Health-Related Quality of Life After Transcatheter Aortic Valve Replacement

With great interest we read the recent report by Reynolds et al. (1) reporting on the health-related quality-of-life (HRQOL) outcomes in Cohort A of the PARTNER (Placement of Aortic Transcatheter Valves) randomized controlled trial. Using 3 different standardized questionnaires at 1, 6, and 12 months, HRQOL was analyzed in a total of 628 patients with severe, symptomatic aortic valve stenosis at high surgical risk who were randomized to transcatheter aortic valve replacement (TAVR) via the transapical or transfemoral approach or to surgical aortic valve replacement (SAVR). Health status improved substantially between baseline and 1 year after both TAVR and SAVR. TAVR via the transfemoral but not the transapical route was associated with short-term advantages compared with surgery. Although evidence is accumulating that patients at high risk for SAVR undergoing TAVR derive HRQOL benefits, the investigators should be commended for this important study, because it represents the first randomized study investigating HRQOL dynamics after TAVR in comparison with SAVR, adding an important piece of evidence to the field.

We would greatly appreciate the investigators' comments on how New York Heart Association functional class developed over time. As long as valve function is durable, one would expect that functional benefits can be maintained in the longer term as well. However, data derived from Cohort B of the PARTNER trial and other studies suggest that functional status slightly worsens at 12 months (2–4). We concur with the investigators that the results of available studies encompass only a maximal follow-up period of 1 year, which may be too short. Therefore, the longer term dynamics of HRQOL changes in TAVR patients remain elusive.

Did the investigators attempt to evaluate and correlate HRQOL outcomes with New York Heart Association functional class or with any of the baseline characteristics? The identification of patient-related or procedure-related parameters predictive of the extent of HRQOL benefits would be highly desirable to facilitate better risk stratification and patient selection and to improve guidance of patient-centered clinical decision making. It has been observed that the extent of benefit seems to be inferior for patients with oxygen-dependent chronic obstructive pulmonary disease (2). Also, lower operator experience, female sex, and vascular complications have been reported to be independent predictors of lower HRQOL improvements at 1 year (3). In our prospective cohort, mitral valve regurgitation >1+ was predictive of lower HRQOL improvements. Only at 3 months did this association reach statistical significance. Likewise, female sex was associated with less improvement at 3 months, corroborating the results described by Fairbairn et al. (3). Notably, we could not observe any association with Society of Thoracic Surgeons score or log Euro-© 2013 by the American College of Cardiology Foundation ISSN 0735-1097/$36.00

dynamic parameters, or comorbidities (4).

Larger patient numbers in conjunction with longer follow-up will be necessary to identify reliable patient-related and procedure-related factors predictive of the extent of HRQOL benefits and to answer the question of whether benefits are durable conclusively. In the future, it will be of interest to determine how HRQOL benefits compare between TAVR and SAVR in patients at lower surgical risk (5).

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REFERENCES


Reply

We agree with many of the points raised in the letter by Dr. Deutsch and colleagues and appreciate their interest in our work. We have not as yet made any formal correlations between patient-level health status measures and New York Heart Associ-
demonstrates a strong association between metabolic syndrome and the outcomes of atrial fibrillation ablation in patients with metabolic syndrome. We read with interest the paper by Mohanty et al. (1), which presents the outcomes of atrial fibrillation ablation in patients with metabolic syndrome. The study by Mohanty et al. (1) would reach the same results in the well-balanced cohort. It would be interesting to know whether propensity score matching, which allows for analysis in a well-balanced cohort, might support the editorial comment: “perhaps we learned that trigger elimination, even if in 1-time procedure, can be effective despite an ongoing primary arrhythmia-provoking process” (5).

The contradictory findings by Mohanty et al. (1) might be (in part) explained by several limitations of their study. First, the presented study group was not as homogenous as ours, with significant differences in LAS and upstream therapy drugs. The LAS is known to be one of the strongest predictors of outcome after AF ablation (6). If LAS was significantly bigger in NPAF, the LAS is known to be one of the strongest predictors of outcome after AF ablation (6). If LAS was significantly bigger in NPAF, without MS, the expected results could have been as described by investigators (1). Renin-angiotensin-aldosterone system blockers protect from AFCA in patients with PAF (7). Most of the patients with MS (82%) received angiotensin-converting enzyme inhibitors compared with patients without MS (28%). If the similar proportion was in the PAF group, which we could have expected better outcome in patients with MS (i.e., no significant difference as described) (1). The role of statins post-pulmonary vein isolation has not been established (6), but the published meta-analysis reported statins to be more effective for prevention of PAF (8). Again, a higher number of patients with MS (91%) received lipid-lowering than patients without MS (30%). Second, the results should be checked—keeping in mind the noncompletely homogenous study group—with a propensity score matching, which allows for analysis in a well-balanced cohort. It would be interesting to know whether Mohanty et al. (1) would reach the same results in the well-matched samples. Third, the follow-up period was (only) 21 ± 7 months. The difference in the outcome AFCA in patients with and without MS becomes even more significant within longer follow-up, both in PAF and NPAF groups (2).

Following the latest recommendations (6), we think that it is important to recognize that AF recurrence rates AFCA depend on concomitant diseases, and outcome of AFCA in patient populations not well-represented in clinical trials should be reported. Patients with MS are such a population. Therefore, further discussion and clear data presentation are needed to solve the discrepancy in reported results.

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REFERENCES


Outcomes of Atrial Fibrillation Ablation in Patients With Metabolic Syndrome

We read with interest the paper by Mohanty et al. (1), which demonstrates a strong association between metabolic syndrome and the recurrence of atrial fibrillation after catheter ablation (AFCA) but only in patients with nonparoxysmal atrial fibrillation (NPAF).

Recently, we presented the data of 5-year follow-up in a group of 702 patients after both radiofrequency and cryoballoon AFCA that proved MS to be the independent predictor of atrial fibrillation (AF)-free survival AFCA, regardless of left atrium size (LAS), type of AF, and energy source used (2). Patients with MS were 1.32× more likely to have AF recurrence than patients without MS. Median time to AF recurrence AFCA was 18.6 months in patients with MS and 28.6 months in patients without MS (p = 0.011) (Fig. 1). Similar results were published by others (3,4), and the discrepancy had already been mentioned by Asirvatham and Jiao (5). Interestingly, our data showed that MS had no impact on outcome after re-do pulmonary vein isolation, which might support the editorial comment: “perhaps we learned that trigger elimination, even if in 1-time procedure, can be effective despite an ongoing primary arrhythmia-provoking process” (5).

The contradictory findings by Mohanty et al. (1) might be (in part) explained by several limitations of their study. First, the presented study group was not as homogenous as ours, with significant differences in LAS and upstream therapy drugs. The LAS is known to be one of the strongest predictors of outcome after AF ablation (6). If LAS was significantly bigger in NPAF, without MS, the expected results could have been as described by investigators (1). Renin-angiotensin-aldosterone system blockers protect from AFCA in patients with PAF (7). Most of the patients with MS (82%) received angiotensin-converting enzyme inhibitors compared with patients without MS (28%). If the similar proportion was in the PAF group, which we could have expected better outcome in patients with MS (i.e., no significant difference as described) (1). The role of statins post-pulmonary vein isolation has not been established (6), but the published meta-analysis reported statins to be more effective for prevention of PAF (8). Again, a higher number of patients with MS (91%) received lipid-lowering therapy than patients without MS (30%). Second, the results should be checked—keeping in mind the noncompletely homogenous study group—with a propensity score matching, which allows for analysis in a well-balanced cohort. It would be interesting to know whether Mohanty et al. (1) would reach the same results in the well-matched samples. Third, the follow-up period was (only) 21 ± 7 months. The difference in the outcome AFCA in patients with and without MS becomes even more significant within longer follow-up, both in PAF and NPAF groups (2).

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