Quality of life assessment after percutaneous aortic valve implantation

Gian Paolo Ussia1*, Massimiliano Mulè1, Marco Barbanti1, Valeria Cammalleri1, Marilena Scarabelli1, Sebastiano Immè1, Davide Capodanno1, Saverio Ciriminna2, and Corrado Tamburino1

1Division of Cardiology, Ferrarotto Hospital, University of Catania, Via Citelli 6, Catania, Italy; and 2Sicilian Health Authority Inspectorate, Sicily, Italy

Received 1 October 2008; revised 26 March 2009; accepted 14 April 2009; online publish-ahead-of-print 13 May 2009

Aims
To assess the NYHA class and the quality of life (QoL) scores after percutaneous aortic valve implantation (PAVI) with the 18-Fr CoreValve® prosthesis.

Methods and results
From April 2007 until August 2008, 57 consecutive patients with aortic stenosis were evaluated for PAVI. Of these, 30 patients with successfully prosthesis implantation had more than 5-month follow-up. QoL assessment was realized with the SF-12v2 Health-Survey, a simple questionnaire designed for self-administration that provides easily interpretable scales for physical [physical component summary (PCS)] and mental [mental component summary (MCS)] health. The questionnaire was administered before and 5 months after PAVI. All 30 patients had a marked upgrading in haemodynamic and echocardiographic parameters (peak-to-peak gradient from 64 ± 23 to 2 ± 0.4; P < 0.001; aortic valve area index from 0.3 ± 0.1 to 0.9 ± 0.3; P < 0.001), with an improvement in New York Heart Association (NYHA) class at discharge and after 5 months. Mean pre-operative SF-12v2 scores showed a severe impairment of perceived quality of life compared with general Italian population.

Conclusion
Our preliminary results show a marked short-term improvement in functional status and physical and mental health in patients underwent PAVI.

Keywords
Aortic stenosis • Percutaneous therapy • Quality of life

Introduction
The most frequent native valve disease of the elderly in Western Countries is aortic stenosis (AS), with a prevalence of 2.5% at 75 years and 8.1% at 85 years.1 It is estimated that about 31% of patients older than 75 years with severe AS are not referred to surgery by their clinical physician or are refused by the cardiac surgeon because of co-morbidities, shorter life expectancy, and perceived high surgical risk.2 In this subset of patients, percutaneous aortic valve implantation (PAVI) seems to be an effective therapeutic option with good procedural success and low mortality rate3 and Quality of Life (QoL) assessment could be of paramount importance in evaluating the efficacy of this novel procedure.4 The aim of this study was to evaluate quality of life changes following PAVI for severe AS in a group of elderly patients at high surgical risk.

Methods
Patients
From April 2007 until August 2008, all consecutive patients with symptomatic severe AS were evaluated for PAVI. All patients eligible for the procedure had to meet basic criteria for intervention from the Task Force on the management of valvular heart disease of the European Society of Cardiology.5 For all of them, the high surgical risk was mandatory to be considered for PAVI. The inclusion criteria were as follows: (i) symptomatic native aortic valve stenosis with an aortic valve area <1 cm²; (ii) echocardiographic aortic valve annulus

* Corresponding author. Tel: +39 0957436210, Fax: +39 0957436220, Email: gpussia@hotmail.com

Published on behalf of the European Society of Cardiology. All rights reserved. © The Author 2009. For permissions please email: journals.permissions@oxfordjournals.org.
Quality of life in percutaneous aortic valve implantation

Quality of life assessment

The Medical Outcomes Trust Short Form 12-Item Health Survey (SF-12) Version 1.0 is a multi-purpose, short-form health survey developed as a brief, practical, multi-purpose, and shorter alternative to the SF-36, one of the most widely used generic health status instruments to assess health-related quality of life. Adjunctive risk criteria were: liver cirrhosis, hostile thorax, chest radiation, severe connective tissue diseases, and porcelain aorta.

Patients were eligible for QoL assessment if they were not affected by dementia and were able to read and write Italian.

Exclusion criteria were femoral, iliac or aortic pathologies hampering catheter’s transit, aortic aneurysm, carotid or vertebral arteries obstruction >70%, coagulopathies, myocardial infarction or cerebrovascular accident occurred in the previous month, tricuspid or mitral valvular regurgitation of severe degree, left ventricular or atrial thrombus, uncontrolled atrial fibrillation, sepsis or active endocarditis, hypersensitivity, or contraindications to any medication used in the study.

Pre-procedure assessment included medical history, physical examination, trans-thoracic echocardiography (TTE), carotid and aortic arch ultrasound, left and right carotid catheterization, coronary angiography, aortography and iliac-femoral arteriography, and when necessary, computed tomography angiography. Cognitive disorders were assessed by means of the Mini Mental State examination.

All patients gave their informed written consent after receiving complete information about risk and benefits of this procedure. Our study population is composed by those patients who received the QoL questionnaire before PAVI and at 5-month follow-up.

Device and procedure description

The device used was the third generation 18-French (F) CoreValve Revalving System for PAVI (CoreValve Inc., Irvine, CA, USA) which features a self-expandable biological valve.

Full details of the procedure and medical management are described elsewhere. All procedures were performed with surgical back up, under fluoroscopic guidance, in a standard catheterization laboratory.

General anaesthesia was employed when intra-procedural transoesophageal echocardiography (TEE) was deemed necessary, otherwise patients were under deep sedation and analgesia. Artery haemostasis was obtained through the Prostar XL 10-F system (Abbott Vascular, Abbott Park, IL, USA).

Device success was defined as stable device placement and function as assessed by angiography and echocardiography. Acute procedural success was defined as device success without any periprocedural major adverse cardiovascular and cerebrovascular events within 48 h from prosthesis implantation, defined as the composite of death from any cause, myocardial infarction, cardiac tamponade, stroke, urgent, or emergent conversion to surgery or balloon valvuloplasty, emergent percutaneous coronary intervention, cardiogenic shock, endocarditis, or aortic dissection.

After the procedure, all patients were routinely transferred to the intensive care unit for the first 48 h. The in-hospital follow-up consisted in vital parameters monitoring, daily platelet blood count and TTE. Before the discharge, an ECG Holter and a chest X-Ray were performed. As a part of our protocol, a clinical cardiology check-up, TTE, and ECG Holter were scheduled at 15 and 30 days, and routine cardiology check-ups monthly thereafter.

Statistical analysis

Continuous variables were presented as mean ± standard 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. All data were processed using the Statistical Package for Social Sciences, version 15 (SPSS, Chicago, IL, USA).

Results

Figure 1 shows included and excluded patients. Thirty of 39 patients (77%) successfully undergoing PAVI completed SF-12v2 both at baseline and at 5-month follow-up and were enrolled in this study. Baseline characteristics of these patients are summarized in Table 1. Waiting time before hospitalization for the PAVI procedure was 25 ± 11 days. All PAVI procedures were performed under local anaesthesia except the first two which were under general anaesthesia with endotracheal intubation and intraoperative TEE monitoring.
Scores of perceived quality of life both at baseline and at follow-up are schematized in Figure 2. Overall, patients experienced a clear improvement with regard to physical functioning (13.3 vs. 48.3, \( P < 0.001 \)), role-physical (24.6 vs. 57.7, \( P < 0.001 \)), bodily pain (44.2 vs. 71.7, \( P = 0.002 \)), general health (14.0 vs. 54.5, \( P < 0.001 \)), vitality (34.2 vs. 60, \( P < 0.001 \)), social functioning (39.2 vs. 73.3, \( P < 0.001 \)), role-emotional (38.3 vs. 62.1, \( P = 0.002 \)), and mental health scores (45.0 vs. 68.3, \( P < 0.001 \)). None of the patients in this study experienced a worsening of their quality of life after the procedure based on the subscale profiles.

Mean pre-procedural SF-12v2\(^2\) scores showed a severe impairment of perceived quality of life compared with general Italian population 75 years, both for physical (baseline-PCS 28.5) and mental scores (baseline-MCS 37.8) (Figure 3). After 5 months, a striking improvement in both scores (PCS 41.3-MCS 48.3; \( P < 0.001 \)) was observed. Interestingly, both the physical and the mental score summaries at 5 months of these post-PAVI patients were not significantly different from the anticipated thresholds of the general Italian population over the age of 75 years.

Overall, the enrolled patients experienced a reduction of aortic gradients and no significant periprosthetic leaks (Table 2). One procedural failure occurred because of initial malpositioning of the prosthesis, but it was successfully managed with the deployment of a second prosthesis (valve-in-valve technique).\(^{15,16}\) Major adverse cardiac and cerebrovascular events (MACCEs) within 48 h after implantation were observed in one patient (3%) who experienced non-fatal pericardial tamponade and remained event-free during the 30-day follow-up period. Thus, acute device success and procedural success were achieved in 29 patients (97%) and 28 of 30 patients (93%), respectively.

Other acute complications and follow-up outcomes are reported in Table 3. Periprocedural events not included in the definition of MACCE were vascular access complications (20%) consisting of four cases of femoral artery pseudoaneurysm successfully managed with ultrasound guided compression repair\(^3\) or surgical repair, and two cases of total occlusion of the femoral artery treated with thromboendarterectomy. The incidence of new onset complete heart block requiring for permanent pacemaker implantation was 20% (5 of 25 patients without a previously implanted pacemaker). Finally, major bleeding defined as bleeding associated with haemoglobin decrease of \( > 5 \) g/dL (or a haematocrit decrease of 15%) occurred in one patient (3%).

The average post-procedural length of stay was 8 ± 5 days and all patients were prescribed a period of rehabilitation. At discharge, mean NYHA class improved from 2.7 ± 0.6 to 2.1 ± 0.6 (\( P < 0.001 \)). Further improvement was observed after 5 months to mean NYHA class of 1.8 ± 0.5 (\( P = 0.004 \) when compared with discharge and \( P < 0.001 \) when compared with baseline).
Table 1 Preoperative clinical characteristics

<table>
<thead>
<tr>
<th></th>
<th>n = 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male, n (%)</td>
<td>13 (43)</td>
</tr>
<tr>
<td>Age, years ± SD</td>
<td>81.7 ± 4.7</td>
</tr>
<tr>
<td>Diabetes, n (%)</td>
<td>10 (33)</td>
</tr>
<tr>
<td>Hypertension, n (%)</td>
<td>25 (83)</td>
</tr>
<tr>
<td>Dyslipidaemia, n (%)</td>
<td>15 (50)</td>
</tr>
<tr>
<td>Log Euroscore, % ± SD</td>
<td>25.3 ± 8.1</td>
</tr>
</tbody>
</table>

Comorbidities
- COPD, n (%) 5 (17)
- Prior MI, n (%) 10 (33)
- Prior stroke/TIA, n (%) 3 (10)
- Prior PCI/CABG, n (%) 20 (67)
- Porcelain Aorta, n (%) 14 (47)
- AF, n (%) 3 (10)
- CRF, n (%) 14 (47)

Symptoms
- NYHA I, n (%) 30 (100)
- NYHA II, n (%) 10 (33)
- NYHA III, n (%) 18 (60)
- NYHA IV, n (%) 2 (7)
- Angina, n (%) 14 (47)
- Dyspnoea, n (%) 30 (100)
- Syncope, n (%) 8 (27)

Data are presented as value and percent of patient group.

COPD, chronic obstructive pulmonary disease; MI, myocardial infarction; TIA, transient ischaemic attack; PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft; AF, atrial fibrillation; CRF, chronic renal failure; NYHA, New York Heart Association.

*CRF defined as serum creatinine >2.0 g/dL.

Discussion

The main finding of this study is that PAVI in patients with severe AS and high risk for perioperative complications after surgery is followed by early improvements in quality of life.

With increased life expectancy for a rapidly greying population, AS in elderly people is becoming a new critical issue for physicians. Treatment decisions for elderly patients are more difficult because concomitant diseases, frail constitution, and impaired cognitive functions, all factors that must be taken into account in treatment decision-making. Aortic stenosis progresses rapidly in old patients and conservative strategies have not been proven to be effective, with a medically treated 4-year survival of 24%.21,22 The purpose of this study was to demonstrate that the short-term improvement in NYHA functional class after PAVI, described by many authors,3,9 matches a significant improvement in the personal perceived quality of life of the patient.

Pre-procedural SF-12v2 scores of our patient cohort demonstrated a severe impairment in perceived quality of life, compared with the general Italian population over the age of 73 years, both for mental and physical scores. A sub-analysis of eight health-scales indicated markedly low scores for physical functioning, role-physical, general health, mental health, role-emotional, and social functioning. Slightly higher scores for bodily pain and vitality were noted. Higher pre-procedural bodily pain scores are probably related to the low impact of AS on perceived pain, whereas higher pre-procedural vitality scores might be related to the absence of cognitive disorders in our population.

Symptoms relief and improvement in self-rated health after PAVI were observed in all patients included in this series, whereas the low rate of post-procedural morbidities did not prolong the recovery time and did not have a significant impact on the patient's quality of life. According to the literature, these findings underline the impact of severe AS on the patients’ well-being, also in those with preserved left ventricular ejection fraction. This reinforces the value of valve replacement in octogenarians with preserved cognitive function and good life expectancy upon resolution of the AS.

The SF-36 has been used extensively with cardiac patient population, and some studies have investigated changes in QoL in patients older than 80 years after surgical aortic valve replacement (SAVR).19 However, the SF-36 contains 36 items and thus places a considerable burden on both patients and investigators.20 We have chosen to explore the general status of patients with a widely accepted QoL assessment instrument, the Short Form 12 version 2 questionnaire. Because of his briefness, it is easy to use and to understand and can be completed by most participants in less than a third of the usual time needed to complete the SF-36,10,11 reducing respondent burden and improving response rates.

These characteristics were, in our opinion, important key features for its application to a population of elderly patients. In fact, the use of the SF-12v2 instead of the SF-36 questionnaire was also motivated by the increased age of our study population which can influence the ability of patients to comprehend the questionnaire. The MOS-SF36 developer group observed that older patients tended to have lower response rates in general (65–75%) and that the response rates may be improved by using a shortened questionnaire. On the other hand, precision of SF-surveys varies inversely with length and the longer SF-36 offers a greater degree of precision than the SF-12. Version 2.0 (SF-12v2) improvements significantly increased the precision of this survey, so that the difference between the updated survey and the SF-36 is significantly smaller than the difference between original versions of the SF-36 and SF-12. As a result, SF-12v2 yields results that are comparable to those that would be obtained with the original SF-36 and is recommended for efforts focused on detecting small-group differences and classifying individuals.

When comparing and analysing the procedural and mid- and long-term follow-up parameters of new technology vs. cardiac surgery, greater attention should be paid to quality of life aspects after PAVI in order to avoid underestimating results.4

Despite several studies showing that SAVR in over 75-year-old patients can be performed with an acceptable operative mortality and morbidity, surgery is denied in one-third of these patients because of advanced age and co-morbidities.21 According to the recent European and American consensus recommendations, in this subset of patients there may be a role for less invasive strategies such as PAVI.22,23
Preliminary results obtained from feasibility trials and surveillance registries have demonstrated good results in terms of feasibility, safety, and short-term efficacy, but no randomized studies comparing PAVI to conventional surgery have been undertaken to date. Since surgery represents the gold standard, it will be imperative to scientifically compare PAVI to SAVR results.

The success after SAVR using both mechanical and biological prostheses is usually reported in terms of mortality and morbidity, also in publications regarding elderly patients. Measuring morbidity and mortality provides only a small amount of information about the patient’s physical, functional, emotional, and mental well-being after aortic valve replacement. While improvement in well-being after surgery is reported, and while it is known that the older people take longer to recover from surgery because of postoperative complications, few data are available in the literature about quality of life changes. In elderly and frail patients, operative outcomes should not only take the improvement of life expectancy and the survival rate into account, but also the gain of comfort in daily life. It was reported in several studies that when they underwent SAVR, despite a more compromised clinical and mental baseline conditions, octogenarians experimented an improvement in symptoms, physical ability, and general well-being comparable with younger patients.

Olsson et al., using a different QoL questionnaire, found no difference in quality of life when comparing patients 65–75 years of age with those ≥80 years. Three months after surgery, they described a significant improvement in both groups concerning

**Figure 2** Results of eight health concepts derived from MOS SF-12v2 questionnaire compared before undergoing PAVI and 5 months after the procedure ($P < 0.001$).

**Figure 3** Results of PCS and MCS scores before and at 5 months after PAVI compared with general Italian population. Data obtained show that patients have a significant improvement in physical and mental status after PAVI ($P < 0.001$). PCS and MCS scores in a representative sample of Italian population 75 year old (5283 adults).
the depression score had decreased significantly in both groups. The changes in quality of life did not differ significantly between the two groups apart from a reduction in fainting spells. This reduction was more pronounced in the older patient group. The majority of patients in both groups reported considerably reduced symptoms, rather than the type of treatment therapy. Such a comparison might be useful to determine specifically whether improved quality of life is related to the early relief of symptoms, rather than the type of treatment per se. However, it is well known that poor prognosis is likely when medical management alone is advocated. Thus, a proper control group with 5-month follow-up for this comparison was difficult to achieve.

To our knowledge, there have been no other studies reported in the literature regarding quality of life changes after PAVI and our objective is to draw attention to the need for larger scale assessments of these outcomes which are very relevant to patient well-being.

Finally, although the shorter SF-12v2 form improves efficiency and lowers cost for both profiles and summary scales, the SF-12 has some limitations, since it reproduces the eight-scale profile with fewer levels than SF-36 scales and yields less precise scores, as would be expected for single-item and two-item scales. However, because survey length and respondent burden may be an issue in some clinical settings, such as in elderly and frail patient, the choice between the SF-12 and the SF-36 is not only a choice between less and more information about health status.

### Study limitations

The small sample size of study population and the single site-data collection are limitations of the present study. However, it has to be considered that PAVI is an innovative technique adopted recently in a small number of centres in Europe, with a relatively small number of patients for each centre and short follow-up. Since short-term transient improvement was reported following other procedures as aortic balloon valvuloplasty, which did not preclude this technique to be abandoned, we cannot exclude that longer follow-up could be associated with poorer outcomes and worse quality of life. Longer follow-up would also be required in order to establish if patients have reached a plateau in their quality of life after 5 months from the procedure.

Another caveat is the absence of a control group to compare the outcome following PAVI with the outcome under medical therapy. Such a comparison might be useful to determine specifically whether improved quality of life is related to the early relief of symptoms, rather than the type of treatment per se. However, it is well known that poor prognosis is likely when medical management alone is advocated. Thus, a proper control group with 5-month follow-up for this comparison was difficult to achieve.

To our knowledge, there have been no other studies reported in the literature regarding quality of life changes after PAVI and our objective is to draw attention to the need for larger scale assessments of these outcomes which are very relevant to patient well-being.

Finally, although the shorter SF-12v2 form improves efficiency and lowers cost for both profiles and summary scales, the SF-12 has some limitations, since it reproduces the eight-scale profile with fewer levels than SF-36 scales and yields less precise scores, as would be expected for single-item and two-item scales. However, because survey length and respondent burden may be an issue in some clinical settings, such as in elderly and frail patient, the choice between the SF-12 and the SF-36 is not only a choice between less and more information about health status.

### Table 2 Baseline and post-procedural echo and haemodynamic parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Pre</th>
<th>Post</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LVEF, % ± SD</td>
<td>52 ± 9</td>
<td>51 ± 6</td>
<td>0.8</td>
</tr>
<tr>
<td>AAVAi, cmHg/mq ± SD</td>
<td>0.35 ± 11</td>
<td>0.9 ± 0.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Peak pressure gradient, mmHg ± SD</td>
<td>87 ± 23</td>
<td>17 ± 8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mean pressure gradient, mmHg ± SD</td>
<td>58 ± 17</td>
<td>9 ± 4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Peak-to-peak gradient, mmHg ± SD</td>
<td>64 ± 23</td>
<td>17 ± 8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mitral regurgitation, n (%)</td>
<td>15 ± 8</td>
<td>8 ± 8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Aortic regurgitation, n (%)</td>
<td>1 ± 1</td>
<td>– (–)</td>
<td>– (–)</td>
</tr>
<tr>
<td>Periprosthetic leaks, n (%)</td>
<td>– (–)</td>
<td>18 ± 8</td>
<td>– (–)</td>
</tr>
</tbody>
</table>

Data are presented as value ± SD or percent of patient group.
LVEF, left ventricular ejection fraction; AAVAi, aortic valve area indexed on body surface area.

<table>
<thead>
<tr>
<th>Event</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In hospital</td>
<td></td>
</tr>
<tr>
<td>Death, n (%)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>MI, n (%)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Stroke, n (%)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Non fatal cardiac tamponade</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Peripheral vascular accidents, n (%)</td>
<td>6 (20)</td>
</tr>
<tr>
<td>Conservative management</td>
<td>3 (10)</td>
</tr>
<tr>
<td>Surgical management</td>
<td>3 (10)</td>
</tr>
<tr>
<td>AVB III, n (%)</td>
<td>6 (20)</td>
</tr>
<tr>
<td>New PM implantation</td>
<td>6 (20)</td>
</tr>
<tr>
<td>New LBBB, n (%)</td>
<td>11 (37)</td>
</tr>
<tr>
<td>Transient</td>
<td>5 (17)</td>
</tr>
<tr>
<td>Permanent</td>
<td>6 (20)</td>
</tr>
<tr>
<td>5-month follow-up</td>
<td></td>
</tr>
<tr>
<td>Death, n (%)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>MI, n (%)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Stroke, n (%)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

Data are presented as value ± SD or percent of patient group.
AVB III, third degree atrio-ventricular block; PM, pace maker; LBBB, left bundle branch block.

### Table 3 Clinical outcomes

<table>
<thead>
<tr>
<th>Event</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In hospital</td>
<td></td>
</tr>
<tr>
<td>Death, n (%)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>MI, n (%)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Stroke, n (%)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

Data are presented as value ± SD or percent of patient group.

### Study limitations

The small sample size of study population and the single site-data collection are limitations of the present study. However, it has to be considered that PAVI is an innovative technique adopted recently in a small number of centres in Europe, with a relatively small number of patients for each centre and short follow-up. Since short-term transient improvement was reported following other procedures as aortic balloon valvuloplasty, which did not preclude this technique to be abandoned, we cannot exclude that longer follow-up could be associated with poorer outcomes and worse quality of life. Longer follow-up would also be required in order to establish if patients have reached a plateau in their quality of life after 5 months from the procedure.

Another caveat is the absence of a control group to compare the outcome following PAVI with the outcome under medical therapy. Such a comparison might be useful to determine specifically whether improved quality of life is related to the early relief of symptoms, rather than the type of treatment per se. However, it is well known that poor prognosis is likely when medical management alone is advocated. Thus, a proper control group with 5-month follow-up for this comparison was difficult to achieve.

To our knowledge, there have been no other studies reported in the literature regarding quality of life changes after PAVI and our objective is to draw attention to the need for larger scale assessments of these outcomes which are very relevant to patient well-being.

Finally, although the shorter SF-12v2 form improves efficiency and lowers cost for both profiles and summary scales, the SF-12 has some limitations, since it reproduces the eight-scale profile with fewer levels than SF-36 scales and yields less precise scores, as would be expected for single-item and two-item scales. However, because survey length and respondent burden may be an issue in some clinical settings, such as in elderly and frail patient, the choice between the SF-12 and the SF-36 is not only a choice between less and more information about health status.
outcomes, but also between more and less practical survey tools. Time will tell how to best judge those tradeoffs.

Conclusions

Percutaneous aortic valve implantation patients with severe AS and high risk for cardiac surgery related complications may lead to significant short-term improvements in symptoms, functional status, and quality of life.

Funding

This study was supported by a research grant from Associazione Cuore e Ricerca di Catania.

Conflict of interest: G.P.U. is a physician proctor for the CoreValve ReValving® Incorporation.

References