American Heart Journal Plus: Cardiology Research and Practice 19 (2022) 100184

Contents lists available at ScienceDirect

American Heart Journal Plus: Cardiology Research and Practice

journal homepage: www.sciencedirect.com/journal/american-heart-journal-plus-cardiology-research-and-practice

Short communication

Utilization and outcomes of aortic valve replacements (from the United States readmissions database)

Shashank Shekhar [a], Abhishek Ajay [a], Toshiaki Isogai [a], Roop Kaw [b], Anas Saad [a], Ankit Agrawal [a], Hassan Lak [a], Tikal Kansara [a], Amgad Mentias [a], Amar Krishnaswamy [a], Lars Svensson [c], Samir R. Kapadia [a,*]

[a] Department of Cardiovascular Medicine, Heart and Vascular Institute, Cleveland Clinic, Cleveland, OH 44195, USA
[b] Department of Hospital Medicine and Outcomes Research, Anesthesiology, Cleveland Clinic, Cleveland, OH, USA
[c] Department of Thoracic & Cardiovascular Surgery, Heart, Vascular, and Thoracic Institute, Cleveland Clinic, Cleveland, OH, USA

ARTICLE INFO

Keywords:
Transcatheter aortic valve replacement
Surgical aortic valve replacement
Heart failure
Aortic stenosis

ABSTRACT

Study objective: Assess the utilization of aortic valve replacements (AVR).
Design: Retrospective analysis of the Nationwide Readmissions Database (2016–2018).
Setting: Nationwide.
Participants: Heart failure patients with concomitant aortic stenosis (CHF + AS cohort) or aortic stenosis with aortic regurgitation (CHF + AS+AR cohort).
Interventions: Transcatheter aortic valve implantation (TAVI), surgical aortic valve replacement (SAVR), no-AVR.
Main outcome measures: Utilization of treatment interventions.
Results: In the CHF + AS cohort, TAVI, SAVR and no-AVR were done in 9.3 %, 10.8 % and 79.9 % of patients respectively. Similarly, majority of CHF + AS+AR patients were managed with no-AVR (53.2 %). Of patients managed with no-AVR in the first six months of each year, only 7.9 % of CHF + AS and 11.8 % of CHF + AS+AR patients underwent AVR in the subsequent six months of the year. No-AVR patients had worse short-term outcomes in comparison to AVR recipients.
Conclusion: More studies are needed to understand the timing, indications and utilization of AVR in this population.

1. Introduction

Aortic valve diseases (AVD), if left untreated, may lead to congestive heart failure (CHF), and patients face a poor prognosis with a 4-year mortality of approximately 50% [1]. The number of hospitalizations with AVD increased approximately 1.5 times from 2012 to 2016 in the United States [2]. The mainstay treatment strategy for these patients is aortic valve replacement (AVR), either by surgical (SAVR) or transcatheter (TAVI) approach. Therefore, we aimed to assess the utilization of AVR in real-world clinical practice and compared the outcomes of patients undergoing AVR with those managed conservatively (no-AVR).

2. Methods

We used the International Classification of Diseases-10th revision codes to identify adult patients with CHF and aortic stenosis (CHF + AS cohort) or aortic stenosis with aortic regurgitation (CHF + AS+AR cohort) from the Nationwide Readmissions Database (2016–2018) [3]. This study was exempt from ethical approval because of the de-identified data in the publicly available database. Those with underlying sepsis, endocarditis, dementia, history of myocardial infarction, history of percutaneous coronary intervention, cancers or drug abuse were excluded from the current analysis in order to remove the common patient- and physician-related reasons for not performing AVR. Treatment strategies identified were TAVI, SAVR and no-AVR.

3. Results

In the CHF + AS cohort ($n = 347,257$), TAVI, SAVR and no-AVR were done in 9.3 %, 10.8 % and 79.9 % of patients respectively (median age,

* Corresponding author at: Department of Cardiovascular Medicine, Cleveland Clinic, 9500 Euclid Avenue, J2-3, Cleveland, OH 44195, USA.
E-mail address: kapadis@ccf.org (S.R. Kapadia).

https://doi.org/10.1016/j.ahjo.2022.100184
Received 12 July 2022; Accepted 14 July 2022
Available online 19 July 2022

Table 1
Patient characteristics and outcomes.

Variable	CHF + AS (*N* = 347,257)			CHF + AS + AR (N = 34,357)		
	TAVI	SAVR	No-AVR	TAVI	SAVR	No-AVR
	n = 32,402	*n* = 37,616	*n* = 277,239	*n* = 3961	*n* = 12,113	*n* = 18,283
	(9.3 %)	(10.8 %)	(79.9 %)	(11.5 %)	(35.3 %)	(53.2 %)
Age (years)	82 (76–86)	71 (65–77)	81 (72–87)	80 (73–86)	66 (58–73)	78 (68–86)
Women	16,323 (50.4 %)	13,613 (36.19 %)	150,018 (54.1 %)	1867 (47.1 %)	3895 (32.2 %)	9180 (50.2 %)
Obesity	6556 (20.2 %)	10,741 (28.6 %)	51,643 (18.6 %)	725 (18.3 %)	3076 (25.4 %)	2955 (16.2 %)
Systolic heart failure	2805 (8.7 %)	2616 (6.9 %)	29,293 (10.6 %)	402 (10.2 %)	1062 (8.8 %)	2228 (12.2 %)
Hypertension	28,588 (88.2 %)	30,896 (82.1 %)	240,072 (86.6 %)	3496 (88.3 %)	9261 (76.5 %)	15,596 (85.3 %)
Imaging done	8649 (26.7 %)	13,916 (37.0 %)	8394 (3.0 %)	1237 (31.2 %)	4963 (40.9 %)	1125 (6.2 %)
Dyslipidemia	22,316 (68.9 %)	25,828 (68.7 %)	159,015 (57.46 %)	2735 (69.1 %)	7391 (61.0 %)	10,571 (57.8 %)
Smoker	11,927 (36.8 %)	15,418 (40.1 %)	98.827 (35.7 %)	1581 (39.9 %)	5059 (41.8 %)	7059 (38.61 %)
Atrial fibrillation	11,696 (36.1 %)	16,756 (44.5 %)	110,090 (39.7 %)	1372 (34.6 %)	5014 (41.4 %)	7090 (38.8 %)
Pulmonary hypertension	5100 (15.7 %)	3785 (10.1 %)	42,033 (15.2 %)	753 (19.0 %)	1356 (11.2 %)	3732 (20.4 %)
Concomitant mitral valve disease	4894 (15.1 %)	5304 (14.1 %)	39,457 (14.2 %)	1088 (27.5 %)	2227 (18.4 %)	6033 (33.0 %)
Concomitant tricuspid valve disease	2077 (6.4 %)	1708 (4.5 %)	16,679 (6.0 %)	497 (12.6 %)	758 (6.3 %)	3448 (18.9 %)
Prior CVA	86 (0.27 %)	77 (0.20 %)	679 (0.24 %)	20 (0.5 %)	29 (0.24 %)	62 (0.34 %)
Outcomes						
In-hospital mortality	357 (1.1 %)	698 (1.9 %)	8397 (3.0 %)	70 (1.8 %)	152 (1.3 %)	501 (2.7 %)
In-hospital stroke	583 (1.8 %)	593 (1.6 %)	12,454 (4.5 %)	58 (1.5 %)	176 (1.5 %)	915 (5 %)
30-day readmission	3136/29452 (10.7 %)	3956/34019 (11.6 %)	46,637/247278 (18.8 %)	365/3562 (10.3 %)	1110/11000 (10.1 %)	3268/16277 (20.1 %)
6-month in-hospital mortality[a]	293/16186 (1.8 %)	180/19535 (0.9 %)	6575/147600 (4.5 %)	31/1980 (1.6 %)	36/6238 (0.6 %)	404/9554 (4.2 %)
6-month readmission[a]	4264/16186 (26.3 %)	4079/19535 (20.9 %)	65,509/147600 (44.4 %)	498/1980 (25.2 %)	1064/6238 (17.1 %)	4215/9554 (44.1 %)
TAVI within 6-months of being discharged alive after no-AVR[a]	–	–	8159/147600 (5.5 %)	–	–	591/9554 (6.2 %)
SAVR within 6-months being discharged alive after no-AVR[a]	–	–	3564/147600 (2.4 %)	–	–	534/9554 (5.6 %)

Using the ICD-10 codes, we identified Heart Failure patients (ICD-10: I11.0, I50.1, I50.2, I50.3, I50.4, I50.8, I50.9) with Aortic Stenosis (ICD-10: I06.0, I35.0, Q23.0) and Aortic Stenosis with Regurgitation (ICD-10: I06.2, I35.2) undergoing TAVI (ICD-10: 02RF37H, 02RF37Z, 02RF38H, 02RF38Z, 02RF3JH, 02RF3JZ, 02RF3KH, 02RF3KZ) and SAVR (ICD-10: 02RF0, 02RF4, X2RF032, X2RF432). Dyslipidemia, defined as disorders of lipid metabolism (E78.0, E78.00, E78.01, E78.1, E78.2, E78.3, E78.4, E78.5, E78.81, E78.89, E8889, E78.9) and obesity defined as obese, overweight and/or having a BMI 30 or higher (E66.x, O9921.x, Z683.x, Z684.x, Z6854) were identified using their ICD-10 codes. Continuous variables expressed as median (IQR 25–75), and compared using Mann–Whitney *U* test or Student *t*-test. Categorical variables expressed as n (%) or n/total n (%) and were compared using Fisher's exact test or chi-squared test.

[a] Includes only patients discharged alive between January and June 2016–2017 (to allow for 6 month follow up) who could be followed up for 6 months. AS = aortic stenosis; AR = aortic regurgitation; CHF = congestive heart failure; CVA = cerebrovascular accidents; TAVI = transcatheter aortic valve implantation; SAVR = surgical aortic valve replacement; AVR = aortic valve replacement; ICD = International Classification of Diseases.

82 vs. 71 vs. 81 years). No-AVR patients in comparison to TAVI and SAVR recipients had higher in-hospital, 30-day and 6-months adverse outcomes (See Table 1). After adjusting for baseline characteristics, no-AVR in comparison to AVR group was associated with higher in-hospital mortality (OR: 1.71; 95%CI 1.59–1.83; $p < .001$), stroke rate (OR: 3.25; 95%CI 3.04–3.48; $p < .001$), 30-day readmission rates (OR: 1.86; 95%CI 1.80–1.91; $p = .000$), 6-month in-hospital mortality (OR: 3.08; 95%CI 2.79–3.41; $p < .001$), and 6-month readmission rates (OR: 2.62; 95%CI 2.55–2.70; $p = .000$). Only 5.5 % and 2.4 % of no-AVR patients subsequently underwent TAVI and SAVR respectively in the following 6 months after being discharged alive.

Similarly, majority of CHF + AS+AR patients were managed with no-AVR (53.2 %) and had poorer outcomes in comparison to TAVI and SAVR recipients. In this cohort, after adjusting for baseline characteristics, no-AVR in comparison to AVR group was associated with higher in-hospital mortality (OR: 1.53; 95%CI 1.27–1.84; $p < .001$), stroke rate (OR: 3.88; 95%CI 3.29–4.58; $p < .001$), 30-day readmission rates (OR: 2.11; 95%CI 1.96–2.27; $p < .001$), 6-month in-hospital mortality (OR: 4.48; 95%CI 3.36–5.98; $p < .001$), and 6-month readmission rates (OR: 3.20; 95%CI 2.96–3.46; $p < .001$). Only 6.2 % and 5.6 % of no-AVR patients in this cohort subsequently received TAVI and SAVR respectively in the following 6 months after being discharged alive.

4. Discussion

We observed that despite the advances in TAVI and SAVR technologies, a considerable number of CHF patients with AVD still do not undergo valve replacements, and eventually have worse short-term outcomes in comparison to AVR recipients. Of patients managed conservatively in the first six months of each year, only 7.9 % of CHF + AS and 11.8 % of CHF + AS+AR patients subsequently underwent valve replacements in the following six months of the year. The concern with conservative management is that if an intervention is attempted later on a severely progressed aortic valve disease, patients are at an even higher risk of perioperative mortality and complicated postoperative courses [4]. Patient refusal despite physician recommendation for valve replacement, under-recognition of symptoms, underestimation of the impact of AS treatment, and over-estimation of the operative risk could be potentially avoidable reasons for non-operative therapy in patients who could benefit from valve replacements. A study looking at medically managed AS patients found that they were less likely to believe that they were given enough information about the available treatment options [5]. This also reflects a potential gap in communication between patients and physicians.

This study has limitations relating to the data source, which lacks data on the severity of AVD. To minimize the potential bias raised by this limitation, we only included CHF patients with underlying AVD to plausibly capture more severe cases. The definitive treatment for these patients with valve replacement was accomplished in 20 % of AS and 40 % of AS+AR patients. Although the exact reasons for not undergoing AVR are difficult to assess because the dataset is an administrative database, possible causes of this may include the lack of referral to

appropriate experts, lack of specific care paths, and, to some extent, the lack of understanding of the seriousness of the problem. The American Heart Association and the American College of Cardiology are working on several initiatives to streamline the management of aortic valve disease patients with a proper referral, better care paths, and more education on treatment options to improve outcomes of these patients [6]. Ongoing clinical trials like the TAVR UNLOAD trial may provide further data on the utility of TAVI in addition to optimal heart failure therapy by reducing the valvular hemodynamic load [1]. More studies are needed to understand the timing, indications and utilization of AVR in this population.

CRediT authorship contribution statement

Shashank Shekhar: Conceptualization, Methodology, Analysis, Writing Original draft, Review and Editing.

Abhishek Ajay: Data Analysis, Validation, Software.

Toshiaki Isogai: Conceptualization, Methodology, Data Curation, Supervision.

Roop Kaw: Conceptualization, Methodology, Data Curation, Writing- Review and Editing Supervision.

Anas Saad: Data Curation, Methodology, Resources.

Ankit Agrawal: Methodology, Writing, Validation.

Hassan Lak: Methodology, Writing, Validation.

Tikal Kansara: Methodology, Writing, Validation.

Amgad Mentias: Conceptualization, Methodology, Writing Review and Editing, Supervision.

Amar Krishnaswamy: Conceptualization, Methodology, Writing Review and Editing, Supervision.

Lars Svensson: Conceptualization, Methodology, Writing Review and Editing, Supervision.

Samir R. Kapadia: Conceptualization, Methodology, Writing original draft, Writing- Review and Editing, Resources, Supervision.

Declaration of competing interest

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.

Acknowledgments

This study was possible with a generous gift from Jennifer and Robert McNeil. The funders had no role in the design and conduct of the study, in the collection, analysis, and interpretation of the data, and in the preparation, review, or approval of the manuscript.

References

[1] E. Spitzer, N.M. Van Mieghem, P. Pibarot, R.T. Hahn, S. Kodali, M.S. Maurer, T. M. Nazif, J. Rodes-Cabau, J.M. Paradis, A.P. Kappetein, O. Ben-Yehuda, G.A. van Es, F. Kallel, W.N. Anderson, J. Tijssen, M.B. Leon, Rationale and design of the transcatheter aortic valve replacement to UNload the left ventricle in patients with ADvanced heart failure (TAVR UNLOAD) trial, Am. Heart J. 182 (2016) 80–88.

[2] A.M. Goldsweig, H.J. Tak, L.-W. Chen, H.D. Aronow, B. Shah, D.S. Kolte, P. Velagapudi, N. Desai, M. Szerlip, J.D. Abbott, The evolving Management of Aortic Valve Disease: 5-year trends in SAVR, TAVR, and medical therapy, Am. J. Cardiol. 124 (2019) 763–771.

[3] Healthcare Cost and Utilization Project (HCUP). NRD Overview. https://www.hcup-us.ahrq.gov/nrdoverview.jsp. Accessed March 19, 2022.

[4] M. Miyake, C. Izumi, T. Taniguchi, T. Morimoto, M. Amano, S. Nishimura, T. Kitai, T. Kato, K. Kadota, K. Ando, Y. Furukawa, T. Inada, M. Inoko, K. Ishii, G. Sakaguchi, F. Yamazaki, T. Koyama, T. Komiya, K. Yamanaka, N. Nishiwaki, N. Kanemitsu, T. Saga, T. Ogawa, S. Nakayama, H. Tsuneyoshi, A. Iwakura, K. Shiraga, M. Hanyu, N. Ohno, A. Fukumoto, T. Yamada, J. Nishizawa, J. Esaki, K. Minatoya, Y. Nakagawa, T. Kimura, C.A.R. Investigators, Early surgery vs. Surgery after watchful waiting for asymptomatic severe aortic stenosis, Circ. J. 82 (2018) 2663–2671.

[5] K. Dharmarajan, J. Foster, M. Coylewright, P. Green, J.P. Vavalle, O. Faheem, P. H. Huang, A. Krishnaswamy, V.H. Thourani, L.A. McCoy, T.Y. Wang, The medically managed patient with severe symptomatic aortic stenosis in the TAVR era: patient characteristics, reasons for medical management, and quality of shared decision making at heart valve treatment centers, PLoS One 12 (2017), e0175926.

[6] Association AH, Aortic Stenosis Initiative Learning Collaborative 1: 6.17.2020, American Heart Association, 2020.