THE TEXAS HEART INSTITUTE® JOURNAL

Clinical Investigation

Transcatheter Aortic Valve Replacement for Severe Aortic Valve Stenosis: Do Patients Experience Better Quality of Life Regardless of Gradient?

Anthony Simone, MD[1,2]; Juka S. Kim, BS[1]; Jeanne Huchting, NP[1]; Asim Rafique, MD[1]; Ruhsen Ozcaglayan, MD[1]; Richard J. Shemin, MD[3]; Olcay Aksoy, MD[1]; Murray H. Kwon, MD[3]

[1]Department of Cardiology, David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, California
[2]Department of Cardiology, Kaiser Permanente Los Angeles Medical Center, Los Angeles, California
[3]Department of Cardiac Surgery, David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, California

Abstract

Background: Aortic valve replacement improves survival for patients with low-gradient aortic valve stenosis, but there is a paucity of data on postoperative quality of life for this population.

Methods: In a single-center retrospective analysis of 304 patients with severe aortic valve stenosis who underwent transcatheter aortic valve replacement, patients were divided into 4 groups based on mean pressure gradient, left ventricular ejection fraction, and stroke volume index. Using the Kansas City Cardiomyopathy Questionnaire-12, quality of life was assessed immediately before and 1 month after transcatheter aortic valve replacement.

Results: Most patients in the low-flow, low-gradient group were men; this group had higher relative rates of cardiovascular disease and type 2 diabetes than the paradoxical low-flow, low-gradient group; the normal-flow, low-gradient group; and the high-gradient group. All-cause mortality did not differ significantly among the groups at 1 month after surgery, and all groups experienced a significant improvement in quality-of-life scores after surgery. The mean improvement was 27 points in the low-flow, low-gradient group, 25 points in the paradoxical low-flow, low-gradient group, 30 points in the normal-flow, low-gradient group, and 30 points in the high-gradient group (all $P < .001$).

Conclusion: Quality of life improves significantly across all subgroups of aortic valve stenosis after transcatheter aortic valve replacement, regardless of flow characteristics or aortic valve gradients.

Keywords: Aortic valve stenosis; quality of life; surveys and questionnaires; transcatheter aortic valve replacement

Introduction

Aortic valve stenosis (AS) is the most common degenerative valvular disease in developed countries and is becoming a growing healthcare burden as the population ages. The prevalence of AS steadily increases with age, with 1 estimate noting a prevalence of 0.2% in individuals 50 to 59 years of age, increasing to 9.8% in those 80 to 89 years of age.[1] High-gradient AS (HG-AS)—defined as an aortic valve area (AVA) of 1.0 cm^2 or less and a mean pressure gradient (MPG) of 40 mm Hg or higher—constitutes the majority of AS.[2] Although it has been well established that aortic valve replacement prolongs survival in patients with symptomatic HG-AS, the approach to low-gradient AS is less-clearly defined.[3,4]

Patients with low-gradient, severe AS—defined as an AVA of 1.0 cm^2 or less and an MPG of less than 40 mm Hg—present with a complex set of physiologic findings. Although one of the most common etiologies of the low-flow state is reduced left ventricular ejection fraction (LVEF), other pathologic findings—such as diastolic dysfunction, other valvular disease, pulmonary hypertension, right ventricular failure, and rhythm disturbances—

Citation: Simone A, Kim JS, Huchting J, Rafique A, Ozcaglayan R, Shemin RJ, Aksoy O, Kwon MH. Transcatheter aortic valve replacement for severe aortic valve stenosis: do patients experience better quality of life regardless of gradient? *Tex Heart Inst J.* 2023;50(1):e217659. doi:10.14503/THIJ-21-7659

Corresponding author: Anthony Simone, MD, 1526 N Edgemont St, 2nd Floor, Los Angeles, CA 90027(anthony.m.simone@kp.org)

may also lead to low-flow states. This heterogeneous group of patients with low-gradient AS is divided into those with low-flow, low-gradient AS (LFLG-AS; LVEF <50%), paradoxical low-flow, low-gradient AS (pLFLG-AS; LVEF ≥50%, stroke volume index [Svi] <35 mL/m^2), or normal-flow, low-gradient AS (NFLG-AS; LVEF ≥50%, Svi ≥35 mL/m^2). The presence of a low gradient often leads to discrepancies in valvular evaluation, with uncertainty about the severity of stenosis and the perceived benefits of intervention.

Patients with low-gradient AS, like their peers with high gradients, have a dismal prognosis with conservative management. However, their estimated 2-year survival rate of 50% increases to 80% with aortic valve replacement.[5] Previous studies have evaluated the mortality benefits of transcatheter aortic valve replacement (TAVR) for patients with low-gradient AS,[6-9] highlighting improved event-free survival compared with surgical aortic valve replacement, and postoperative outcomes that are comparable to those of patients with HG-AS.[10-12] However, there remains a paucity of data on quality of life (QOL) after valve replacement in this population. This study aims to compare post-TAVR outcomes among patients with LFLG-AS, pLFLG-AS, NFLG-AS, and HG-AS to help inform appropriate clinical decision-making for patients with different subgroups of AS.

Abbreviations and Acronyms

AS	aortic valve stenosis
AVA	aortic valve area
BMI	body mass index
CABG	coronary artery bypass graft
HG-AS	high-gradient aortic valve stenosis
KCCQ-12	Kansas City Cardiomyopathy Questionnaire-12
LFLG-AS	low-flow,low-gradient aortic valve stenosis
LOS	length of stay
LVEF	left ventricular ejection fraction
MPG	mean pressure gradient
NFLG-AS	normal-flow, low-gradient aortic valve stenosis
NYHA	New York Heart Association
PAD	peripheral arterial disease
PCI	percutaneous coronary intervention
pLFLG-AS	paradoxical low-flow, low-gradient aortic valve stenosis
QOL	quality of life
STS	Society of Thoracic Surgeons
TAVR	transcatheter aortic valve replacement
UCLA	University of California, Los Angeles

Patients and Methods

This study was approved by the institutional review board of the University of California, Los Angeles (UCLA). All investigations were performed in compliance with human-studies guidelines for this institution and with the guidelines of the US Food and Drug Administration.

Records were obtained from a database of patients with severe AS who underwent TAVR at UCLA Ronald Reagan Medical Center between January 2016 and December 2018. Patients with a prior TAVR or surgical aortic valve replacement were excluded, as were those for whom any essential information was not available, including QOL scores (n = 16), identifying information (n = 1), or AS gradient (n = 1). Subgroups were created based on the findings of the most recent pre-TAVR transthoracic echocardiogram.

Patients were assessed at a preoperative visit, at 1 month after surgery, and at 1 year after surgery. The Kansas City Cardiomyopathy Questionnaire-12 (KCCQ-12) was used to assess QOL across 4 domains (QOL, social limitations, physical limitations, and symptom frequency). Each domain was scored on a scale of 0 (worst) to 100 (best), and the total combined KCCQ-12 score was also scaled from 0 to 100. Trans thoracic echocardiography was performed before TAVR and at 1 month after surgery.

Statistical Analysis

Continuous parametric variables were expressed as the mean (SD), and categorical variables were expressed as the number and percentage. Statistical differences between groups were analyzed using analysis of variance, and post hoc analysis of between-group comparisons was performed using a Bonferroni test. Categorical variables were compared using the χ^2 test unless there were very few numbers, in which case they were compared using Fisher exact test. Comparison of pre- and post-TAVR variables—including KCCQ-12 scores, LVEF, and New York Heart Association (NYHA) classification—was done using a paired *t* test. Comparison of NYHA class pre- and post-TAVR was done using the McNemar-Bowker test. A 2-sided $P < .05$ was considered statistically significant. Data were analyzed using SPSS software, version 25.0 (IBM).

TABLE I. Patient Demographics[a]

						P value[b]					
	LFLG-AS (n = 49)	pLFLG-AS (n = 80)	NFLG-AS (n = 45)	HG-AS (n = 130)	*P* value for subgroup comparison	LFLG vs pLFLG	LFLG vs NFLG	LFLG vs HG	pLFLG vs NFLG	pLFLG vs HG	NFLG vs HG
Age, mean (SD), y	79.1 (10.4)	79.1 (8.4)	83.0 (7.4)	80.7 (9.5)	.1	.999	.255	.999	.149	.999	.925
Female sex, No. (%)	13 (27)	39 (49)	30 (67)	69 (53)	<.001	—	—	—	—	—	—
PAD, No. (%)	20 (41)	31 (39)	13 (29)	24 (18)	.003	—	—	—	—	—	—
Type 2 diabetes, No. (%)	24 (49)	28 (35)	10 (22)	40 (31)	.039	—	—	—	—	—	—
Prior stroke, No. (%)	2 (4)	7 (9)	1 (2)	11 (8)	.437	—	—	—	—	—	—
Prior PCI, No. (%)	22 (45)	19 (24)	9 (20)	29 (22)	.011	—	—	—	—	—	—
Prior CABG, No. (%)	15 (31)	13 (16)	4 (9)	12 (9)	.002	—	—	—	—	—	—
Pacemaker, No. (%)	6 (12)	11 (14)	4 (9)	11 (8)	.63	—	—	—	—	—	—
Hypertension, No. (%)	45 (92)	73 (91)	42 (93)	117 (90)	.92	—	—	—	—	—	—
BMI, mean (SD), kg/m^2	25.8 (5.1)	27.7 (6.1)	25.8 (6.1)	26.2 (7.0)	.22	.580	.999	.999	.546	.560	.999
Smoking, No. (%)	2 (4)	1 (1)	0 (0)	5 (4)	.45	—	—	—	—	—	—
STS risk score, mean (SD)	9.1 (5.5)	6.4 (4.5)	6.3 (3.2)	6.0 (3.7)	<.001	.003	.007	<.001	.999	.999	.999

BMI, body mass index; CABG, coronary artery bypass graft; HG-AS, high-gradient aortic valve stenosis; LFLG-AS, low-flow, low-gradient aortic valve stenosis; NFLG-AS, normal-flow, low-gradient aortic valve stenosis; PAD, peripheral arterial disease; PCI, percutaneous coronary intervention; pLFLG-AS, paradoxical low-flow, low-gradient aortic valve stenosis; STS, Society of Thoracic Surgeons.

[a] *P* values for subgroup comparisons and post hoc Bonferroni analysis are included.
[b] Cells marked "—" indicate that Bonferroni analysis is not applicable.

Results

Of the 304 patients who met the study inclusion criteria, 49 had LFLG-AS, 80 had pLFLG-AS, 45 had NFLG-AS, and 130 had HG-AS. The AS subgroups were similar with respect to patient age, body mass index, presence of hypertension, smoking status, pacemaker history, and stroke history. The LFLG-AS group had a smaller proportion of female patients (27%) than did the pLFLG-AS group (49%) and the HG-AS group (53%) ($P < .001$; Table I). Women represented 67% of the NFLG-AS group. Ischemic disease was more prominent in patients with LFLG-AS, who had a higher prevalence of prior percutaneous coronary intervention (45%; $P = .011$) and prior coronary artery bypass graft (31%; $P = .002$). The LFLG-AS group had a higher relative prevalence of diabetes mellitus in particular and more comorbidities in general, as suggested by a significantly higher Society of Thoracic Surgeons (STS) short-term cardiac surgery risk score (9.1 [5.5]; $P < .001$) compared with the other 3 groups.

Transthoracic echocardiography was performed immediately before and 1 month after TAVR. At baseline, the mean (SD) AVA had significant variation and was lowest in the HG-AS group at 0.65 (0.18) ($P < .001$; Table II). As expected, the high-gradient group had the largest mean (SD) gradient at 51 (9.4) ($P < .001$), and the lower-gradient subgroups had similar mean (SD) gradients (LFLG-AS, 27 [7.8]; pLFLG-AS, 28 [6.6];

TABLE II. Echocardiographic Findings

	Mean (SD)					*P* value[b]					
	LFLG-AS (n = 49)	pLFLG-AS (n = 80)	NFLG-AS (n = 45)	HG-AS (n = 130)	*P* value for subgroup comparison[a]	LFLG vs pLFLG	LFLG vs NFLG	LFLG vs HG	pLFLG vs NFLG	pLFLG vs HG	NFLG vs HG
Aortic valve area, cm^2	0.67 (0.18)	0.71 (0.12)	0.78 (0.13)	0.65 (0.18)	<.001	.999	.008	.999	.138	.032	<.001
Gradient, mean (SD), mm Hg	27 (7.8)	28 (6.6)	31 (6.4)	51 (9.4)	<.001	.999	.103	<.001	.424	<.001	<.001
LVEF pre-TAVR, %	32 (9.0)	62 (6.4)	64 (5.8)	58 (14.1)	<.001	<.001	<.001	<.001	.999	.019	.011
LVEF post-TAVR, %	37 (12.4)	62 (6.9)	64 (6.2)	63 (8.9)	<.001	<.001	<.001	<.001	.999	.999	.999
LVEF change, %; *P* value[b]	5 (10.1); .002	0 (6.7); .943	0 (5.1); .718	5 (11.5); <.001	<.001	.042	.056	.999	.999	.009	.022
Stroke volume index, mL/m^2[c]	—	28 (5)	43 (6)	—	—	—	—	—	—	—	—

HG-AS, high-gradient aortic valve stenosis; LFLG-AS, low-flow, low-gradient aortic valve stenosis; LVEF, left ventricular ejection fraction; NFLG-AS, normal-flow, low-gradient aortic valve stenosis; pLFLG-AS, paradoxical low-flow, low-gradient aortic valve stenosis; TAVR, transcatheter aortic valve replacement.

[a] *P* values for subgroup comparisons and post hoc Bonferroni analysis are included.
[b] *P* value for paired *t* test.
[c] Cells marked "—" indicate that Bonferroni analysis is not applicable.

TABLE III. KCCQ-12 Quality of Life Component Scoring 1 Month After TAVR[a]

	Mean (SD); *P* value for paired *t* test					*P* value					
	LFLG-AS (n = 49)	pLFLG-AS (n = 80)	NFLG-AS (n = 45)	HG-AS (n = 130)	*P* value for subgroup comparison	LFLG vs pLFLG	LFLG vs NFLG	LFLG vs HG	pLFLG vs NFLG	pLFLG vs HG	NFLG vs HG
Physical limitation change	8 (29); .088	11 (26); <.001	14 (24); <.001	12 (23); <.001	.71	.999	.999	.999	.999	.999	.999
Symptom frequency change	21 (25); <.001	14 (21); <.001	18 (25); <.001	17 (26); <.001	.57	.999	.999	.999	.999	.999	.999
Quality of life change	30 (29); <.001	34 (23); <.001	36 (27); <.001	36 (25); <.001	.57	.999	.999	.999	.999	.999	.999
Social limitations change	27 (33); <.001	17 (28); <.001	26 (29); <.001	26 (30); <.001	.17	.566	.999	.999	.826	.239	.999
Overall KCCQ-12 pre-TAVR	46 (30)	48 (24)	49 (22)	52 (26)	.51	.999	.999	.999	.999	.999	.999
Overall KCCQ-12 post-TAVR	73 (25)	73 (26)	79 (23)	82 (21)	.07	.999	.999	.284	.999	.130	.999
Overall KCCQ-12 change	27 (31); <.001	25 (24); <.001	30 (28); <.001	30 (28); <.001	.7	.999	.999	.999	.999	.999	.999

HG-AS, high-gradient aortic valve stenosis; KCCQ-12, Kansas City Cardiomyopathy Questionnaire-12; LFLG-AS, low-flow, low-gradient aortic valve stenosis; NFLG-AS, normal-flow, low-gradient aortic valve stenosis; pLFLG-AS, paradoxical low-flow, low-gradient aortic valve stenosis.

[a] All values are relative to a 100-point scale. *P* values for subgroup comparisons and post hoc Bonferroni analysis are included.

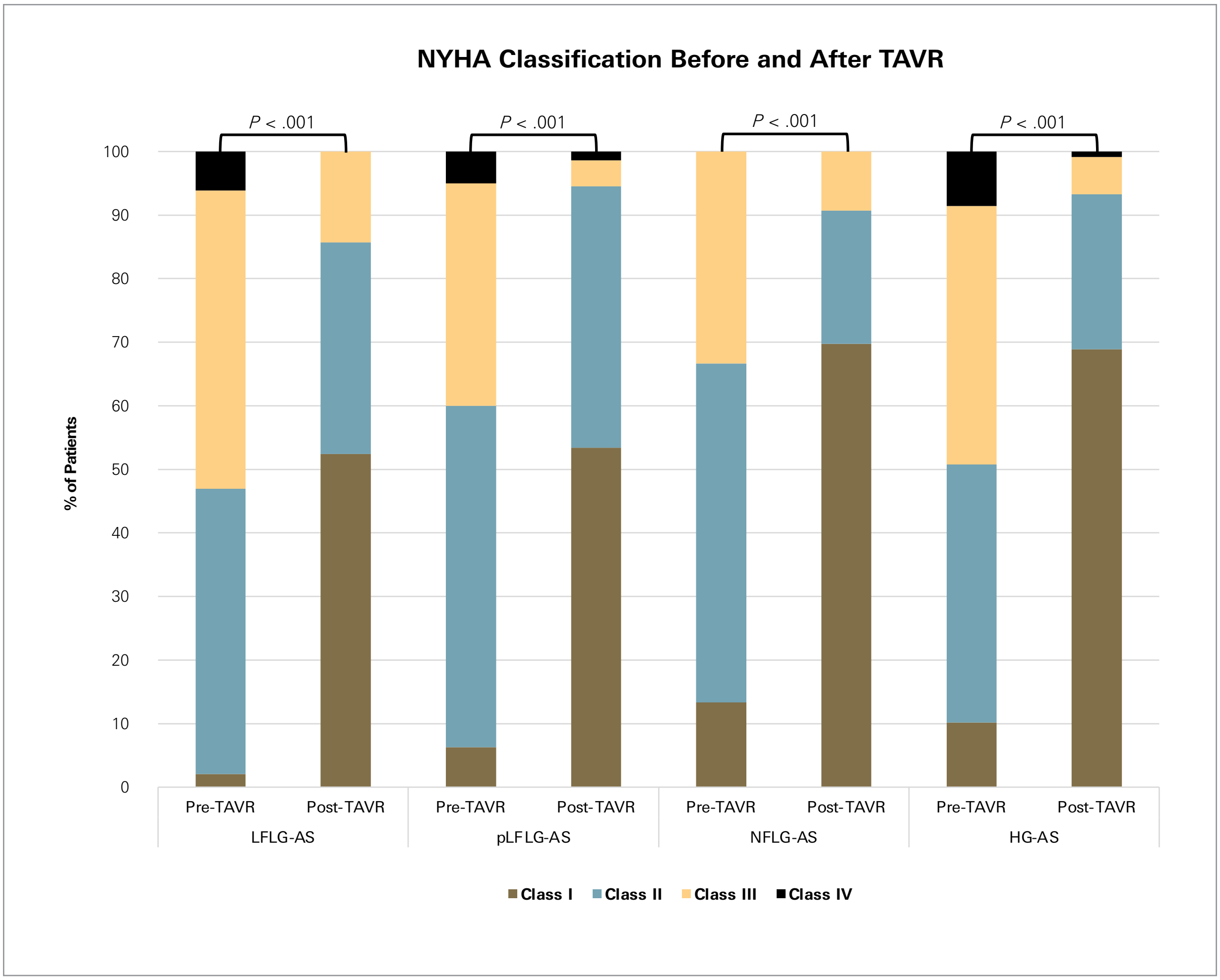

Fig. 1 All 4 subgroups of severe AS show a dramatic shift in NYHA class distribution 1 month after TAVR, with very few patients falling into class III or IV after valve replacement. Statistical comparisons use the McNemar-Bowker test, with $P < .05$ considered statistically significant.

AS, aortic valve stenosis; HG-AS, high-gradient aortic valve stenosis; LFLG-AS, low-flow, low-gradient aortic valve stenosis; NFLG-AS, normal-flow, low-gradient aortic valve stenosis; NYHA, New York Heart Association; pLFLG-AS, paradoxical low-flow, low-gradient aortic valve stenosis; TAVR, transcatheter aortic valve replacement.

NFLG-AS, 31 [6.4]). The LFLG-AS and HG-AS groups showed improvements in the mean (SD) LVEF after TAVR (LFLG-AS, 5% [10.1%]; $P = .002$; HG-AS, 5% [11.5%]; $P < .001$), but the LVEF in the pLFLG-AS and NFLG-AS groups remained unchanged. As expected, the pLFLG-AS group had a mean (SD) Svi of 28 (5), and the NFLG-AS group had a mean (SD) Svi of 43 (6).

Baseline overall KCCQ-12 scores were similar across all 4 AS categories, and there were significant improvements in each group at 1 month. The mean (SD) improvements were 27 (31) points in the LFLG-AS group, 25 (24) points in the pLFLG-AS group, 30 (28) points in the NFLG-AS group, and 30 (28) points in the HG-AS group ($P < .001$; Table III). In addition to the clear improvement in overall KCCQ-12 scores, each of the 4 AS subgroups showed substantial improvement at 1 month in almost all individual QOL domains.

Of the 263 patients who completed the KCCQ-12 at 1 month, 197 (75%) were subsequently reassessed at 1 year. The remaining 66 patients (25%) were either lost to follow up, had limited follow up, or had died by the time of the 1-year appointment. For the patients who completed KCCQ-12 testing at 1 year, the mean overall scores for all 4 AS subgroups were similar to those obtained at the 1-month assessment. The mean (SD) 1-year KCCQ-12 scores for each group were: LFLG-AS,

TABLE IV. Functional Assessment and Mortality Outcomes

	LFLG-AS (n = 49)	pLFLG-AS (n = 80)	NFLG-AS (n = 45)	HG-AS (n = 130)	*P* value for subgroup comparison[a]	*P* value[a,b] LFLG vs pLFLG	LFLG vs NFLG	LFLG vs HG	pLFLG vs NFLG	pLFLG vs HG	NFLG vs HG
LOS, mean (SD), d	6.4 (6.0)	7.9 (14.3)	3.0 (3.4)	4.5 (5.5)	.007	.999	.299	.999	.015	.034	.999
Overall KCCQ-12 change, mean (SD); *P* value[c]	27 (31); <.001	25 (24); <.001	30 (28); <.001	30 (28); <.001	.7	.999	.999	.999	.999	.999	.999
NYHA pre-TAVR, No. (%)					.151						
Class I	1 (2)	5 (6)	6 (14)	13 (10)		—	—	—	—	—	—
Class II	22 (45)	43 (54)	24 (56)	52 (41)		—	—	—	—	—	—
Class III	23 (47)	28 (35)	15 (35)	52 (41)		—	—	—	—	—	—
Class IV	3 (6)	4 (5)	0 (0)	11 (8)		—	—	—	—	—	—
NYHA-post-TAVR, No. (%)					.029						
Class I	22 (53)	39 (54)	30 (70)	82 (69)		—	—	—	—	—	—
Class II	14 (33)	30 (41)	9 (21)	29 (24)		—	—	—	—	—	—
Class III	6 (14)	3 (4)	4 (9)	7 (6)		—	—	—	—	—	—
Class IV	0 (0)	1 (1)	0 (0)	1 (1)		—	—	—	—	—	—
30-d mortality, No. (%)	1 (2.0)	2 (2.5)	1 (2.2)	4 (3.1)	.999	—	—	—	—	—	—
1-y mortality, No. (%)	7 (14.0)	9 (11.4)	3 (6.8)	13 (10.2)	.674	—	—	—	—	—	—

HG-AS, high-gradient aortic valve stenosis; KCCQ-12, Kansas City Cardiomyopathy Questionnaire-12; LFLG-AS, low-flow, low-gradient aortic valve stenosis; LOS, length of stay; NFLG-AS, normal-flow, low-gradient aortic valve stenosis; NYHA, New York Heart Association; pLFLG-AS, paradoxical low-flow, low-gradient aortic valve stenosis; TAVR, transcatheter aortic valve replacement.

[a] *P* values for subgroup comparisons and post hoc Bonferroni analysis are included.
[b] Cells marked "—" indicate that Bonferroni analysis is not applicable.
[c] *P* value for the paired *t* test.

78 (23); pLFLG-AS, 81 (23); NFLG-AS, 86 (14); and HG-AS, 86 (18) (Supplementary Table I).

The NYHA classification improved after TAVR for all AS subgroups ($P < .001$; Fig. 1). At pre-TAVR baseline, most patients were classified as class II and class III (Table IV). Consistent with the KCCQ-12 data, most patients improved postoperatively, falling mostly into class I and class II. Only 2 patients were categorized as class IV after TAVR, compared with 18 before TAVR.

The patients in the NFLG-AS group tended to have the shortest hospital stays, with a mean (SD) length of stay of 3.0 (3.4) days compared with 6.4 (6.0) days for the LFLG-AS group and 7.9 (14.3) days for the pLFLG-AS group ($P = .007$).

At the 1-year mark, there remained no difference in mortality across the 4 groups (LFLG-AS, 14.0%; pLFLG-AS, 11.4%; NFLG-AS, 6.8%; and HG-AS, 10.2%; $P = .674$).

Discussion

Understanding the benefits of TAVR within various AS subgroups is of critical importance. The prevalence of AS is substantially higher in older adult patients, many of whom have comorbid cardiovascular disease and poor functional status. Although post-TAVR mortality benefit has been well studied, the effect of TAVR on QOL remains largely unexplored.[4,11,13] Not only has there been controversy about the diagnosis of true severe AS across the physiologic spectrum, the data for QOL and how it is affected by TAVR has not been well studied. In this analysis, changes in QOL across the spectrum of hemodynamic presentations of AS were studied based on AS flow states and gradients.

The baseline KCCQ-12 scores were similar across all 4 subgroups of AS, and TAVR resulted in a statistically significant improvement in overall KCCQ-12 scores, regardless of AS subgroup. There was substantial improvement across all 4 domains of the questionnaire, including the "QOL" and "social limitations" categories. In this population, the KCCQ-12 reveals important social benefits that may not be fully captured by other functional assessments.

Although there is a paucity of data on QOL outcomes for AS subgroups, a recent study did compare KCCQ-12 overall scores after TAVR in patients with low-flow and normal-flow AS and found improved QOL scores at 1 month.[14] Previous work has defined poor outcomes after TAVR as either death or a decrease in KCCQ-12 score by 10 points or more.[15] By this metric, the mortality data and increases in KCCQ-12 scores seen in the present study further confirm that TAVR yields meaningful benefit for patients in all 4 AS subgroups. The present study also showed an overall improvement in NYHA classification, affirming the observed benefit of TAVR for physical capacity and functional status. This shift was striking: only a small fraction of patients remained in class IV after TAVR, with the overwhelming majority falling into class I or II. The available data suggest that improvements in KCCQ-12 may be preserved at the 1-year mark.

There were no noted differences in 1-month or 1-year mortality among the 4 groups. These results are consistent with those of previous studies that showed similar 30-day mortality among AS subgroups.[12,16-19] Researchers have shown that 1-year mortality for pLFLG-AS and LFLG-AS is significantly higher than for HG-AS, but the present analysis may be underpowered to detect this difference.[11,20,21]

The presence of both normal flow and a low gradient in the NFLG-AS group is seemingly contradictory; however, this finding is purportedly a product of discrepancies in the criteria for severe AS. One study of 333 cardiac catheterizations for severe AS found that using an AVA cutoff of 1 cm^2 may correspond more closely to an MPG of 30 mm Hg rather than the standard 40 mm Hg.[22] Of note, the NFLG-AS group in the present study had the largest mean AVA and MPG of the 3 lower-gradient subgroups. This group also had generally favorable outcomes, a finding that is consistent with those of prior studies showing that these patients have less advanced disease and better survival.[2,9,23,24]

Ultimately, the decision to proceed with TAVR for patients in the various subgroups of severe AS should be primarily based on underlying physiology and surgical risk. However, when the risk profile or mortality benefit is equivocal, expected QOL improvement can help inform the decision to proceed with TAVR.

Limitations

This study is based on data from a single center, which may limit the generalizability of the conclusions to the general population. The analysis is retrospective, nonrandomized, and does not include comparisons to patients managed with surgery or conservative therapy. Because of the nature of the intervention and the absence of a true control group (which would involve a sham procedure), some degree of placebo effect cannot be ruled out.

Regardless, this retrospective analysis shows a clinically significant QOL benefit for patients in all severe AS subgroups who are managed with TAVR. However, QOL information at 1 year is missing for some of the patients in this study.

Future work should expand on this analysis and include a larger number of patients from multiple sites. Extending the follow-up QOL assessment to 1 year or longer will reveal information about the durability of the initial QOL improvement. As the TAVR procedure itself improves in terms of safety, technical ability, and device technology, repeat analysis may reveal even more substantial benefit.

Conclusion

Patients with severe AS experience substantially improved QOL after TAVR, as assessed by the KCCQ-12 score, regardless of their baseline valve gradient.

Published: 25 January 2023

Conflict of Interest Disclosure: Dr Murray H. Kwon and Dr Richard J. Shemin are paid consultants of Edwards Lifesciences.

Funding/Support: None.

References

1. Eveborn GW, Schirmer H, Heggelund G, Lunde P, Rasmussen K. The evolving epidemiology of valvular aortic stenosis. the Tromsø study. *Heart.* 2013;99(6):396-400. doi:10.1136/heartjnl-2012-302265
2. Clavel MA, Magne J, Pibarot P. Low-gradient aortic stenosis. *Eur Heart J.* 2016;37(34):2645-2657. doi:10.1093/eurheartj/ehw096
3. Reardon MJ, Van Mieghem NM, Popma JJ, et al; SURTAVI Investigators. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. *N Engl J Med.* 2017;376(14):1321-1331. doi:10.1056/NEJMoa1700456
4. Gleason TG, Reardon MJ, Popma JJ, et al; CoreValve U.S. Pivotal High Risk Trial Clinical Investigators. 5-year outcomes of self-expanding transcatheter versus surgical aortic valve replacement in high-risk patients. *J*

Am Coll Cardiol. 2018;72(22):2687-2696. doi:10.1016/j.jacc.2018.08.2146
5. Clavel MA, Fuchs C, Burwash IG, et al. Predictors of outcomes in low-flow, low-gradient aortic stenosis: results of the multicenter TOPAS study. *Circulation.* 2008;118(14 suppl):S234-S242. doi:10.1161/CIRCULATIONAHA.107.757427
6. Connolly HM, Oh JK, Schaff HV, et al. Severe aortic stenosis with low transvalvular gradient and severe left ventricular dysfunction: result of aortic valve replacement in 52 patients. *Circulation.* 2000;101(16):1940-1946. doi:10.1161/01.cir.101.16.1940
7. Levy F, Laurent M, Monin JL, et al. Aortic valve replacement for low-flow/low-gradient aortic stenosis operative risk stratification and long-term outcome: a European multicenter study. *J Am Coll Cardiol.* 2008;51(15):1466-1472. doi:10.1016/j.jacc.2007.10.067
8. Tribouilloy C, Lévy F, Rusinaru D, et al. Outcome after aortic valve replacement for low-flow/low-gradient aortic stenosis without contractile reserve on dobutamine stress echocardiography. *J Am Coll Cardiol.* 2009;53(20):1865-1873. doi:10.1016/j.jacc.2009.02.026
9. Dayan V, Vignolo G, Magne J, Clavel MA, Mohty D, Pibarot P. Outcome and impact of aortic valve replacement in patients with preserved LVEF and low-gradient aortic stenosis. *J Am Coll Cardiol.* 2015;66(23):2594-2603. doi:10.1016/j.jacc.2015.09.076
10. Kugelman N, Jaffe R, Aronson D, ET AL. Outcome of patients with low-gradient aortic stenosis undergoing transcatheter or surgical aortic valve replacement. *Cardiovasc Revasc Med.* 2020;21(3):257-262. doi:10.1016/j.carrev.2019.05.002
11. Fischer-Rasokat U, Renker M, Liebetrau C, et al. 1-year survival after TAVR of patients with low-flow, low-gradient and high-gradient aortic valve stenosis in matched study populations. *JACC Cardiovasc Interv.* 2019;12(8):752-763. doi:10.1016/j.jcin.2019.01.233
12. Shah B, McDonald D, Paone D, et al. Outcomes after transcatheter aortic valve replacement in patients with low versus high gradient severe aortic stenosis in the setting of preserved left ventricular ejection fraction. *J Interv Cardiol.* 2018;31(6):849-860. doi:10.1111/joic.12561
13. Deeb GM, Reardon MJ, Chetcuti S, et al; CoreValve US Clinical Investigators. 3-year outcomes in high-risk patients who underwent surgical or transcatheter aortic valve replacement. *J Am Coll Cardiol.* 2016;67(22):2565-2574. doi:10.1016/j.jacc.2016.03.506
14. Ahmed A, Alsidawi S, Bae R, et al. Changes in quality of life in patients with low-flow aortic stenosis undergoing transcatheter aortic valve replacement. *Catheter Cardiovasc Interv.* 2020;96(4):972-978. doi:10.1002/ccd.28805
15. Arnold SV, Afilalo J, Spertus JA, et al; U.S. CoreValve Investigators. Prediction of poor outcome after transcatheter aortic valve replacement. *J Am Coll Cardiol.* 2016;68(17):1868-1877. doi:10.1016/j.jacc.2016.07.762
16. Condado JF, Block PC. Is it really "paradoxical" or just the ventricle? *Catheter Cardiovasc Interv.* 2016;87(4):805-806. doi:10.1002/ccd.26470
17. Bavishi C, Balasundaram K, Argulian E. Integration of flow-gradient patterns into clinical decision making for patients with suspected severe aortic stenosis and preserved LVEF: a systematic review of evidence and meta-analysis. *JACC Cardiovasc Imaging.* 2016;9(11):1255-1263. doi:10.1016/j.jcmg.2016.01.035
18. Debry N, Sudre A, Amr G, et al. Transcatheter aortic valve implantation for paradoxical low-flow low-gradient aortic stenosis patients. *Catheter Cardiovasc Interv.* 2016;87(4):797-804. doi:10.1002/ccd.26253
19. Ribeiro HB, Lerakis S, Gilard M, et al. Transcatheter aortic valve replacement in patients with low-flow, low-gradient aortic stenosis: the TOPAS-TAVI registry. *J Am Coll Cardiol.* 2018;71(12):1297-1308. doi:10.1016/j.jacc.2018.01.054
20. Reinthaler M, Schwabe A, Landmesser U, et al. 'Paradoxical' low-flow, low-gradient severe aortic valve stenosis: an entity with limited improvement following transcatheter aortic valve implantation. *J Heart Valve Dis.* 2014;23(4):441-449.
21. Kataoka A, Watanabe Y, Kozuma K, et al; OCEAN-TAVI Investigators. Prognostic impact of low-flow severe aortic stenosis in small-body patients undergoing TAVR: the OCEAN-TAVI registry. *JACC Cardiovasc Imaging.* 2018;11(5):659-669. doi:10.1016/j.jcmg.2016.12.028
22. Minners J, Allgeier M, Gohlke-Baerwolf C, Kienzle RP, Neumann FJ, Jander N. Inconsistent grading of aortic valve stenosis by current guidelines: haemodynamic studies in patients with apparently normal left ventricular function. *Heart.* 2010;96(18):1463-1468. doi:10.1136/hrt.2009.181982
23. Eleid MF, Sorajja P, Michelena HI, Malouf JF, Scott CG, Pellikka PA. Flow-gradient patterns in severe aortic stenosis with preserved ejection fraction: clinical characteristics and predictors of survival. *Circulation.* 2013;128(16):1781-1789. doi:10.1161/CIRCULATIONAHA.113.003695
24. Kanwar A, Thaden JJ, Nkomo VT. Management of patients with aortic valve stenosis. *Mayo Clin Proc.* 2018;93(4):488-508. doi:10.1016/j.mayocp.2018.01.020