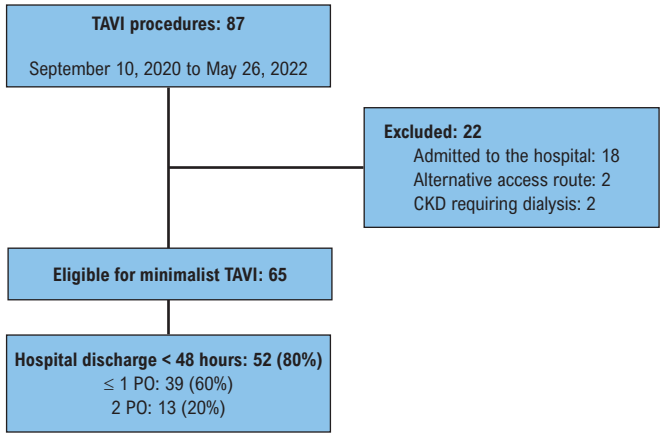
Viability and Safety of Early Hospital Discharge after Minimalist TAVI in the Brazilian Unified Health System

Marcos Almeida Meniconi,[1,2] Fernanda Jacques Calçado Oliveira,[2] Alberto Colella Cervone,[2] Dorival Julio Della Togna,[2] Fausto Feres,[2] Auristela Isabel de Oliveira Ramos,[2] Dimytri Alexandre de Alvim Siqueira[2]

Instituto do Coração do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo,[1] São Paulo, SP – Brazil

Instituto Dante Pazzanese de Cardiologia,[2] São Paulo, SP – Brazil

Central Illustration: Viability and Safety of Early Hospital Discharge after Minimalist TAVI in the Brazilian Unified Health System



Arq Bras Cardiol. 2023; 120(9):e20230328

Results after transcatheter aortic valve implantation with a minimalist approach. CKD: chronic kidney disease; PO: postoperative days; TAVI: transcatheter aortic valve implantation.

Introduction

Transcatheter aortic valve implantation (TAVI) has established itself as the treatment of choice for octogenarian patients with aortic stenosis.[1] Broadly speaking, TAVI with a minimalist approach (M-TAVI) refers to the performance of the procedure under conscious sedation and local anesthesia, percutaneous femoral access, monitoring with transthoracic echocardiography, and early mobilization. Studies have indicated the safety of M-TAVI with hospital discharge within 24 hours after the procedure[2,3] with reduced hospital costs,[4,5] which is a relevant aspect from the perspective of national public health. Thus, the objective of this study was to evaluate the feasibility and safety of a multidisciplinary institutional M-TAVI protocol with the goal of hospital discharge within 48 hours, implemented in a tertiary hospital that is part of the Brazilian Unified Health System (SUS).

Keywords

Transcatheter Aortic Valve Replacement; Aortic Valve Stenosis; Unified Health System

Mailing Address: Marcos Almeida Meniconi •
Universidade de São Paulo Instituto do Coração – Hemodinâmica – Av. Dr. Enéas de Carvalho, 44. Postal code 05403-000, São Paulo, SP – Brazil
E-mail: meniconimarcos@gmail.com
Manuscript received May 12, 2023, revised manuscript July 17, 2023, accepted July 17, 2023
Editor responsible for the review: Pedro Lemos

DOI: https://doi.org/10.36660/abc.20230328

Methods

This was an observational, prospective, single-center study with a selection of patients who consecutively underwent TAVI from September 2020 to May 2022.

Inclusion and exclusion criteria

Patients aged ≥ 18 years, with important aortic stenosis and elective indication for TAVI were selected. Patients with any of the following were excluded: significant left ventricular dysfunction (left ventricular ejection fraction < 30%); need for alternative access route (other than femoral); creatinine clearance < 15 ml/min/1.73 m^2; presence of blood dyscrasia

or severe thrombocytopenia (< 50,000/mm^3); performance of another surgical or percutaneous interventional procedure during the same hospitalization period.

Data collection and statistical analysis

Data were collected by means of a questionnaire, electronic medical records, and/or telephone contact, systematically applied 30 days after hospital discharge. Quantitative variables were presented as mean ± standard deviation or interquartile range. Categorical variables were expressed as a proportion of the whole (%).

The clinical outcomes analyzed included death from all causes, death from cardiovascular causes, stroke, vascular and hemorrhagic complications, and the need for a permanent pacemaker within 30 days; the length of hospital stay and the need for hospital readmissions within 30 days were also evaluated. Outcomes were defined according to the Valve Academic Research Consortium 3.[6]

Results

From September 2020 to May 2022, 87 patients underwent TAVI, with 65 patients (74.7%) undergoing the minimalist strategy; 22 met exclusion criteria (Central Figure). There was no loss to follow-up.

Patients who underwent M-TAVI had a mean age of 79.9 ± 4.8 years, and 27 (41.5%) were women. Patients had low surgical risk, according to the STS and Euroscore II scores (means of 2.4% ± 1.45% and 3.0% ± 2.15%, respectively). The most prevalent comorbidities were systemic arterial hypertension in 51 (78.4%) patients, diabetes mellitus in 26 (40%), and coronary artery disease in 25 (38.4%). Six patients (9.2%) had a bicuspid aortic valve (Table 1).

Admission electrocardiography revealed the following: sinus rhythm in 52 (80%) patients, atrial fibrillation in 9 (13.8%), permanent pacemaker rhythm in 4 (6.2%), first-degree atrioventricular block in 14 (21.5%), left bundle branch block in 7 (10.8%), and right bundle branch block in 5 (7.7%).

Table 2 describes the prostheses used, amount of contrast, and performance of pre- or post-dilation.

Baseline transthoracic echocardiogram demonstrated the following: mean aortic valve area of 0.65 (± 0.15) cm^2, mean aortic transvalvular gradient of 53 ± 18.4 mmHg, estimated mean pulmonary artery systolic pressure of 35 ± 12 mmHg, and mean left ventricular ejection fraction of 55.2% ± 0.11% (Simpson method). Immediately after TAVI, the mean effective aortic orifice area increased to 2.1 ± 0.5 cm^2, and the mean aortic transvalvular gradient was 4.7 (± 3.5) mmHg. The incidence of paravalvular leak ≥ moderate was 4.6% (n = 3).

Two deaths occurred: 1 due to cardiovascular causes and 1 due to SARS-CoV-2 infection. Two patients (3%) required permanent pacemaker implantation. Major bleeding occurred in 3 (4.6%) cases, requiring surgical conversion (Table 3).

Length of hospital stay

The mean length of hospital stay was 52.1 hours or 2.17 days. Hospital discharge in under 48 hours after TAVI was

Table 1 – Baseline characteristics

Characteristics	n (standard deviation)
Age (years)	79.9 (± 4.8)
Female sex	27 (41.5%)
Body mass index (kg/m²)	28.4 (± 6.2)
Distance to home (km)	19.4 (± 7.5)*
NYHA functional class	I: 4 (6.2%)
	II: 40 (61.5%)
	III: 21 (32.3%)
	IV: 0
CCS angina grade	Sem angina: 43 (66%)
	I: 1 (1.5%)
	II: 15 (23%)
	III: 5 (8%)
	IV: 1 (1.5%)
Systemic arterial hypertension	51 (78.4%)
Diabetes mellitus	26 (40%)
Dyslipidemia	35 (53.8%)
Creatinine clearance (mL/min/1.73 m²)	> 60: 37 (57%)
	45 a 59: 19 (29.2%)
	30 a 44: 9 (13.8%)
Coronary artery disease	25 (38.4%)
Prior stroke	6 (9.2%)
Neoplasia	9 (13.8%)
Tobacco use	21 (32.3%)
Chronic obstructive pulmonary disease	3 (4.6%)
Peripheral arterial disease	7 (10.8%)
Prior revascularization surgery	10 (15.4%)
Percutaneous coronary intervention	5 (7.7%)
Bicuspid aortic valve	6 (9.2%)
STS score (%)	2.4 (± 1.45)
Euroscore II (%)	3.0 (± 2.15)

** Outliers were excluded (values > 53.1 km and < 6.9 km).*

Table 2 – Procedure characteristics

Prosthesis type	Evolut R® (Medtronic®): 1 (1.5%) Sapien 3® (Edwards Lifesciences®): 14 (21%) Accurate Neo® (Boston Scientific®): 12 (18.5%) Myval® (Meril Life Sciences®): 38 (59%)
Pre-dilation (n)	34 (52.3%)
Post-dilation (n)	19 (29.2%)
Contrast (ml)	108 (± 30)

Table 3 – In-hospital clinical outcomes

In-hospital outcomes	n (%)
Total deaths	2 (3%)
Death from cardiovascular causes	1 (1.5%)
Stroke	0
Major vascular complication	1 (1.5%)
Major life-threatening bleeding	3 (4.6%)
Permanent pacemaker implantation	2 (3%)
Anesthetic conversion	3 (4.6%)
Valve annulus rupture	1 (1.5%)
Coronary obstruction	0
Second prosthesis implant	0

achieved in 52 (80%) patients, with 39 (60%) discharged within 24 hours (Figure 1).

Hospital discharge was delayed (> 48 hours) due to presence of moderate paravalvular leak (n = 1), post-renal acute kidney injury (n = 1), femoral artery pseudoaneurysm (n = 1), major vascular complication (n = 1), minor bleeding (n = 1), surgical conversion (n = 1), and conduction disorders (n = 5).

Hospital readmissions

Four patients (6.1%) were readmitted within 30 days, 2 of them (3%) due to cardiovascular causes (decompensated heart failure and stroke). The non-cardiovascular causes were pathological fracture of the femur and epistaxis. No deaths occurred within 30 days after hospital discharge.

Discussion

The mean length of hospital stay of 2.17 days is similar to that of a large 2019 registry from the United States[7] and the 3M-TAVR clinical trial.[3] In this series, the indication for permanent pacemaker within 30 days was only 3%, in contrast to 20.1% in the Brazilian national multicenter registry from 2008 to 2015.[8] This result can be explained by the predominance of balloon-expandable prosthesis and higher implant in relation to the valve annulus.

Limitations

The single-center design of this study can limit the reproducibility and generalization of the results of the protocol instituted. The small number of patients in this sample prevents a more robust statistical analysis. This study also lacks cost-effectiveness analysis, which is a subject of interest for future initiatives.

Conclusion

In this initial experience, the application of an institutional M-TAVI protocol proved to be safe and feasible in a SUS hospital, as reflected by satisfactory clinical results, reduced hospitalization time, and low hospital readmission rates.

Author Contributions

Conception and design of the research; Analysis and interpretation of the data and Critical revision of the manuscript for important intellectual content: Meniconi MA, Oliveira FJC, Cervone AC, Togna DJD, Feres F, Ramos AIO, Siqueira DAA; Acquisition of data: Meniconi MA, Cervone AC, Siqueira DAA; Statistical analysis; Obtaining financing; Writing of the manuscript: Meniconi MA, Siqueira DAA.

Potential conflict of interest

No potential conflict of interest relevant to this article was reported.

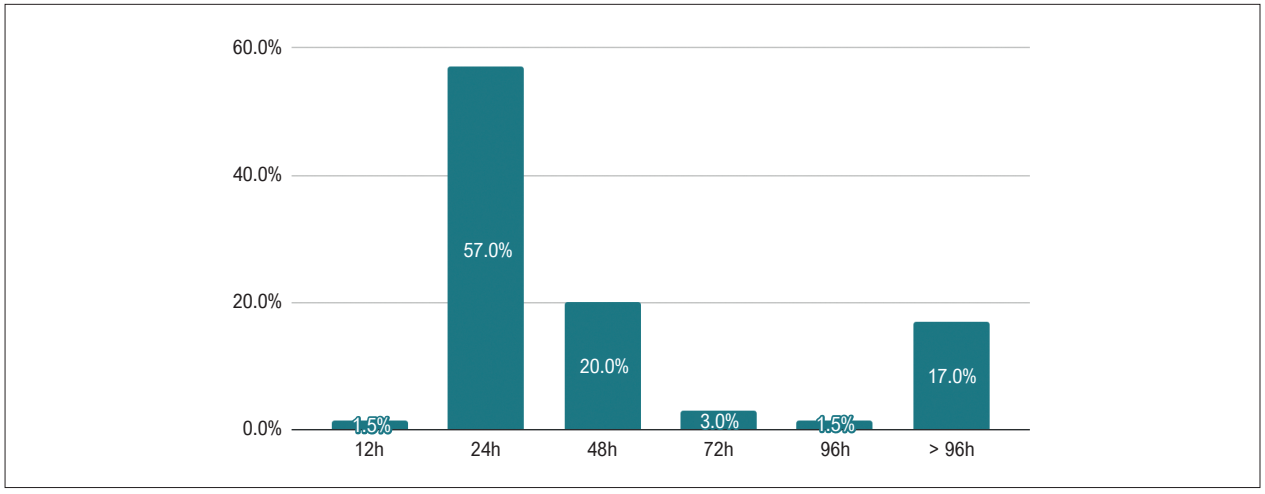


Figure 1 – *Time to hospital discharge after M-TAVI.*

Sources of funding

There were no external funding sources for this study.

Study association

This article is part of the thesis of master submitted by Marcos Almeida Meniconi, from Instituto Dante Pazzanese de Cardiologia – Universidade de São Paulo.

Ethics approval and consent to participate

This study was approved by the Ethics Committee of the Instituto Dante Pazzanese de Cardiologia under the protocol number CAAE: 42516121.6.0000.5462. All the procedures in this study were in accordance with the 1975 Helsinki Declaration, updated in 2013. Informed consent was obtained from all participants included in the study.

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