Short Term Quality of Life Following Transcatheter Aortic Valve Replacement

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Abstract

Background: Transcatheter aortic valve replacement (TAVR) is the recommended therapy for patients with severe calcific aortic stenosis (AS) who are not suitable candidates for surgery. The aim of this study is to evaluate the quality of life (QOL) for patients with severe AS who underwent TAVR with the Core Valve Medtronic prosthesis.

Methods: An analysis of patients who underwent TAVR with the Medtronic self-expanding Core Valve system (Medtronic, Inc.) at the University of Miami hospital was conducted between April 2011, and March 2014. Demographic and clinical data were obtained from inpatient and outpatient clinical records. QOL assessment was realized with the SF-12 Health-Survey. The questionnaire was administered at baseline, 6 months and 1 year after TAVR. Missing values were treated with median based imputation.

Results: A total of 71 patients underwent TAVR therapy. Of these, 63 patients successfully completed or partially completed the SF-12 questionnaire at 6 months follow up. Mean age was 85.0 ± 8.2 years and 65% were male. Eight patients (11.3%) died during follow up. After 6 months, a significant improvement in both scores (PCS 37.0; p < 0.001 and MCS 52.5 p < 0.001) was observed.

Conclusions: The main finding of this study is that TAVR in patients with severe AS is followed by early improvements in quality of life. The results show a marked improvement in functional status and a significant improvement in quality of life in both physical and mental components.

Introduction

Transcatheter Aortic Valve Replacement (TAVR) has emerged as an alternative treatment modality for patients with severe aortic stenosis (AS) who are at high or extreme risk for surgical aortic valve replacement (SAVR) [1]. Previous studies have shown that TAVR results in substantial reductions in symptoms and mortality [2-5]. Despite these health benefits, the assessment of quality of life (QOL) remains critical in these patients who often express quality of life over quantity of life [6]. The aim of this study is to evaluate the changes in quality of life in elderly patients with severe AS who underwent TAVR.

Methods and Patient selection

From April 2011 until March 2014, 71 consecutive patients were referred to the University of Miami Hospital for evaluation of TAVR. All patients eligible for the procedure had to be considered at high or extreme risk for SAVR if 2 cardiac surgeons and 1 interventional cardiologist at the clinical site estimated high (≥ 15% and ≤ 50%) or extreme (≥ 50%) risk for mortality or irreversible morbidity at 30 days with SAVR. Inclusion criteria were as follows: severe symptomatic aortic stenosis defined as an aortic valve area 0.8 cm² or aortic valve index 0.5 cm²/m² and either a mean aortic valve gradient > 40 mm Hg or a peak aortic valve velocity > 4.0 m/s at rest or with a dobutamine stress if the left ventricular ejection fraction was < 50%.

Principal exclusion criteria were an active gastrointestinal hemorrhage within the prior 3 months, a major stroke within the prior 6 months, or a life expectancy < 1 year. All patients underwent TAVR via an iliofemoral, transaortic or subclavian approach, using the Medtronic self-expanding Core Valve system (Medtronic, Inc.). All patients gave their informed written consent after receiving complete information about risk and benefits of the study and procedure.

Quality of Life assessment

QOL was prospectively assessed using the SF-12 Health-Survey at baseline, 6 months and 1 year follow-up [7,8]. The SF-12 questionnaire consists of 12 questions, which measure functioning in 8 multi-item domains of daily life, such as: physical functioning, role limitation due to physical health problems, bodily pain, general health, vitality as a measure of energy and fatigue, social functioning, role limitations due to emotional problems, and mental health related to psychological distress and psychological well-being. The Mental Component Summary (MCS) and the Physical Component Summary (PCS) are the 2 meta-scores of the SF-12, which combines the 8 domains and represent overall physical and mental functioning [8]. Higher SF-12 scores indicate better QOL, positive changes in SF-12 scores indicate improvement in QOL, and a negative change indicates deterioration. The scoring system and the interpretation of results of SF-12 has been explained elsewhere [8]. The questionnaires were administered by dedicated research staff to the participating patients during their screening for the TAVR procedure at the outpatient clinic and at their scheduled 6-months and 1-year clinical visit. After explaining the method and the purpose, the patients were then asked to complete the questionnaire.

Continuous Analysis

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deviations and compared with the use of the paired t-test or the Wilcoxon signed-rank test, as appropriate. Categorical variables were presented as counts and percentages and compared with the use of McNemar's test. A two-sided P-value of less than 0.05 was considered of statistical significance. Missing values were handled using multiple imputation. All data were processed using the Statistical Package for Social Sciences, version 15 (SPSS, Chicago, IL, USA).

Results

In this cohort 71 (100%) of the patients successfully underwent TAVR. In total 63 out of the 71 (89%) patients (67% male, median age 85 years) fully or partially completed SF-12 both at baseline and 6 months follow-up. The 30-day mortality was 2% and 8 (11.3%) patients had died at 6 months follow-up. In the all cohort, 1 patient died for cardiovascular causes, 2 for respiratory failure, 1 for aspiration pneumonia, 2 for sepsis and 2 for cancer. The remaining 6 patients were not able or willing to return to follow-up. For these 6 patients, multiple imputation was used for the missing data. Patients with missing SF-12 data at 6 months tended to be sicker than those is the analytic cohort, with more lung disease and higher STS mortality scores and euroscore (Figure 1) shows the postoperative follow-up of the entire cohort. Of the total of 63 analyzed, 51 patients underwent TAVR via iliofemoral approach, 7 via transaortic approach and 4 via subclavian approach. Baseline characteristics of the patients are summarized in (Table 1).

Clinical outcomes

There was a significant difference in mean gradient (49.1 ± 11.1 to 10.0 ± 4.5 mmHg; p < 0.001) one day after TAVR compared to baseline. Echocardiographic parameters 6 months after TAVR showed a significant difference in mean gradient (49.1 ± 11.1 to 8.4 ± 6.4 mmHg; p < 0.001) and aortic valve area (0.60 ± 0.17 to 1.65 ± 0.45 cm²; p < 0.001) compared to baseline. The left ventricular ejection fraction increased after 6 months, but this change did not achieve statistical significance (61 ± 11 to 63 ± 8 p=0.4741) Seventeen (27%) of the patients required a new PPM within 30 days after TAVR. The reason for PPM was a new onset complete heart block in 7 (11%) of the patients. Ten patients (16%) developed a new left bundle branch block within one month after the procedure. Two patients (3%) suffered from a non-fatal stroke and remained event-free during the 6 month follow up. NYHA class improved from 2.5 ± 0.6 to 1.3 ± 0.5 after 1 month and from 2.5 ± 0.6 to 1.2 ± 0.5 (P < 0.001) after 6 months when compared to baseline. The average post-procedural length of stay was 6.4 ± 2.3 days. Other clinical outcomes of the studied patients are reported in (Table 2).

Quality of Life

Mean pre-procedural SF-12 scores showed an impairment of perceived quality of life compared with general U.S. population > 75 years, both for physical (baseline-PCS 30.1 vs 40.0) and mental scores (baseline-MCS 44.5 vs. 50.0) [9]. Summary scores of quality of life at both baseline and at follow-up are schematized in (Figure 2). Mean pre-procedural PCS and MSC of SF-12 showed a significant improvement after 6 months of follow-up (30.1 vs 37.0, p = 0.001; 44.5 vs 52.5, p < 0.001).

Forty-six (65%) of the patients completed 1 year follow up by the time of inclusion. Preliminary results are schematized in (Figure 2).

Discussion

The main finding of this single center observational study is that the quality of life in both physical and mental component significantly improved 6 months after TAVR in patients with severe aortic stenosis with excessive surgical risk. Pre-procedural SF-12 scores of this cohort showed impairment in quality of life compared with the general USA population.
Study limitations

The small sample size of study population and the single-site data collection are limitations of the present study. Because of the small cohort we were not able to identify predictors for patient selection regarding the worsening or improvement of QOL. The single-site data collection potentially limits the generalizability of the present study.

Another limitation of the present study is missing data due to drop-out or incomplete questionnaires. These missing patients tended to be sicker and had a higher risk for morbidity and mortality. Therefore, we may have overestimated the results. We attempted to address this limitation by performing a multiple imputation of the missing data. The reported results encompass a follow-up period of only 6 months. The 6 months period might have been too short to establish whether the QOL keeps improving, worsens or reaches a plateau. The extrapolations from our own data suggest that after one year, there might be a greater improvement in the mental score and physical score, however these changes are not significant. Hence, further inclusion of patients and longer follow up is needed to observe the longer-term dynamics of QOL after TAVR.

Conclusion

The main finding of this study is that TAVR in patients with severe AS is followed by early improvements in quality of life. The results show a marked improvement in functional status and a significant improvement in quality of life in both physical and mental components. The question whether this effect will last in the longer term remains to be determined.

References


