Unexpected peak of mortality: The COVID-19 burden on Bergamo transcatheter aortic valve implantation register

To the Editor,

The coronavirus disease 2019 (COVID-19) outbreak has overwhelmed Northern Italy, just like rest of the world. The province of Bergamo has been one of the hardest-hit areas in Northern Italy since the beginning of COVID-19 epidemic (1). The "ASST Papa Giovanni XXIII" public hospital is a tertiary reference center for cardiovascular diseases throughout the region of Northern Italy. It is highly specialized for the treatment of valve diseases. In the most critical phases of the epidemic, outpatient visits and non-urgent health services were suspended; however, the cardiovascular emergency network was kept active (2). Patients undergoing transcatheter aortic valve implantation (TAVI) are notoriously frail and exposed to the risk of COVID-19 infection. These patients are mostly affected by the absence of cardiac outpatient follow-up. Methods: We wanted to evaluate the outcomes of our patients who underwent TAVI from 2010 to the end of April 2020 in the Bergamo TAVI registry that is characterized by an annual mortality rate of around 10% with an overall five-year survival of over 50%. Table 1 shows the general characteristics of this population. From January 2010 to April 2020, we obtained the monthly mortality rate (by dividing the number of patients who died in each month by the total number of live patients in the follow-up period). Results: We observed a peak incidence of annual and monthly mortality in the COVID-19 period (from January 2020 to April 2020) that cannot be otherwise explained. The 20 patients who died during the COVID-19 period as compared with the 106 patients who died in the non-COVID period did not differ significantly in the clinical risk profile. The monthly mortality incidence rate was eight times higher during the months of the COVID-19 period (6.6% in the COVID-19 period versus an average monthly mortality incidence

Table 1. Clinical characteristics of patients who underwent TAVI from 2010 to 2020 at the HPG23 Bergamo Hospital

	All patients who underwent TAVI from 2010	Deceased patients at follow-up before COVID-19 (Jan. 2010–2020)	Deceased during COVID-19 Outbreak (Feb. 2020/Apr. 2020)	*P*-value
N° patients (2010-2020)	319	106	20	
Age at TAVI implantation (years±SD)	82±5	82±4	80±4	0.13
Age at last follow-up (April 2020) (years±SD)	86±6	84±8	88±5	0.2
Female sex, n/N (%)	130/319 (40.8%)	48/106 (45.3%)	7/20 (35%)	0.39
Body mass index (Kg/m^2)	24.5±4	25±4	24.5±2.3	0.011
EuroScore I n±SD	20±13	20±12	15±8	0.11
Euroscore II n±SD	5.5±3.3	5.8±3	5±2.8	0.74
STS n±SD	3±1.4	2.9±1.5	3±2.3	0.11
Sapien valve size 23 n/N (%)	140/319 (43.9%)	38/106 (35.8%)	9/20 (45%)	0.06
Sapien valve size 26 n/N (%)	138/319 (42.3%)	56/106 (52.8%)	7/20 (35%)	0.06
Sapien valve size 29 n/N (%)	41/319 (12.8%)	12/106 (11.3%)	4/20 (20%)	0.06
Diabetes on insulin therapy n/N (%)	57/319 (17.9%)	29/106 (27.4%)	3/20(15%)	0.24
Coronary Artery Disease n/N (%)	60/319 (18.9%)	52/106 (49.1%)	8/20 (40%)	0.45
Permanent atrial fibrillation n/N (%)	72/319 (22.6%)	28/106 (26.4%)	2/20 (10%)	0.11
Mean ejection fraction (%)	50±9	49±9	49±9	0.67
Poor mobility n/N (%)	31/319 (9.7%)	17/106 (16%)	0/20	0.054
Peripheral artery disease n/N (%)	142/319 (44.5%)	58/106 (54.8%)	8/20 (40%)	0.22
Renal impairment n/N (%)	129/319 (40.4%)	41/106 (38.7%)	8/20 (40%)	0.91
History of lung disease n/N (%)	72/319 (22.6%)	29/106 (27.4%)	5/20 (25%)	0.82
Pulmonary hypertension n/N (%)	64/319 (20.1%)	25/106 (23.6%)	7/20 (35%)	0.036

The second column shows the characteristics of patients who died during the follow-up from 2010 to 2020. The third column reports the characteristics of patients who died during the COVID-19 epidemic. The fourth column indicates the statistical differences between the deceased patients in the standard follow-up and patients in the follow-up during the COVID-19 period

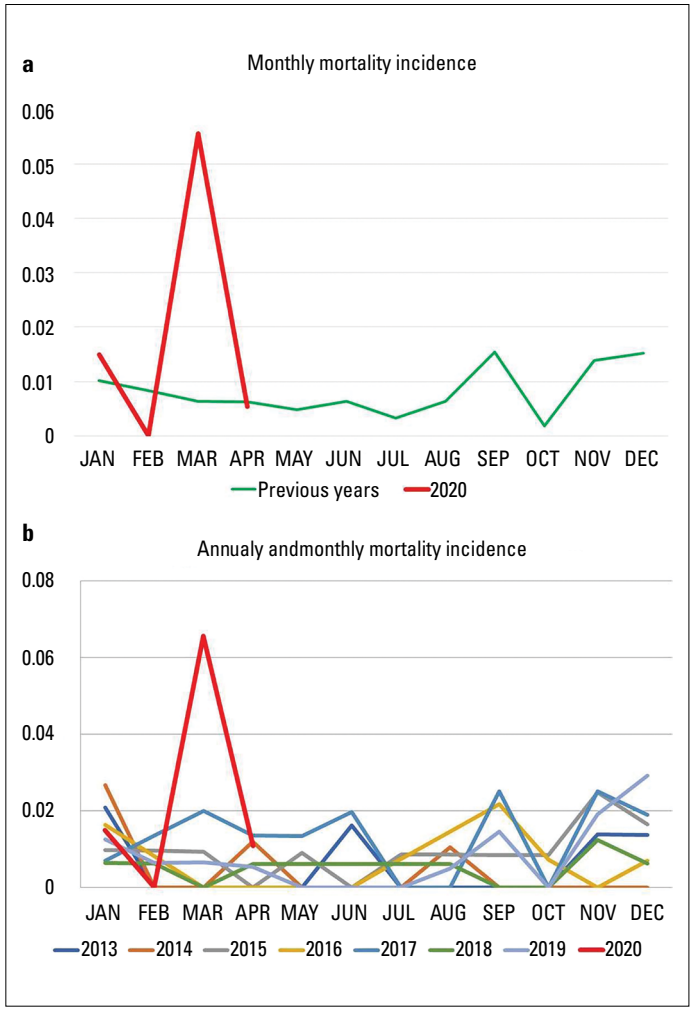

Figure 1. (a) Monthly mortality incidence of patients who underwent TAVI from 2010 to 2020 (the graph line of the COVID-19 period is marked in red as compared to the months from 2010 to January 2020). (b) Annual and monthly incidence of mortality. The mortality peak during the COVID-19 outbreak (February–April 2020). The mortality rate was calculated by dividing the number of patients who died by the total number of patients during the follow-up. Patients with postoperative mortality within 30 days were excluded

value of 0.82% in the non-COVID period). A telephonic follow-up revealed that most of the deceased patients reported the onset of fever, dyspnea, and sudden death during the following days after undergoing TAVI. The data, although preliminary and monocentric, consider all the possible biases and propose the need for more extensive population studies to confirm or deny at least three considerations of this study. Because of their clinical profiles, patients who have undergone TAVI are particularly fragile and presumably vulnerable to COVID-19 infection. It is necessary to understand how to better protect this population for which significant medical and technological resources have been largely invested. It will be essential to comprehend which subgroups of patients who underwent TAVI are most affected by a viral infection and further clarify the cardiovascular predisposition toward a less favorable outcome. It is important to understand the impact of this viral epidemic in the various registries and clinical studies where the viral outbreak could affect the results, especially the medium- and long-term ones in the older and more fragile populations.

Alberto Cereda, Diego Cugola, Giulio Balestrieri, Angelina Vassileva, Orazio Valsecchi
Department of Cardiovascular, ASST Papa Giovanni XXIII Hospital; Bergamo-*Italy*

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Address for Correspondence: Alberto Cereda, MD,
Department of Cardiovascular,
ASST Papa Giovanni XXIII Hospital;
Bergamo-*Italy*
Phone: +393200883375
E-mail: tskcer@hotmail.it

DOI:10.14744/AnatolJCardiol.2020.01955

Paravalvular leak after transcatheter aortic valve implantation

To the Editor,

We read the study of Duran Karaduman et al. (1) with interest. The number of highly satisfactory patients and successful results for a single-center study is truly admirable. When evaluating transcatheter aortic valve implantation (TAVI) applications as the treatment of severe aortic stenosis, there are undoubtedly 2 basic issues to be evaluated. The first is clinical parameters such as postoperative survival and neurological complications. The other is the postoperative high valve gradients and paravalvular leak (PVL) incidence rates that show the durability of the valve. Different rates of PVL can be detected in both surgical aortic valve replacements (SAVR) and TAVI procedures. It has been reported in many studies that there is mild or severe PVL at the rate of 0% to 20% in surgical aortic valve replacements (2-4). In TAVI, this rate is somewhat higher owing to the nature of the procedure. In various studies, this rate has been reported to be as high as 60% for post-TAVI mild PVL (5, 6). However, the point we want to mention here is not to compare or interpret the 2 techniques in terms of this parameter. Another point regarding PVL in the study of Duran Karaduman et al. (1) attracted our attention. It has been reported that mild