Stroke after TAVR - Impact on Clinical Outcome and Patient Reported Quality of Life (QoL): The Michigan Structural Heart Consortium (MISHC) Experience

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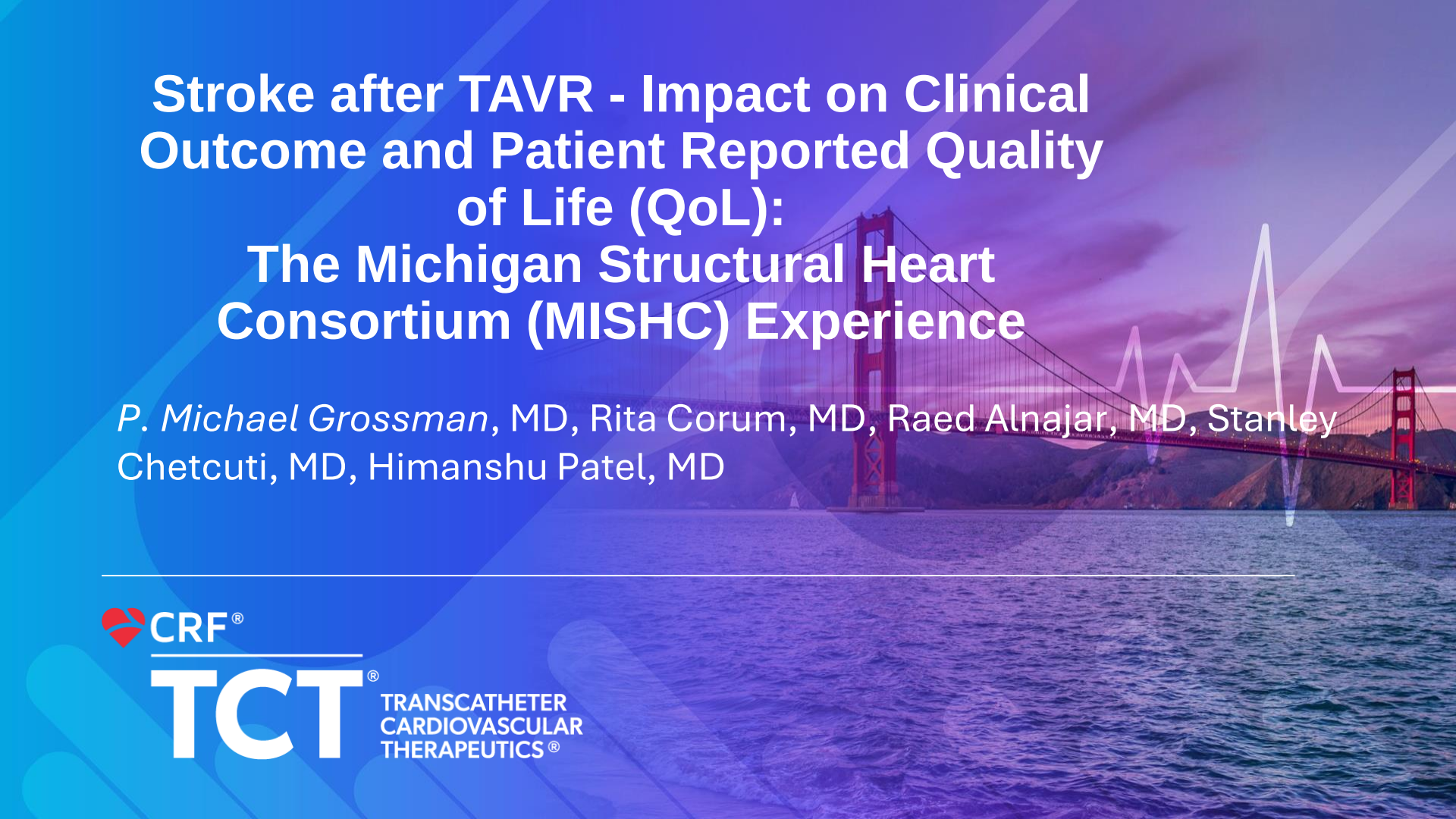

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Nature of Financial Relationship	Ineligible Company
Grant/Research Support	Abbott Medtronic Cardiovascular Edwards Life Sciences Gore Medical National Institutes of Health
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Stroke following TAVR

- Reported incidence 1-4%
- Majority recognized in first 48 hours after TAVR
- Associated with worse clinical outcomes
- Impact on patient reported quality of life (QoL) not well elucidated

- Evaluated the incidence, risk factors and comparative outcomes, including patient reported QoL in real world practice from the Michigan Structural Heart Consortium (MISHC)

What is MISHC?

- Statewide Collaborative Quality Initiative in Michigan
  - Providers
  - Health Care Systems
  - Supported by Blue Cross Blue Shield of Michigan
  - Improve quality and outcomes of patients undergoing TAVR
- Data entered in the TCT database forwarded to MISHC
  - Institutional data abstractors trained by MISHC in database and definitions
  - Audited by annual chart review
  - Data complete and accurate

MISHC

- Thirty-one TAVR institutions in Michigan
- Urban, suburban and rural
- Community hospitals to quaternary referral centers
- TAVR data is organized
- Comparative reports delivered to care teams and healthcare systems
- Data and outcomes shared in unblinded fashion at in-person meetings
- Quality Improvement goals set by collaborative
- Best practices shared

Methods

- 18,633 TAVR patients in Michigan between 1/2016 and 1/2024
- Evaluated demographic, clinical, and procedural characteristics
- QoL measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ) at baseline, 30-days and 1-year post-TAVR
- Comparisons between stroke and non-stroke groups including mean change in KCCQ
- Inverse Probability of Treatment Weighting (IPTW) was applied to adjust for confounding variables

Results: Baseline Characteristics

Variable	Unweighted				IPT Weights		
		Post-Procedure Stroke?			Post-Procedure Stroke?		
	Overall	No	Yes		No	Yes	
	N = 18,633	N = 18,301	N = 332	p	Weighted N = 314	Weighted N = 332	p
Age (mean (SD))	*78.76 (8.55)*	*78.73 (8.57)*	*80.30 (7.69)*	*0.001*	80.33 (7.40)	80.30 (7.69)	0.953
Race (%)				0.166			0.806
White	17,517 (94.0)	17,212 (94.0)	305 (91.9)		291.1 (92.7)	305.0 (91.9)	
Black	837 (4.5)	815 (4.5)	22 (6.6)		18.1 (5.7)	22.0 (6.6)	
Other/Multi-Racial	279 (1.5)	274 (1.5)	5 (1.5)		4.8 (1.5)	5.0 (1.5)	
Sex = Female (%)	*8,392 (45.0)*	*8,214 (44.9)*	*178 (53.6)*	*0.002*	164.7 (52.4)	178.0 (53.6)	0.673
Currently on Dialysis = Yes (%)	607 (3.3)	597 (3.3)	10 (3.0)	0.922	10.4 (3.3)	10.0 (3.0)	0.758
Heart Failure in Last Year = Yes (%)	*1,928 (10.3)*	*1,905 (10.4)*	*23 (6.9)*	*0.048*	21.9 (7.0)	23.0 (6.9)	0.979
Afib/Flutter = Yes (%)	6,975 (37.4)	6,843 (37.4)	132 (39.8)	0.409	123.3 (39.3)	132.0 (39.8)	0.860
Hx Aortic Valve Balloon Valvuplasty = Yes (%)	845 (4.5)	829 (4.5)	16 (4.8)	0.906	15.2 (4.8)	16.0 (4.8)	0.984
Carotid Stenosis = Yes (%)	3,572 (19.2)	3,495 (19.1)	77 (23.2)	0.071	71.5 (22.8)	77.0 (23.2)	0.858
Conduction Defect = Yes (%)	7,795 (41.8)	7,657 (41.8)	138 (41.6)	0.965	130.3 (41.5)	138.0 (41.6)	0.980
Cerebrovascular Accident = Yes (%)	2,180 (11.7)	2,130 (11.6)	50 (15.1)	0.066	43.6 (13.9)	50.0 (15.1)	0.545
Diabetes = Yes (%)	7,454 (40.0)	7,314 (40.0)	140 (42.2)	0.450	129.7 (41.3)	140.0 (42.2)	0.756
MI = Yes (%)	4,102 (22.0)	4,024 (22.0)	78 (23.5)	0.555	70.7 (22.5)	78.0 (23.5)	0.679
PAD = Yes (%)	*5,432 (29.2)*	*5,305 (29.0)*	*127 (38.3)*	*<0.001*	119.4 (38.0)	127.0 (38.3)	0.930
TIA = Yes (%)	1,640 (8.8)	1,602 (8.8)	38 (11.4)	0.106	33.0 (10.5)	38.0 (11.4)	0.587
CABG = Yes (%)	3,252 (17.5)	3,197 (17.5)	55 (16.6)	0.721	53.5 (17.0)	55.0 (16.6)	0.823
Hypertension = Yes (%)	17,018 (91.3)	16,716 (91.3)	302 (91.0)	0.887	286.3 (91.2)	302.0 (91.0)	0.897
Chronic Lung Disease = Yes (%)	6,838 (36.7)	6,704 (36.6)	134 (40.4)	0.180	123.0 (39.2)	134.0 (40.4)	0.667
Hostile Chest = Yes (%)	604 (3.2)	594 (3.2)	10 (3.0)	0.935	10.1 (3.2)	10.0 (3.0)	0.837

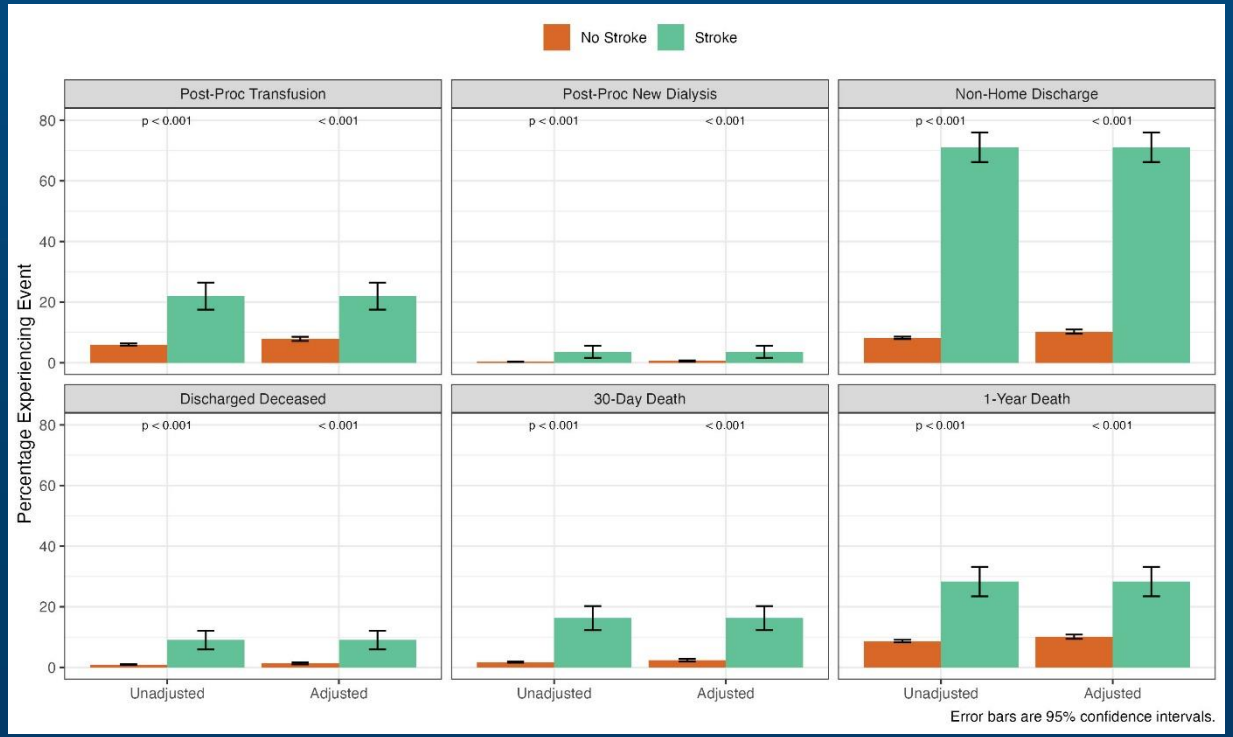
Results: NYHA Class, STS PROM, Heart Team Risk

Variable	Unweighted				IPT Weights		
		Post-Procedure Stroke?			Post-Procedure Stroke?		
	Overall	No	Yes		No	Yes	
	N = 18,633	N = 18,301	N = 332	p	Weighted N = 314	Weighted N = 332	p
NYHA Class w/in 2 Weeks (%)				0.113			0.785
I	329 (1.8)	321 (1.8)	8 (2.4)		5.7 (1.8)	8.0 (2.4)	
II	4,724 (25.4)	4,640 (25.4)	84 (25.3)		78.5 (25.0)	84.0 (25.3)	
III	11,716 (62.9)	11,521 (63.0)	195 (58.7)		190.6 (60.7)	195.0 (58.7)	
IV	1,864 (10.0)	1,819 (9.9)	45 (13.6)		39.1 (12.5)	45.0 (13.6)	
Baseline KCCQ (mean (SD))	*49.58 (24.18)*	*49.65 (24.19)*	*45.97 (23.12)*	*0.006*	46.09 (22.78)	45.97 (23.12)	0.928
STS Risk (%)				0.008			0.893
< 3	6,525 (35.0)	6,431 (35.1)	94 (28.3)		87.5 (27.9)	94.0 (28.3)	
3-8	9,280 (49.8)	9,108 (49.8)	172 (51.8)		166.6 (53.1)	172.0 (51.8)	
> 8	*2,828 (15.2)*	*2,762 (15.1)*	*66 (19.9)*		59.9 (19.1)	66.0 (19.9)	
Heart Team Risk for SAVR (%)				0.001			0.980
Low Risk	2,701 (14.5)	2,671 (14.6)	30 (9.0)		29.7 (9.4)	30.0 (9.0)	
Intermediate Risk	6,203 (33.3)	6,109 (33.4)	94 (28.3)		91.2 (29.0)	94.0 (28.3)	
High Risk	*7,132 (38.3)*	*6,975 (38.1)*	*157 (47.3)*		145.8 (46.4)	157.0 (47.3)	
Extreme Risk	*2,597 (13.9)*	*2,546 (13.9)*	*51 (15.4)*		47.3 (15.1)	51.0 (15.4)	

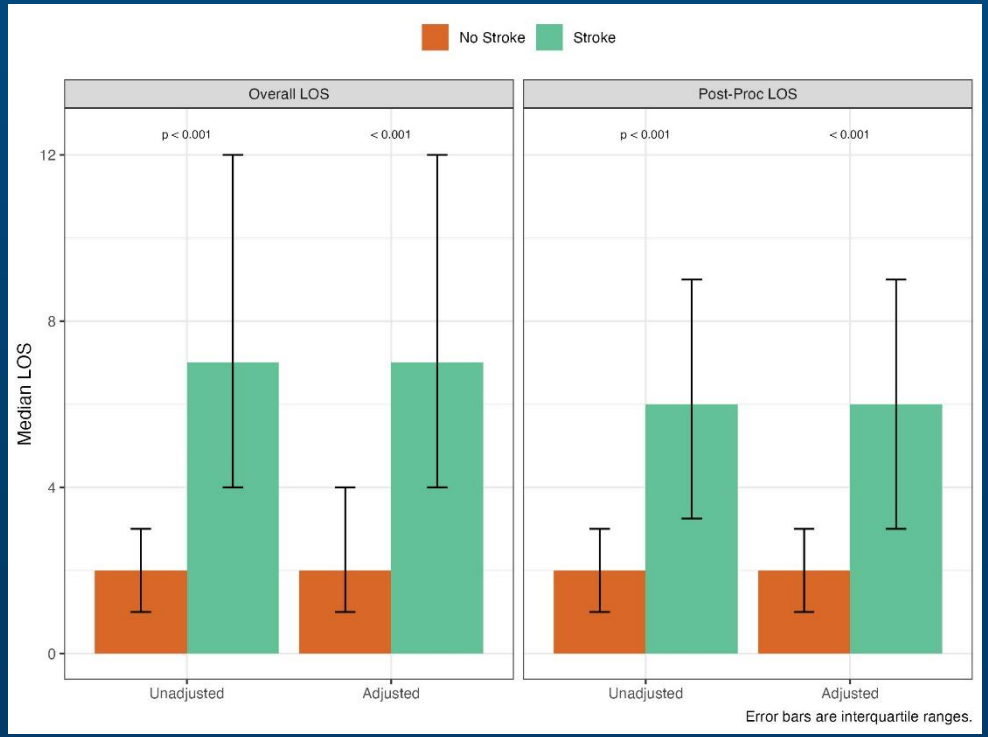
Results: Cardiac Status, Procedural Characteristics

Variable	Unweighted				IPT Weights		
		Post-Procedure Stroke?			Post-Procedure Stroke?		
	Overall	No	Yes		No	Yes	
	N = 18,633	N = 18,301	N = 332	p	Weighted N = 314	Weighted N = 332	p
LVEF (%)				0.698			0.765
Normal	14,852 (79.7)	14,580 (79.7)	272 (81.9)		257.2 (81.9)	272.0 (81.9)	
Mild Dysfunction	1,675 (9.0)	1,650 (9.0)	25 (7.5)		25.0 (8.0)	25.0 (7.5)	
Moderate Dysfunction	1,162 (6.2)	1,143 (6.2)	19 (5.7)		17.9 (5.7)	19.0 (5.7)	
Severe	886 (4.8)	870 (4.8)	16 (4.8)		13.5 (4.3)	16.0 (4.8)	
Not Documented	58 (0.3)	58 (0.3)	0 (0.0)		0.4 (0.1)	0.0 (0.0)	
Arotic Stenosis = Yes (%)	17,333 (93.0)	17,027 (93.0)	306 (92.2)	0.611	291.6 (92.9)	306.0 (92.2)	0.629
Aortic Regurgitation = Yes (%)	368 (2.0)	364 (2.0)	4 (1.2)	0.413	4.0 (1.3)	4.0 (1.2)	0.922
Pre-Procedure Anticoagulant = Yes (%)	2,573 (13.8)	2,524 (13.8)	49 (14.8)	0.670	45.9 (14.6)	49.0 (14.8)	0.940
Pre-Procedure Inotropes = Yes (%)	184 (1.0)	182 (1.0)	2 (0.6)	0.663	2.2 (0.7)	2.0 (0.6)	0.849
Intra-Procedure Inotropes = Yes (%)	7,447 (40.0)	7,297 (39.9)	150 (45.2)	0.057	136.1 (43.3)	150.0 (45.2)	0.505
Procedure Status = Urgent/Emergent/Salvage (%)	*1,423 (7.6)*	*1,385 (7.6)*	*38 (11.4)*	*0.011*	29.8 (9.5)	38.0 (11.4)	0.241
Embolic Protection = Yes (%)	5,459 (29.3)	5,364 (29.3)	95 (28.6)	0.830	92.0 (29.3)	95.0 (28.6)	0.783
Non-Femoral Access = Nonfemoral Access (%)	*820 (4.4)*	*790 (4.3)*	*30 (9.0)*	*<0.001*	25.4 (8.1)	30.0 (9.0)	0.543
Valve-in-Valve Procedure = Yes (%)	1,491 (8.0)	1,469 (8.0)	22 (6.6)	0.407	21.1 (6.7)	22.0 (6.6)	0.944

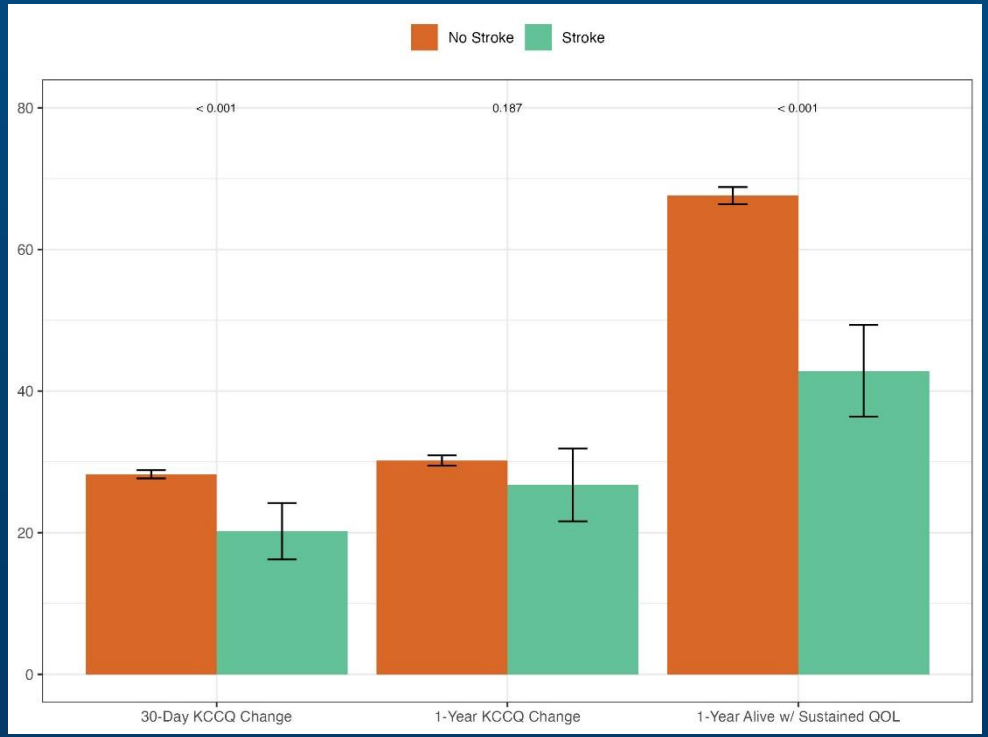
Results: Clinical Outcomes (Unadjusted and Adjusted)



Results: Length of Stay (LOS)



Results: QoL and Alive with Sustained QoL after TAVR



Conclusions

- Stroke after TAVR is not uncommon (1.78%)
- Stroke patients
  - Older
  - Female
  - History of heart failure in last year
  - Peripheral arterial disease
  - More likely to be high or extreme risk for SAVR with STS PROM > 8
  - More likely urgent or emergent status
  - More likely alternative access
  - Lower baseline KCCQ summary score

Conclusions

- Stroke after TAVR associated with
  - Increased risk of death at discharge, 30 days and one-year after TAVR
  - Increased risk of transfusion
  - Increased risk of new dialysis
  - Increased length of hospital stay
  - Increased risk of not discharged to home
- Patient reported Quality of Life
  - Lower at 30 days in those that suffered stroke
- Patients who suffered a stroke after TAVR were much less likely to be alive with a sustained QoL at one year post TAVR
- Continued research designed to avoid stroke after TAVR are needed