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Serial Change in Health-Related Quality of Life Over 1 Year After Transcatheter Aortic Valve Implantation

Predictors of Health Outcomes

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Objectives The goal of this study was to assess serial changes in patient health-related quality of life (HRQOL) over time and identify predictors of patient benefit.

Background Severe aortic stenosis reduces the length and quality of a patient's life. Transcatheter aortic valve implantation (TAVI) is superior to standard medical therapy and noninferior to surgical aortic valve replacement for 1-year mortality. HRQOL is an important outcome measure for which there is limited evidence in TAVI populations.

Methods A total of 102 patients (mean age 80 ± 0.6 years; 49% male) undergoing TAVI consented to participate. Two HRQOL questionnaires—the social functioning (SF)-12v2 with physical component summaries (PCS) and mental component summaries (MCS) and the EQ-5D (with a visual analog scale [VAS])—were completed at baseline, 30 days, 6 months, and 1 year according to the recommendations of the Valve Academic Research Consortium. A SF-6D utility measure was calculated from the SF-12 survey.

Results HRQOL significantly improved over 1 year (PCS $p = 0.02$; EQ-5D $p = 0.02$; VAS $p = 0.01$; SF-6D $p = 0.03$), becoming similar to age-adjusted U.S. population norms. The greatest change occurred from baseline to 30 days ($p < 0.001$), with further significant improvements to 6 months ($p < 0.01$). An insignificant decline occurred between 6 months and 1 year ($p > 0.05$), but a linear pattern of change remained for PCS, EQ-5D, and VAS ($p < 0.05$). Male sex (SF-6D $p = 0.01$) and increased operator experience (PCS, EQ-5D, and VAS $p < 0.05$) were independent predictors of a greater improvement in HRQOL.

Conclusions HRQOL significantly improved early after TAVI and was maintained out to 1 year. Patient factors, procedural complications, and operator experience are predictors of health benefit at 1 year. (J Am Coll Cardiol 2012;59:1672–80) © 2012 by the American College of Cardiology Foundation

Symptomatic aortic stenosis (AS) reduces the quality and duration of an individual's life. Transcatheter aortic valve implantation (TAVI) is indicated as a treatment for the large number of patients with severe AS unsuitable for surgical aortic valve replacement (SAVR) (1). Clinical trial and registry data have demonstrated high procedural success, significantly improved survival compared with medical therapy, and noninferiority in mortality to SAVR at 1 year (2–4). Health-related quality of life (HRQOL) assessments are important clinical outcome measures of medical treatments. The Valve Academic Research Consortium recommended that quality of life questionnaires be used as a TAVI clinical benefit endpoint and that they should be conducted over 4 separate time points (baseline, 30 days, 6 months, and 1 year) (5). Quality of life is particularly relevant for TAVI patients; in an elderly population with multiple comorbidities, the absolute survival benefit may be less substantial, increasing the importance of quality-attained years. In addition, identification of particular risk factors and predictors of HRQOL would allow the "heart

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team" to better inform patients of their likely individual benefits from this high-risk procedure.

Health utility values are a measure of preferences for health states, which are essential for the calculation of quality-adjusted life-years (QALYs) within the framework of cost-utility analyses. Cost-utility analyses are the preferred approach, with QALYs the preferred metric of organizations charged with evaluating the cost-effectiveness of medical technologies for the purpose of healthcare resource allocation and decision making (6).

Quality of life data on TAVI populations are sparse (7,8), and at the time of writing, only the PARTNER study has published HRQOL results over the range of recommended time points (9), with no reports of health utility values for this patient group. Health utility values, especially multiple assessments over a long time period, are important to allow cost-effective analyses and decision analytical modeling to be undertaken.

The goals of this study were to assess serial changes in HRQOL and health utility at 30 days, 6 months, and 1 year after TAVI and to identify the clinical variables that predict patient benefit.

Methods

A total of 102 patients who underwent TAVI at our institution between May 2008 and May 2010 provided written informed consent to the study, which was approved by the institutional ethics committee and performed in accordance with the Declaration of Helsinki. Patient selection for TAVI was performed by a multidisciplinary heart team that included a cardiologist, cardiothoracic surgeon, and cardiac anesthetist. Using echocardiography, severe AS was defined as a peak velocity >4 m/s or a calculated aortic valve area <0.8 cm^2. All individuals were symptomatic and deemed unsuitable for SAVR due to high calculated surgical risk (EuroSCORE >20) or inoperable comorbidities. Pre-operative assessments included invasive angiography of the coronary and iliac arteries and transesophageal echocardiography. Patients were deemed unsuitable for TAVI if the aortic annulus was <20 or >27 mm. Exclusion criteria were the inability to comprehend English language or impaired cognition.

Transcatheter aortic valve implantation. TAVI was performed under general anesthesia using the 18F CoreValve Revalving System (Medtronic, Inc., Minneapolis, Minnesota) as described previously (10). A transfemoral approach was used where possible, with percutaneous access and closure. A surgical subclavian approach was performed in patients without suitable femoral access. Aortic valvuloplasty under rapid pacing control was followed by CoreValve implantation (26 or 29 mm) with post-dilation as required. The primary operator was identical for all procedures, and the results reflect all cases sequentially performed after proctorship.

Quality of life assessments. HRQOL was assessed using 2 generic, validated questionnaires: the SF-12v2 health outcomes questionnaire (QualityMetric Inc., Lincoln, Rhode Island) and the EQ-5D questionnaire (EuroQOL). Each patient completed a questionnaire at baseline, 30 days, 6 months, and 1 year. The initial survey was conducted by interview with a trained health care specialist, and later time points were completed by postal or telephone survey. Patient characteristics, comorbidities, New York Heart Association (NYHA) functional class, procedural risk factors, and variables were collected before TAVI. Post-operative complications (e.g., vascular hemorrhage, permanent pacemaker implantation) and mortality were collected post-TAVI.

Abbreviations and Acronyms

ANOVA = analysis of variance
AS = aortic stenosis
BP = bodily pain
GH = general health
HRQOL = health-related quality of life
MCS = mental component score
NYHA = New York Health Association
PCS = physical component score
QALY = quality-adjusted life-year
RE = role emotional
RP = role physical
SAVR = surgical aortic valve replacement
SF = social functioning
TAVI = transcatheter aortic valve implantation
VT = vitality

The SF-12v2 is based on the 36-item Short-Form Health Survey but is shorter and simpler to complete and is thus more suitable to an elderly population. It uses 8 dimensions to assess HRQOL: physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH). Responses applied to the patient's health over the previous 4 weeks. These responses were then graded and scored from 0 to 100, with a higher score reflecting a better HRQOL. In addition, 2 separate component summary scores are provided, distinguishing between physical (physical component score [PCS]) and mental (mental component score [MCS]) health.

EQ-5D and SF-6D are 2 health-based utility measures. Utility measures typically provide an index (quality of life weighting) between 0 and 1, where 1 reflects full health and 0, death. Utility values are combined in economic evaluations with survival data to calculate QALY gains from new treatments and technologies. EQ-5D uses 5 domains to assess health states: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. It is scored using the U.K. population tariff time-tradeoff valuation exercise. Patients also completed a visual analog scale (VAS) of worst imaginable (0) to best possible (100) health. Answers applied to the day of completing the questionnaire. SF-6D is a utility-based measure that is calculated using the SF-12 scores converted to SF-6D utility scores using a U.K. tariff (11). This provides an additional domain (vitality) and different recall period (4 weeks) from the EQ-5D. Differences in the change of scores suggest that SF-6D has a higher sensitivity in severe disease processes (12).