

THE DURATION OF ANTICOAGULANT TREATMENT AND ITS ASSOCIATION WITH HRQOL AND TREATMENT SATISFACTION IN PATIENTS WITH AF AFTER TAVR: RESULTS FROM ENVISAGE-TAVI AF

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INTRODUCTION

- AF occurs in approximately 33% of patients after transcatheter aortic valve replacement (TAVR), and oral anticoagulation is generally recommended as treatment¹⁻⁷
- Although oral anticoagulants have been studied extensively in patients with AF after TAVR, these studies primarily evaluate efficacy and safety⁸⁻¹⁰
- Patient-reported outcomes (PROs) assist physicians in understanding the impact of treatment on patient well-being and potential treatment influence on factors such as medication adherence and persistence^{11,12}
- The association between anticoagulation treatment duration with PROs and treatment satisfaction in patients with AF after TAVR remains unknown

AF, atrial fibrillation; PRO, patient-reported outcome; TAVR, transcatheter aortic valve replacement.

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OBJECTIVE

- To evaluate if a longer duration of anticoagulation treatment is positively associated with PROs and treatment satisfaction in patients with AF after TAVR

METHODS

- ENVISAGE-TAVI AF (NCT02943785) was a global, prospective, randomized, controlled, open-label, multicenter, adjudicator-masked trial that compared the efficacy and safety of edoxaban with VKAs in patients with AF after successful TAVR¹
- Treatment satisfaction and convenience were evaluated at month 3 and month 12 postbaseline²
- Patients were stratified by treatment duration: <6 months, 6 months to 1 year, 1 to 1.5 years, 1.5 to 2 years, and >2 years
- A mixed-effect model for repeated measures assessed least squares (LS) mean differences between treatment durations while controlling for relevant covariates

Assessment tools

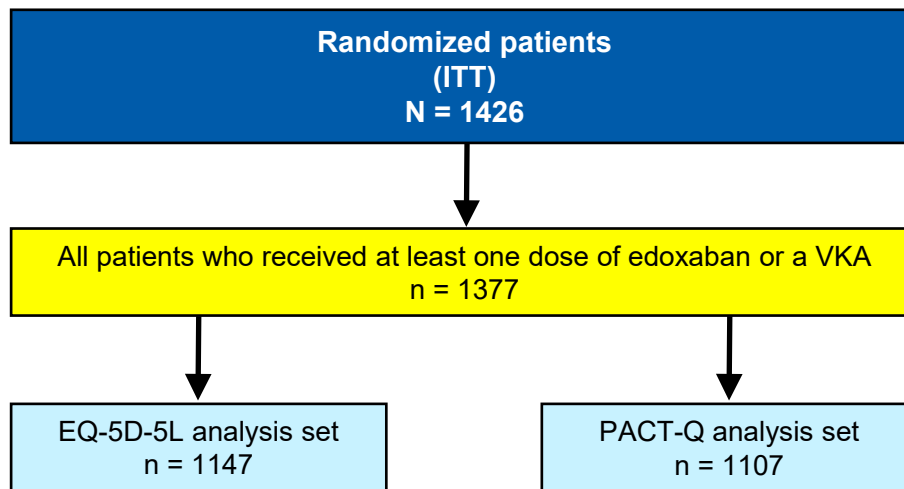
EuroQol 5-Dimension, 5-Level (EQ-5D-5L) evaluated mobility, self-care, pain/discomfort, usual activities, and anxiety/depression³

EuroQol 5-Dimension visual analog scale (EQ-5D VAS) measured self-rated health³

Perception Anticoagulant Treatment Questionnaire (PACT-Q) module 2 assessed patients' satisfaction and perceived convenience with their anticoagulant treatment²

RESULTS

- Of 1426 patients enrolled in ENVISAGE-TAVI AF between April 2017 and January 2020, the EQ-5D-5L analysis set included 1147 (80.4%) patients, and the PACT-Q analysis set included 1107 (77.6%) patients



RESULTS

Baseline demographics and clinical characteristics were similar across treatment durations for both analysis sets

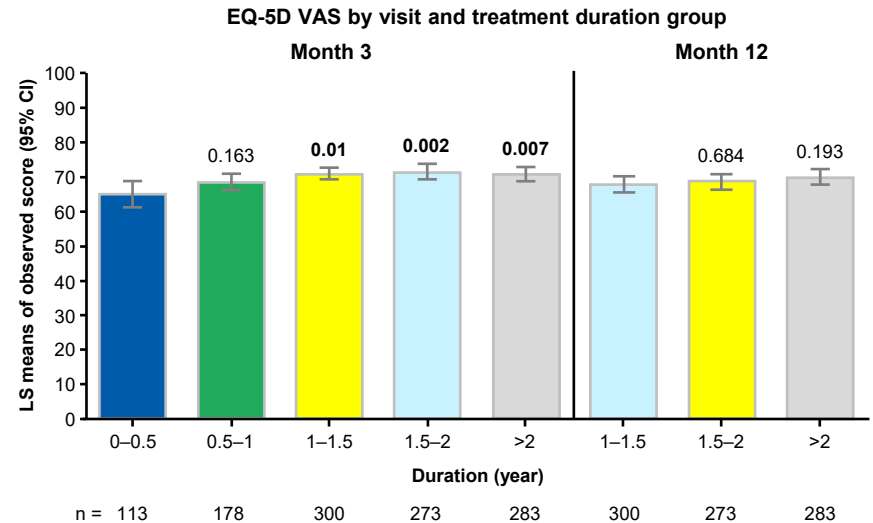
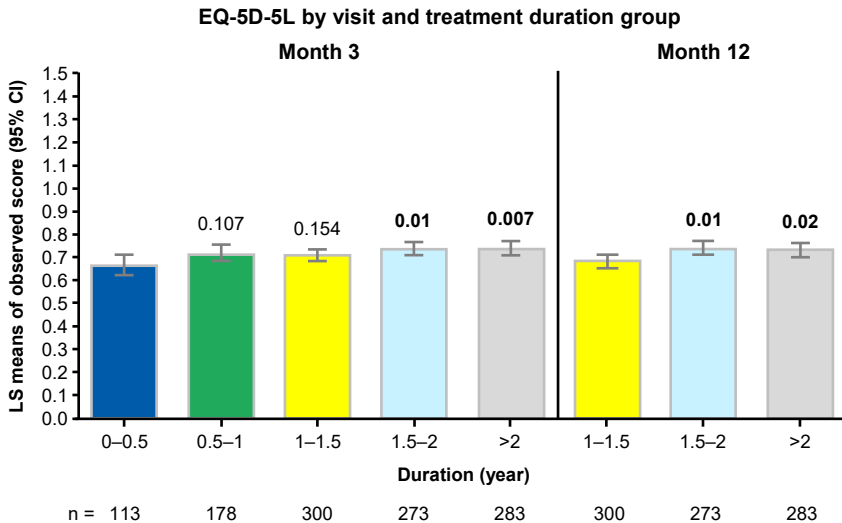
	EQ-5D-5L (n = 1147)					PACT-Q (n = 1107)				
	<6 mo n = 113	6 mo–1 yr n = 178	1–1.5 yr n = 300	1.5–2 yr n = 273	>2 yr n = 283	<6 mo n = 109	6 mo–1 yr n = 173	1–1.5 yr n = 295	1.5–2 yr n = 267	>2 yr n = 263
Age, years, mean ± SD	82.3 ± 4.9	82.2 ± 5.8	81.8 ± 5.3	82.3 ± 5.3	81.4 ± 5.5	82.2 ± 5.0	82.2 ± 5.9	81.8 ± 5.3	82.3 ± 5.3	81.3 ± 5.5
Sex, male	58 (51.3)	92 (51.7)	157 (52.3)	152 (55.7)	155 (54.8)	56 (51.4)	90 (52.0)	154 (52.2)	148 (55.4)	146 (55.5)
Race										
White	90 (79.6)	144 (80.9)	241 (80.3)	220 (80.6)	256 (90.5)	86 (78.9)	140 (80.9)	237 (80.3)	214 (80.1)	237 (90.1)
Asian	9 (16.8)	28 (15.7)	52 (17.3)	49 (17.9)	10 (3.5)	19 (17.4)	28 (16.2)	52 (17.6)	49 (18.4)	10 (3.8)
Black or African American	0 (0.0)	3 (1.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
Other ^a	3 (2.7)	2 (1.1)	5 (1.7)	1 (0.4)	14 (4.9)	3 (2.8)	2 (1.2)	4 (1.4)	1 (0.4)	13 (4.9)
Missing	1 (0.9)	1 (0.6)	2 (0.7)	3 (1.1)	3 (1.1)	1 (0.9)	1 (0.6)	2 (0.7)	3 (1.1)	3 (1.1)
BMI, mean ± SD, kg/m²	27.3 ± 5.9	27.1 ± 4.8	27.6 ± 5.6	27.0 ± 5.1	29.1 ± 5.9	27.4 ± 5.9	27.1 ± 4.8	27.6 ± 5.6	26.8 ± 5.1	29.1 ± 6.0
CrCl, mean ± SD, mL/min	56.7 ± 23.2	56.4 ± 22.4	58.3 ± 22.2	57.4 ± 24.6	62.7 ± 27.2	57.0 ± 22.9	56.3 ± 22.6	58.4 ± 22.3	57.4 ± 24.5	62.9 ± 27.0
Congestive heart failure	90 (79.6)	157 (88.2)	255 (85.0)	224 (82.1)	237 (83.7)	86 (78.9)	152 (87.9)	252 (85.4)	219 (82.0)	223 (84.8)
History of stroke	24 (21.1)	34 (19.1)	48 (16.0)	50 (18.3)	48 (17.0)	21 (19.3)	32 (18.5)	48 (16.3)	49 (18.4)	43 (16.3)
History of MI	15 (13.3)	22 (12.4)	42 (14.0)	34 (12.5)	46 (16.3)	15 (13.8)	21 (12.1)	41 (13.9)	34 (12.7)	43 (16.3)
History of hypertension	106 (93.8)	166 (93.3)	261 (87.0)	247 (90.5)	260 (91.9)	102 (93.6)	161 (93.1)	257 (87.1)	241 (90.3)	241 (91.6)
History of diabetes	45 (39.8)	58 (32.6)	96 (32.0)	102 (37.4)	131 (46.3)	43 (39.4)	55 (31.8)	95 (32.2)	98 (36.7)	122 (46.4)
History of PCI or CABG	37 (32.7)	57 (32.0)	94 (31.3)	81 (29.7)	88 (31.1)	35 (32.1)	56 (32.4)	91 (30.8)	81 (30.3)	85 (32.3)
CHA₂DS₂-VASc score, mean ± SD	4.52 ± 1.4	4.7 ± 1.4	4.3 ± 1.4	4.5 ± 1.3	4.5 ± 1.3	4.5 ± 1.4	4.7 ± 1.3	4.3 ± 1.4	4.5 ± 1.3	4.5 ± 1.3
HAS-BLED, mean ± SD	1.7 ± 0.7	1.7 ± 0.8	1.5 ± 0.7	1.5 ± 0.8	1.5 ± 0.8	1.7 ± 0.7	1.7 ± 0.8	1.5 ± 0.7	1.5 ± 0.8	1.5 ± 0.8

Data presented as n (%) unless otherwise noted. ^aIncludes patients of other races and those who chose not to report race.

BMI, body mass index; CABG, coronary artery bypass grafting; CHA₂DS₂-VASc, Congestive heart failure, Hypertension, Age ≥75 years (doubled), Diabetes, previous Stroke (doubled), Vascular disease, Age 65 to 74, and Sex Category; CrCl, creatinine clearance; EQ-5D-5L, EuroQol 5-Dimension, 5-Level; HAS-BLED, Hypertension, Abnormal liver/renal function, Stroke history, Bleeding history or predisposition, Labile international normalized ratio, Elderly, Drug/alcohol usage; MI, myocardial infarction; PACT-Q, Perception Anticoagulant Treatment Questionnaire; PCI, percutaneous coronary intervention; SD, standard deviation.

RESULTS

- In total, >90% of patients were treated for >6 months
- At month 3, LS mean EQ-5D-5L scores were significantly higher in patients receiving treatment for 1.5–2 years and >2 years vs <6 months
- At month 12, patients treated for 1.5–2 years and >2 years vs 1–1.5 years had significantly higher LS mean EQ-5D-5L scores
- At month 3, LS mean EQ-5D VAS scores were significantly higher in patients receiving treatment for 1–1.5 years, 1.5–2 years, and >2 years vs <6 months

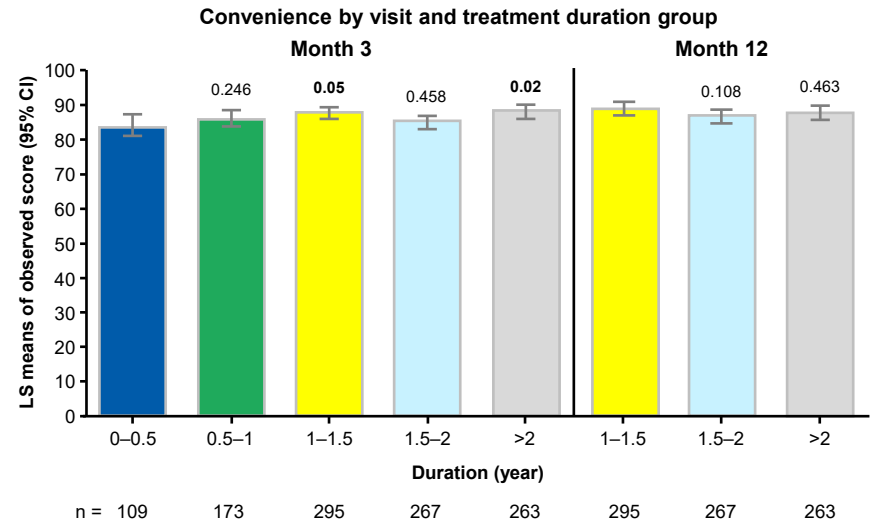
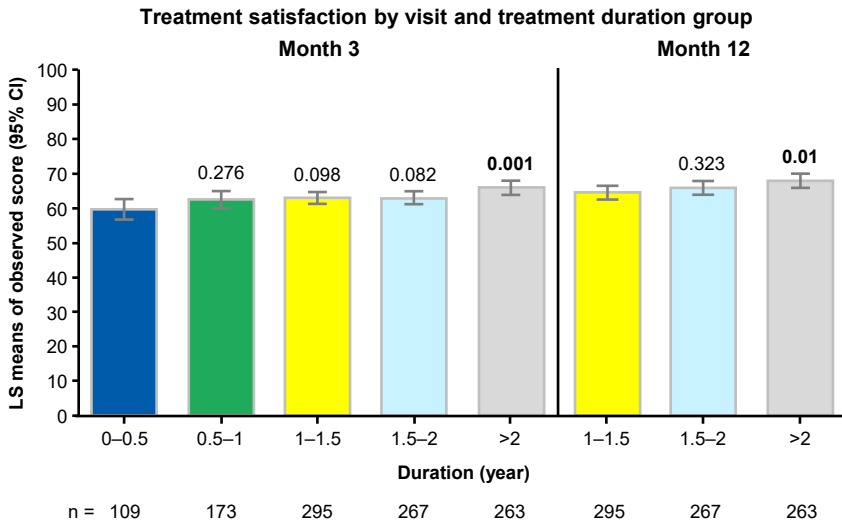


For statistical comparisons, 0–0.5 years was the reference group for month 3, and 1–1.5 years was the reference group for month 12. The *P*-value for each comparison is listed above each bar in the graph. Bolded *P*-values denote significance with a value of *P* < 0.05.

CI, confidence interval; EQ-5D-5L; EuroQol 5-Dimension, 5-Level; EQ-5D VAS, EuroQol 5-Dimension visual analog scale; LS, least squares.

RESULTS

- Patients receiving treatment for >2 years vs <6 months had significantly higher LS mean treatment satisfaction scores at month 3
- Patients receiving treatment for >2 years vs those treated for 1–1.5 years had a significantly higher LS mean treatment satisfaction score at month 12
- In patients receiving treatment for 1–1.5 years and >2 years vs <6 months, LS mean convenience scores were significantly higher at month 3



CONCLUSIONS

- In this ENVISAGE-TAVI AF post hoc analysis of patients with AF post TAVR, improved health-related quality of life (HRQoL) and treatment satisfaction were associated with longer vs shorter duration of anticoagulant treatment
- Prolonged anticoagulant treatment duration appears to be associated with significantly higher treatment satisfaction and significantly improved HRQoL in patients with AF after TAVR

ACKNOWLEDGMENTS

Medical writing and editorial support were provided by Chuck Blajszczak, PhD, of AlphaBioCom, a Red Nucleus company, and funded by Daiichi Sankyo, Inc.

DISCLOSURES

CH is a clinical proctor for Edwards Lifesciences and Boston Scientific; reports payment for speaker bureaus and support for attending meetings from Daiichi Sankyo, Inc.; and reports advisory board participation for Daiichi Sankyo, Inc. **NMVM** reports grants or contracts from Abbott; Abiomed; Boston Scientific; Daiichi Sankyo, Inc.; Edwards Lifesciences; Medtronic; PulseCath BV; and Siemens. **XY**, **LS**, and **SG** are employees of Evidera PPD, LLC. **RW**, **MU**, **CC**, **JJ**, and **XY** are employees of Daiichi Sankyo, Inc. **GD** reports research grants to institution and support for attending meetings from Bayer and Daiichi Sankyo, Inc., and consulting fees from Daiichi Sankyo.