largely by hospital resources and the burden of COVID-19 admissions at any given time and hospital.

Author Contribution Statement

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Paul Fefer, MD: Conceptualization; Investigation; Methodology; Software; Supervision; Validation; Writing - review & editing.

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Disclosure

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

1. Shah PB, Welt FP, Mahmud E, Phillips A, Kleiman NS, Young MN, Sherwood M, Batchelor W, Wang DD, Davidson L, Wyman J, Kada-vath S, Szerlip M, Hermiller J, Fullerton D, Anwaraddin S. Triage considerations for patients referred for structural heart disease interven-tion during the coronavirus disease 2019 (COVID-19) pandemic: an ACC /SCAI consensus statement. JACC Cardiovasc Interv 2020;13: 1484–1488.

2. Driggin E, Madhavan MV, Bikdeli B, Chuich T, Laracy J, Biondi-Zoccai G, Brown TS, Der Ngoghoghossian C, Zidar DA, Hatney J, Bro-die D, Beckman J, Kirtane AJ, Stone GW, Krumholz HM, Parikh SA. Cardiovascular considerations for patients, health care workers, and health systems during the coronavirus disease 2019 (COVID-19) pan-demic. J Am Coll Cardiol 2020;75:2352–2371.

3. Wu Z, McGoogan JM. Characteristics of and important lessons from the coronavirus disease 2019 (COVID-19) outbreak in China: summary of a report of 72314 cases from the Chinese center for disease control and prevention. JAMA 2020;323:1239–1242.

4. Sengelow M, Cheng S, Biering-Sorensen T, Matsushita K, Koney S, Solomon SD, Folsom AR, Shah AM. Ideal cardiovascular health and the prevalence and severity of aortic stenosis in elderly patients. J Am Heart Assoc 2018;7:e007234.

5. Carabello BA, Paulus WJ. Aortic stenosis. Lancet 2009;373:956–966.

6. Malaisrie SC, McDonald E, Kruse J, Russell H, McCarthy P, Andrei AC. Mortality while waiting for aortic valve replacement. Ann Thorac Surg 2014;98:1546–1554.

7. WHO | Personal protective equipment for COVID-19. https://www.who.int/medical_devices/priority/COVID_19_PPE/en. Last update September 19th 2020.

8. Kaptein AP, Head SJ, Généreux P, Piazza N, van Mieghem NM, Blackstone EH, Brott TG, Cohen DJ, Cutlip DE, van Es GA, Hahn RT, Kirtane AJ, Krucov MW, Kodali S, Mack MJ, Mehran R, Rodés-Cabau J, Vranckx P, Webb JG, Windecker S, Serruys PW, Leon MB. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the valve academic research consortium-2 consensus document. Eur J Cardio-Thorac Surg 2012;42:S45–S60.

9. Worldometer COVID-19 Data. https://www.worldometers.info/coro-navirus. Last update September 19th 2020.

10. Marquis-Gravel G, Redfors B, Leon MB, Généreux P, Medical treat-ment of aortic stenosis. Circulation 2016;134:1766–1784.

11. Rosenhek R, Binder T, Porenta G, Lang I, Christ G, Schember M, Maurer G, Baumgartner H. Predictors of outcome in severe, asympto-matic aortic stenosis. N Engl J Med 2000;343:611–617.

12. Leon MB, Smith CR, Mack M, Miller D, Moses JW, Svensson LG, Tuzcu EM, Webb J, Fontana G, Makkar R, Brown D, Block P, Guyton R, Pichard A, Bavaria JE, Herrmann H, Douglas P, Petersen JL, Akin JJ, Anderson W, Wang D, Pocock S. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo sur-gery. N Engl J Med 2010;363:1597–1607.

13. Campo J, Tsiaras A, Kruse J, Karam A, Andrei A, Liu M, Bonow RO, McCarthy P, Malaisrie SC. Prognosis of severe asymptomatic aortic stenosis with and without surgery. Ann Thorac Surg 2019;108: 74–79.

14. Greve AM, Gerds T, Boman K, Gohlke-Baerwolf C, Rossebo AB, Deveraux RB, Koher L, Ray S, Willenheimer R, Wachtel K. Impact of QRS duration and morphology on the risk of sudden cardiac death in asymptomatic patients with aortic stenosis: the SEAS (syste-matization and echotimizie in aortic stenosis) study. J Am Coll Cardiol 2012;59:1142–1149.

15. Taniguchi T, Morimoto T, Shiomi H, Ando K, Kanamori N, Murata K, Kitai T, Kawas Y, Izumi C, Kato T, Ishii K, Nagao K, Nakagawa Y, Toyofuku M, Saito N, Minatoya K, Kimura T. Sudden death in patients with severe aortic stenosis: observations from the CURRENT AS registry. J Am Heart Assoc 2018;7:e008397.

16. Flores-Marín A, Gómez-Doblas JJ, Caballero-Borrego J, Cabrera-Bueno F, Rodríguez-Bailón I, Mello J, Porras C, Sánchez-Espín G, Such M, Olalla E, de Teresa E, Long- Term predictors of mortality and functional recovery after aortic valve replacement for severe aortic stenosis with left ventricular dysfunction. Rev Esp Cardiol 2010;63: 36–45.

17. Gilliam LD, Marcondolf L, Shames S. Timing of surgery in valvular heart disease: prophylactic surgery vs watchful waiting in the asymptomatic patient. Can J Cardiol 2014;30:1035–1045.

18. Everett RJ, Clavel MA, Pifarot P, Dweck MR. Timing of intervention in aortic stenosis: a review of current and future strategies. Heart 2018 Dec;104:2067–2076.

19. Dweck MR, Joshi S, Murug T, Alpendurada F, Jabbour A, Melina G, Banya W, Gulati A, Rousin I, Raza S, Prasad NA, Wage R, Quarto C, Bueno F, Rodríguez-Bailón I, Melero J, Porras C, Prasad SK. Midwall fibrosis is an independent predictor of mortality in patients with aortic stenosis. J Am Coll Cardiol 2011;58:1271–1279.

20. Bing R, Everett RJ, Tuck C, Sempole S, Lewis S, Harkess R, Mills N, Treibel T, Prasad S, Greenwood J, McCann G, Newby D, Dweck M. Rationale and design of the randomized, controlled early valve replacement guided by biomarkers of left ventricular decompensation in asymptomatic patients with severe aortic stenosis (evolved) trial. Am Heart J 2019;212:91–100.