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ORIGINAL ARTICLE

Quality of life in high-risk patients: comparison of transcatheter aortic valve implantation with surgical aortic valve replacement[†]

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Abstract

OBJECTIVES: To compare health-related quality of life (QoL) in patients undergoing transcatheter aortic valve implantation via transapical access (TA TAVI) with patients undergoing surgical aortic valve replacement (SAVR).

METHODS: One hundred and forty-four high-risk patients referred for aortic valve replacement underwent TAVI screening and were assigned to either TA TAVI ($n = 51$, age 79.7 ± 9.2 years, logistic EuroSCORE 26.5 ± 16.1%, 51% males) or SAVR ($n = 93$, age 81.1 ± 5.3 years, logistic EuroSCORE 12.1 ± 9.3%, 42% males) by the interdisciplinary heart team. QoL was assessed using the Short Form 36 (SF-36) Health Survey Questionnaire and the Hospital Anxiety and Depression Scale. Furthermore, current living conditions and the degree of independence at home were evaluated.

RESULTS: Patients undergoing TA TAVI were at higher risk as assessed by EuroSCORE (26.5 ± 16 vs. 12.1 ± 9, $P < 0.001$) and STS score (6.7 ± 4 vs. 4.4 ± 3, $P < 0.001$) compared with SAVR patients. At the 30-day follow-up, the rate of mortality was similar and amounted to 7.8% for TA TAVI and 7.5% for SAVR patients and raised to 25.5% in TA TAVI and 18.3% in SAVR patients after a follow-up period of 15 ± 10 months. Assessment of QoL revealed no differences in terms of anxiety and depression between TA TAVI and SAVR patients. The SF-36 mental health metascore was similar in both groups (65.6 ± 19 vs. 68.8 ± 22, $P = 0.29$), while a significant difference was observed in the physical health metascore (49.7 ± 21 vs. 62.0 ± 21, $P = 0.015$). After adjustment for baseline characteristics, this difference disappeared. However, every added point in the preoperative risk assessment with the STS score decreased the SF-36 physical health dimension by two raw points at the follow-up assessment.

CONCLUSIONS: Selected high-risk patients undergoing TAVI by using a transapical access achieve similar clinical outcomes and QoL compared with patients undergoing SAVR. Increased STS scores predict worse QoL outcomes.

Keywords: Aortic valve stenosis • Transcatheter • TAVI • Valve replacement • Quality of life

INTRODUCTION

Aortic stenosis is the most frequent degenerative valve disease in developed countries and its prevalence is linked to prolonged life expectancy and the ageing of the population [1]. As aortic stenosis is a chronic disease with a progressive course, the prognosis is dismal when left untreated. Five years after the onset of symptoms [2, 3], only 20% of patients are alive without adequate treatment. Surgical aortic valve replacement (SAVR) is the standard therapy for patients with severe symptomatic aortic stenosis and is able to improve symptoms, survival [1, 4] and health-related quality of life (QoL) [5]. However, with age comes an increase in comorbidities and also an increased risk for SAVR. Especially for these patients, transcatheter aortic valve implantation (TAVI) has emerged as a less-invasive and valuable treatment alternative.

Since being used in man for the first time in 2002 [6], the technology of TAVI has rapidly improved, and implantation via a transapical access [7] route has been developed. The transapical approach represents an attractive alternative and has proved its safety and efficacy. In addition to the achievement of favourable clinical results, the improvement of health-related QoL [8] is of major importance for a patient population at high risk and with limited life expectancy.

The purpose of the present study was to evaluate intermediate-term QoL in high-risk patients undergoing either SAVR or TAVI via transapical access (TA TAVI).

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MATERIALS AND METHODS

Study population

Between November 2007 and June 2010, 144 high-risk patients with severe symptomatic aortic stenosis were referred to our centre for evaluation and underwent either TA TAVI or SAVR.

Assignment to either group was performed by the interdisciplinary heart team on the basis of the individual's risk profile using the EuroSCORE [9] and STS risk calculator [10], the technical feasibility of either therapy or the patients' preferences. Patients undergoing transfemoral TAVI were excluded from this study focusing on QoL after conventional and catheter-based surgical therapy for aortic valve replacement.

Baseline evaluation included the assessment of medical history and a physical examination, the performance of transthoracic and transoesophageal echocardiography, carotid ultrasonography, right and left heart catheterization, coronary- and aortic angiography, and computed tomography with three-dimensional aortic root reconstruction. The preoperative demographics are summarized in Table 1.

Table 1: Baseline characteristics of patients

	TA TAVI ($n = 51$)	SAVR ($n = 93$)	*P*-value
Male	26 (51)	39 (41.9)	0.4
Age (years)	79.7 ± 9.2	81.1 ± 5.3	1.0
Body mass index	26.9 ± 6.5	25.9 ± 4.7	0.7
Diabetes	20 (39.2)	22 (23.7)	0.06
Hypertension	47 (92.2)	83 (89.2)	0.8
Dyslipidaemia	43 (84.3)	61 (65.6)	0.02
Logistic EuroSCORE (%)	26.5 ± 16.1	12.1 ± 9.3	<0.001
STSscore (%)	6.7 ± 3.8	4.4 ± 2.6	<0.001
Chronic obstructive pulmonary disease	13 (25.5)	14 (15.1)	0.2
Peripheral vascular disease	14 (27.5)	7 (7.5)	0.002
Coronary artery disease	38 (74.5)	53 (57)	0.047
Cerebrovascular disease	15 (29.4)	14 (15.1)	0.05
Previous myocardial infarction	14 (27.5)	10 (10.8)	0.02
Previous stroke	3 (5.9)	4 (4.3)	0.9
Glomerular filtration rate (ml/min, Cockcroft)	50.0 ± 24.6	57.3 ± 23	0.06
Pulmonal arterial pressure (>60 mmHg)	12 (23.5)	8 (8.6)	0.02
Left ventricular ejection fraction (%)	49.6 ± 17.2	58.1 ± 10.3	0.006
Aortic valve area (cm^2)	0.6 ± 0.2	0.5 ± 0.2	0.1
Aortic mean gradient (mmHg)	45.7 ± 15.3	52.2 ± 14.1	0.008
Sinus rhythm	37 (72.5)	74 (79.6)	0.2
Dyspnoea			0.001
NYHA I	1 (2.0)	6 (6.5)	
NYHA II	16 (31.4)	44 (47.3)	
NYHA III	28 (54.9)	36 (38.7)	
NYHA IV	6 (11.8)	7 (7.5)	
Syncope	12 (23.5)	16 (17.2)	0.003
Prior sternotomy/re-operation	20 (39.2)	2 (2.2)	<0.001
Prior coronary artery bypass grafting	18 (35.3)	2 (2.2)	<0.001
Prior valve replacement	2 (4)	0 (0)	0.12
Preoperative critical condition	1 (2)	4 (4.3)	0.7

Data are expressed as mean ± SD or *n* (%).

All patients were informed about the specific risks of both treatment modalities and gave written consent for the assigned procedure as well as for data collection and evaluation. The study protocol was in accordance with the local ethics committee guidelines.

Procedure

Transapical aortic valve implantation as well as SAVR techniques have been described previously [11, 12]. The Edwards Sapien bioprosthesis is available for implantation with transapical access in our centre and devices with diameters of 23 and 26-mm were used in the present study. All implantations were performed under general anaesthesia via a small left-sided antero-lateral thoracotomy. Transient epicardial pacemaker electrodes were used for rapid ventricular pacing at 160–180 beats/min during balloon valvuloplasty and device delivery. The prosthesis was placed in the native aortic annulus under fluoroscopic guidance. Prophylactic antibiotic therapy was administered 1 h before the procedure. All patients received weight-adapted heparin during the intervention and dual antiplatelet therapy with 100 mg of aspirin indefinitely and 75 mg of clopidogrel once a day was prescribed for the period of 6 months. SAVR was performed in the customary manner under general anaesthesia using median sternotomy and extracorporeal circulation under full heparinization and myocardial arrest. SAVR patients received the following bio-prosthetic aortic valves in the present study: Carpentier–Edwards Magna ease 19 to 25-mm ($n = 61$), Sorin Mitroflow 19 to 25-mm ($n = 9$), Sutureless ATS Medical Enable 19 to 27-mm ($n = 9$), Sorin Solo Stentless 19 to 23-mm ($n = 6$), Sutureless Sorin Perceval S 23-mm ($n = 6$), Stentless ATS Medical 3F 23-mm ($n = 1$), or St. Jude Trifecta 23-mm ($n = 1$).

Revascularization was performed as a concomitant procedure in 11.8% and as a staged procedure in 25.5% of TA TAVI patients, whereas concomitant coronary artery bypass grafting was performed in 47.3% of patients undergoing SAVR. Intervention as a redo operation was performed in 39.2% of patients with transapical access and 2.2% of patients with conventional SAVR ($P < 0.001$).

QoL assessment

QoL assessment was performed using the Short Form 36 (SF-36) Health Survey Questionnaire and the hospital anxiety and depression scale (HADS) after a mean follow-up of 15 ± 10 months. Both questionnaires are validated and established instruments in assessing the health-related QoL and are routinely used at our institution, as they are self-explanatory and easy to complete. In addition, the patients' current living conditions and degree of independence at home regarding daily life activities were evaluated.

Short Form 36

The SF-36 represents the most widely evaluated generic patient health outcome measure with well-established validity and reliability [13]. It is a self-administered instrument that takes ∼ 15 min to complete. The questionnaire evaluates the health-related QoL of the preceding 4 weeks and as a generic measure

it does not target any specific age, disease or treatment group (www.sf-36.org). The SF-36 has been tested and found suitable for evaluating health-related QoL also for cardiac surgery [14]. The questionnaire consists of 36 questions covering eight general health domains: Physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health. All SF-36 dimensions are scaled from 0 to 100 points, with increasing scores indicating higher subjective perception of QoL. Calculating the summaries of physical as well as mental components results in two meta-scores (Physical Health and Mental Health) representing the overall physical and mental state.

Hospital anxiety and depression scale

The HADS (Fig. 1) is a highly accepted, reliable and valid screening tool in assessing anxiety and depression [15]. It provides a specific subscale instrument for the individual assessment of anxiety (HADS-A) and a subscale for depression (HADS-D). Fourteen mixed items are divided into specific questions referring to HADS-A and specific items for HADS-D. Every question needs to be addressed on a four-point scale (0–3) resulting in an overall score ranging from 0 to 21 points for both the anxiety and the depression scale. A score in the range of 0–7 is considered negative, and 8–10 is suggestive of, and ≥11 is indicative of the probable presence of a mood disorder [16].

Assessment of current living conditions

In conjunction with the SF-36 and HADS questionnaire, three additional items were assessed:

(i) current living conditions (at home completely independent; at home self-caring with minor help; at home with assisted care; in a home for the elderly; in a nursing home);
(ii) autonomy in filling in the form (alone; with the aid of a family member; with the aid of a health-care professional); and
(iii) whether they would undergo the same intervention again.

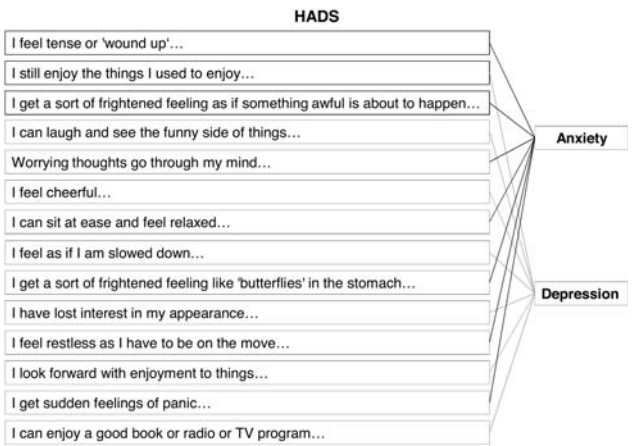

Figure 1: The HADS questions. Seven of the 14 mixed items relate to anxiety (HADS-A subscale) and seven to depression (HADS-D subscale). Each question has a four-point (0–3) response category so that the possible scores range from 0 to 21 for both anxiety and depression.

All questionnaires were answered either in French or German according to the mother tongue and residence in the French- or German-speaking part of Switzerland of the patients. Outstanding returns or incompletely answered questionnaires were completed by telephone interviews within a 2-month period by the same specially trained person.

Statistical analysis

Categorical data are expressed as frequency (percentages); continuous variables are presented as mean ± SD. For the bivariable analyses, we used χ^2-tests for categorical data and the Mann–Whitney *U*-test for continuous variables. The bivariable comparison of the risks for mortality was analysed by means of the log-rank test. For prediction of the QoL from the type of treatment, linear regression modelling was used to adjust for suspected confounding factors: logistic EuroSCORE, STS score, preoperative dyspnoea and preoperative syncope. We performed this linear regression analysis separately for the two metascores of the SF-36, Physical and Mental Health. The same variables were included into two logistic regression analyses, to predict the occurrence of anxiety and depression, both measured with HADS.

All tests used were two-sided, and differences were considered statistically significant for *P*-values of <0.05. The analyses were performed using SPSS Statistics 17.0 for Windows.

RESULTS

Study population

Of 144 patients with symptomatic, severe aortic stenosis, 51 patients (79.7 ± 9 years, 26 males) were allocated to TA TAVI and 93 patients (81.1 ± 5 years, 39 males) underwent SAVR.

At baseline TA TAVI patients were more often in NYHA Class III and IV (66.7 vs. 46.2%, $P < 0.001$) and had more frequent syncope (23.5 vs. 17.2%, $P < 0.002$) compared with SAVR patients. Furthermore, left ventricular ejection fraction was significantly lower in the TA TAVI group compared with SAVR patients (49.6 ± 17 vs. 58.1 ± 10%, $P = 0.006$).

In the TA TAVI group, the estimated risk as assessed by the EuroSCORE (26.5 ± 16 vs. 12.1 ± 9%, $P < 0.001$) and the STS score (6.7 ± 4 vs. 4.4 ± 3%, $P < 0.001$) was significantly higher compared with SAVR-treated patients (Table 1).

Clinical outcomes

Clinical outcome variables are summarized in Table 2. Mortality at 30-day follow-ups were 7.8% for TA TAVI and 7.5% for SAVR patients. Subsequent follow-ups were performed after 3, 6 months, 1 year and at 15 ± 10 months and provided mortality rates of 7.8% vs. 7.5%, 15.7% vs. 11.8%, 21.6% vs. 17.2% and 25.5% vs. 18.3%, respectively, without significant differences between the two groups. Kaplan–Meier survival analysis is illustrated in Fig. 2.

Cerebrovascular events occurred in 5.9% ($n = 3$) of TA TAVI patients compared with 5.4% ($n = 5$) of SAVR patients ($P = 0.9$). The rate of myocardial infarction was low in both groups with 3.9% ($n = 2$) for patients undergoing TA TAVI and none in the SAVR group ($P = 0.12$). Permanent pacemaker implantation was

Table 2: Perioperative and clinical outcomes

	TA TAVI ($n = 51$)	SAVR ($n = 93$)	*P*-value
30-day mortality	4 (7.8)	7 (7.5)	1.0
Overall hospitalization days	14 ± 8	15.3 ± 12.8	0.9
Days in intermediate care	2.4 ± 4.4	2.1 ± 3.0	0.7
Days in intensive care	2.5 ± 4.6	3.6 ± 9.0	0.8
Concomitant revascularization (PCI/CABG)	6 (11.8)	44 (47.3)	<0.001
Need for pacemaker	5 (9.8)	2 (2.2)	0.1
Stroke	3 (5.9)	5 (5.4)	0.9
Myocardial infarction	2 (3.9)	0 (0)	0.12
Bleeding/tamponade necessitating re-intervention	2 (3.9)	5 (5.4)	1.0
Intraoperative transfusions of EC	1.7 ± 3.3	3.9 ± 4.0	<0.001

Data are expressed as mean ± SD or *n* (%). PCI: percutaneous coronary intervention; CABG: coronary artery bypass grafting; EC: erythrocyte concentrates.

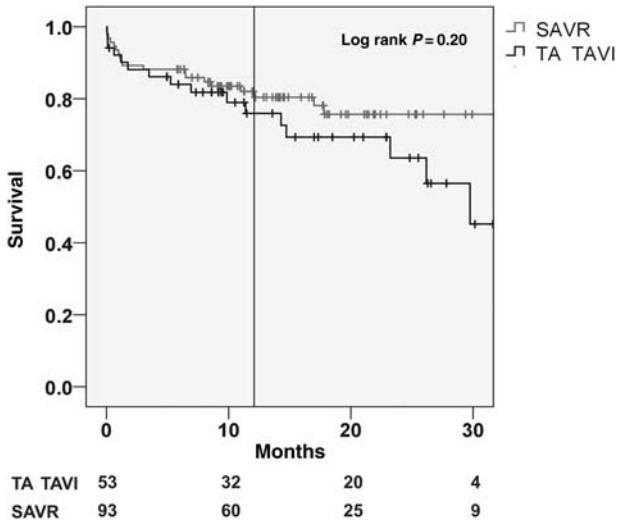

Figure 2: Kaplan–Meier survival analysis of the surgical (SAVR) and the transapical TAVI group. The vertical axis represents the probability of survival. The vertical bar corresponds to the time interval where two-thirds of the patients are still alive.

required in 9.8% of patients ($n = 5$) of TA TAVI patients compared with 2.2% ($n = 2$) in the SAVR group ($P = 0.1$).

Although the need for packed red blood cell transfusions was significantly higher in patients undergoing SAVR (3.9 ± 4 vs. 1.7 ± 3, $P < 0.001$), no difference was observed in terms of re-operation or tamponade, with 3.9% ($n = 2$) for TA TAVI and 5.4% ($n = 5$) for SAVR. TA TAVI patients tended to have a shorter stay at the intensive care unit (2.5 ± 5 vs. 3.6 ± 9 days) and have a shorter overall hospital length of stay (14.0 ± 8 vs. 15.3 ± 13 days).

QoL as assessed by SF-36 and HADS

In the TA TAVI group, 70% of patients spontaneously returned the questionnaires compared with 74% in the surgical group. Overall clinical follow-up was completed in 99.3% of patients, and only one patient in the TA TAVI group was lost to follow-up. The patient flow of the present study including QoL assessment is presented in Fig. 3.

QoL assessment with the SF-36 questionnaire showed no significant differences in TA TAVI and SAVR patients in the subscales of physical functioning (46.8 ± 27 vs. 61.1 ± 27, $P = 0.21$), role-physical (35.5 ± 41 vs. 51.8 ± 40), bodily pain (64.3 ± 27 vs. 71.6 ± 30), vitality (46.6 ± 17.6 vs. 52.5 ± 21), social functioning (75.4 ± 23 vs. 79.9 ± 22), role-emotional (64.5 ± 44 vs. 67.6 ± 44) and mental health (75.7 ± 15 vs. 75.0 ± 18) (Fig. 4). In contrast, the SF-36 subscale for general health (52.4 ± 17 vs. 64.1 ± 17, $P = 0.005$) was significantly lower in the TA TAVI group, which was reflected in the Metascore Physical Health also showing significant lower values in TA TAVI patients when compared with SAVR patients (50.0 ± 21 vs. 62.0 ± 21, $P = 0.015$). However, after adjustment for baseline characteristics in the multivariate model, this difference disappeared. Mental health improvement after TA TAVI or SAVR was similar without significant differences in this SF-36 metascore.

Besides these results, anxiety and depression were also equally distributed between patients undergoing TA TAVI and SAVR. The anxiety scale of the HADS questionnaire amounted to 4.0 ± 4 for the transapical TAVI patients vs. 4.0 ± 3 for SAVR patients ($P = 1.00$), and also the depression scores showed no difference between the groups (4.7 ± 4 vs. 4.0 ± 4). Comparing patients with HADS scores indicating anxiety and depression, we observed no significant statistical differences (Fig. 5). Anxiety was present in 5.7% of SAVR and 12.9% of TA TAVI patients ($P = 0.25$), while depressive disorder was apparent in 17.1% of SAVR and in 12.9% of TA TAVI patients ($P = 0.77$).

Risk-score prediction of QoL outcome

In the multivariable regression model, preoperative risk assessment was a predictor for postoperative QoL. Every added point in the STS score decreased the SF-36 Physical Health dimension by two raw points at follow-up assessment ($P = 0.007$).

Reaffirming the decision to undergo the same intervention

Of the patients treated by TA TAVI 87.1% and 94.3% of patients treated by SAVR reaffirmed their decision to undergo the proposed therapy. At the follow-up of 15 ± 10 months 80.6% of TA TAVI patients compared with 81.4% of SAVR patients reported a substantial improvement in general health conditions as a result of the aortic valve intervention.

Need for re-admission to hospital

During the first 6 months after TA TAVI 29.0% of patients had to be re-admitted to hospital care compared with 14.3% of the patients who underwent SAVR ($P = 0.1$). All of these patients required more than one re-admission in the TA TAVI patient population while 11.4% of SAVR patients required multiple re-admissions ranging from two to five times.

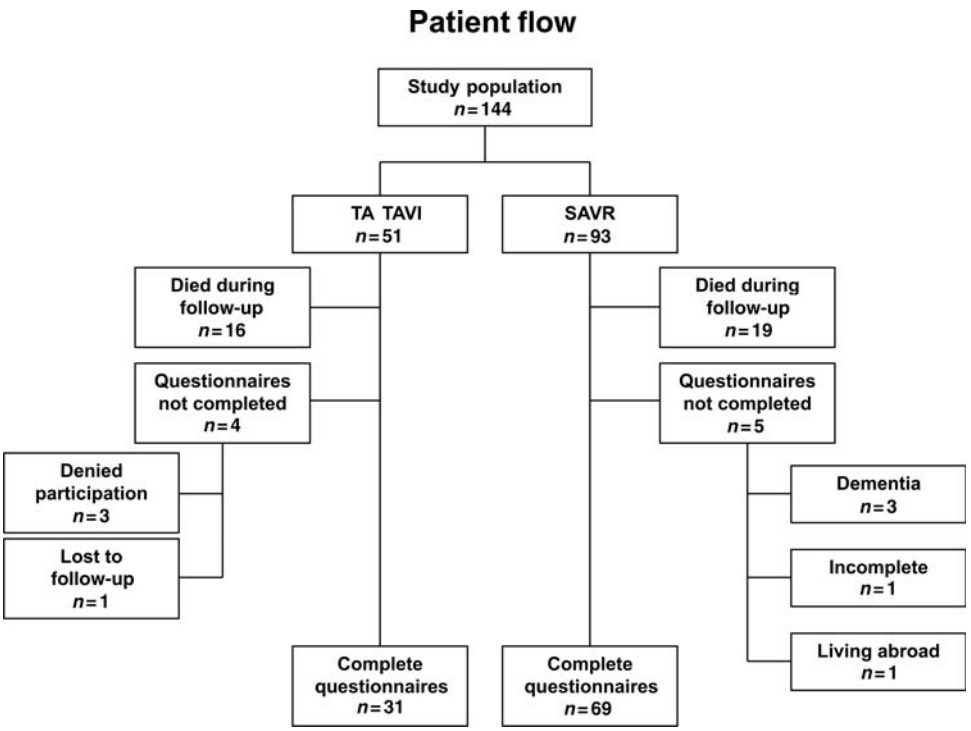

Figure 3: Patient flow of the present study.

Living conditions and degree of independence

At 15 ± 10 months' follow-up 22.6% of patients treated by TA TAVI vs. 41.4% of SAVR patients were living independently without major assistance in daily living activities. Minor assistance was needed in 45.2% after TA TAVI vs. 41.4% after SAVR and major help (i.e. for personal hygiene, dressing) of family members or community health services was required in 19.4% of patients after TA TAVI vs. 10.0% in the SAVR group ($P = 0.19$). At the time of follow-up, an overall 9.7% of TA TAVI and 7.1% of surgically treated patients were living in a geriatric care institution, while 3.2% of TA TAVI and none of the SAVR patients had been admitted to a care and nursing home (Fig. 6).

Study-related questionnaires were completed without any assistance in 64.5% of TA TAVI patients and 65.7% in the SAVR group; 29.0 and 24.3%, respectively, required the help of relatives, and the minority of 6.5 vs. 10.0% were assisted by a healthcare professional ($P = 0.78$).

DISCUSSION

A respectable number of studies have documented the feasibility and the advantages of TAVI in the most recent era. TAVI improves survival compared with medical therapy alone in patients deemed inoperable [17] and is non-inferior to SAVR in terms of mortality in selected high-risk patients [18]. These results might tempt one to extend this seemingly attractive technology to a larger patient pool [19], particularly with regard to the patients' preference for less invasive procedures. But apart from technical and isolated survival data additional clinical criteria are needed to support further decision making.

Assessment of intermediate-term QoL in patients undergoing TAVI is scarce and the comparison with SAVR treatment is missing. Especially in this elderly patient population, the prolongation of lifetime is one aim of treatment, but this is less important from a patient's perspective. When faced with a limited remaining lifetime, QoL is of major importance to these elderly patients and preservation or even improvement of QoL is the primary objective of a therapy approach in a geriatric patient population.

Considering the baseline characteristics of patients included in the present study, both groups are characterized by advanced age and, especially, frailty. Patients in the TA TAVI group were more affected by comorbidities compared with the surgical group as reflected in the increased logistic EuroSCORE (26.5 ± 16.1 vs. 12.1 ± 9.3) as well as the STS score (6.7 ± 3.8 vs. 4.4 ± 2.6). This is comparable with the estimated risk of patients included into the PARTNER Trial (Logistic EuroSCORE of 29.3%) [18] and, furthermore, the preoperative risk presented in the recent publication on the QoL after TAVI by Georgiadou *et al.* [20]. The significant difference in preoperative conditions was, furthermore, expressed in preoperative symptoms, as TA TAVI patients significantly were more often in NYHA Class III and IV when compared with SAVR patients. At admission 67% of TA TAVI patients were in NYHA Class III or IV compared with 47% in the SAVR group ($P < 0.05$), and 24% of TA TAVI patients experienced preoperative syncope compared with 17.2% in the SAVR group ($P = 0.001$). In addition, also left ventricular ejection fraction (49.6 ± 17 vs. 58.1 ± 10%) accounted unfavourably in the TA TAVI group.

Despite differences in risk assessment and disease progression, 30-day mortality (7.8 vs. 7.5%), 6-month mortality (15.7 vs. 11.8%) and 1-year mortality (21.6 vs. 17.2%) did not show any significant differences in both groups and complies well with existing literature data [8, 18, 21].

As demonstrated in this study, TA TAVI patients, although they were at higher surgical risk, with more advanced aortic valve

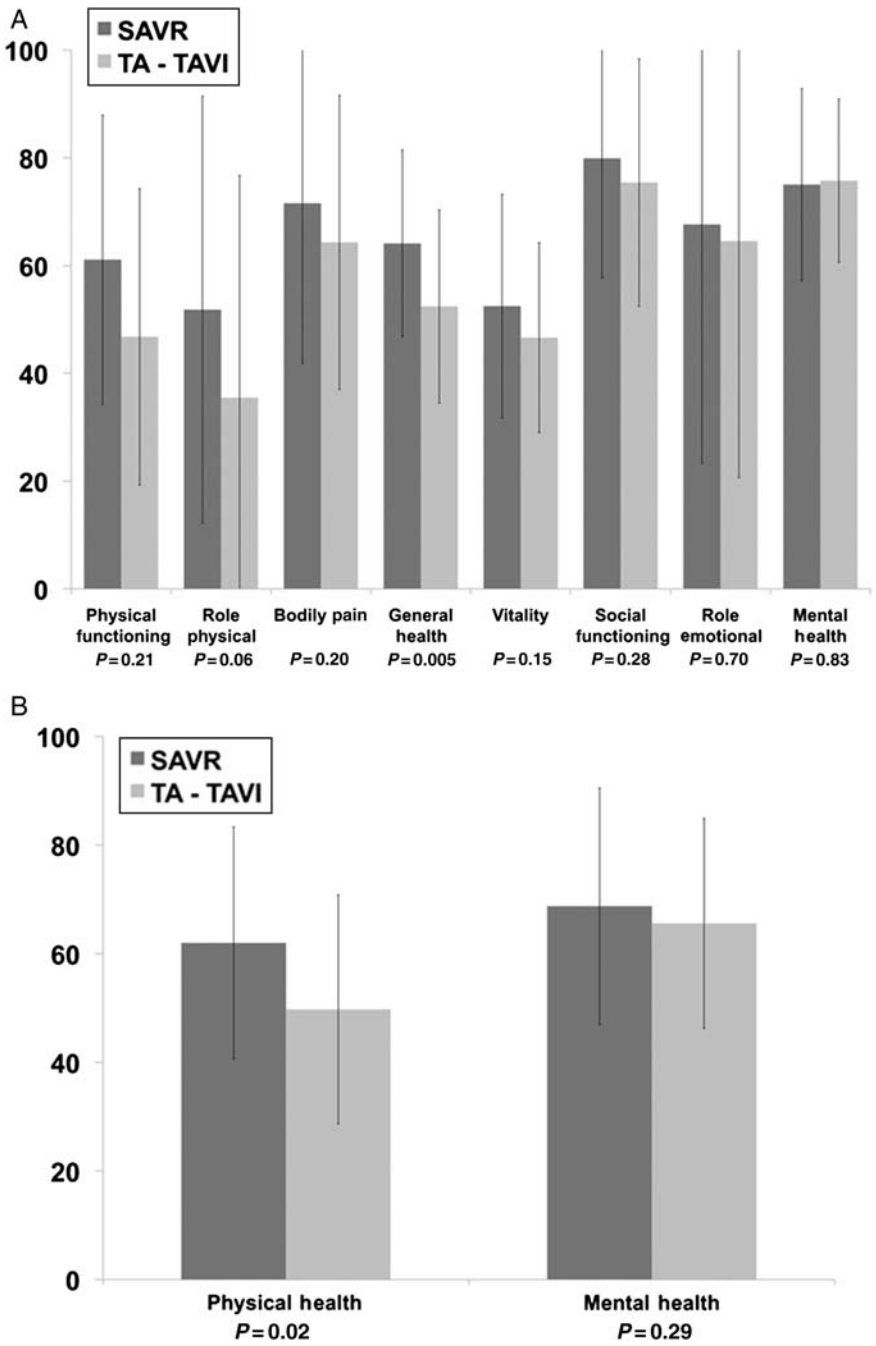

Figure 4: (**A**) Results of the eight SF-36 dimensions in the TA TAVI and SAVR group. (**B**) Summarized SF-36 Metascores.

disease and a heavier symptom burden, presented outcomes comparable with the surgical group. The question that needs to be addressed remains: do TAVI patients have a postoperative QoL comparable with patients undergoing SAVR?

In contrast to previous reports, we focused in this study on the comparison of postoperative QoL in patients receiving TA TAVI and SAVR and used the SF-36 and HADS health-related questionnaires. According to the SF-36 items of physical functioning, role-physical, bodily pain, vitality, social functioning, role-emotional and mental health, patients with TA TAVI showed a similar performance in the QoL as those with SAVR treatment. A significant difference in the subscale general health (Fig. 4), showing lower values in TA TAVI patients compared with the SAVR group, might be explained due to the markedly poorer preoperative condition of the former rather than by the nature of the performed intervention. In the multivariate regression model adjusted for confounding factors, we found that the only preoperative condition to predict a lower QoL outcome was the STS score. Every one point of the STS score added decreased the Physical Health Metascore of the SF-36 by two raw points. In this context, the significantly increased STS score in the TA TAVI group compared with the SAVR group, fully supports the previous statement.

As emotional well-being might be at least as important as physical strength and for this reason the HADS, a self-assessment screening questionnaire designed to simply and yet reliably

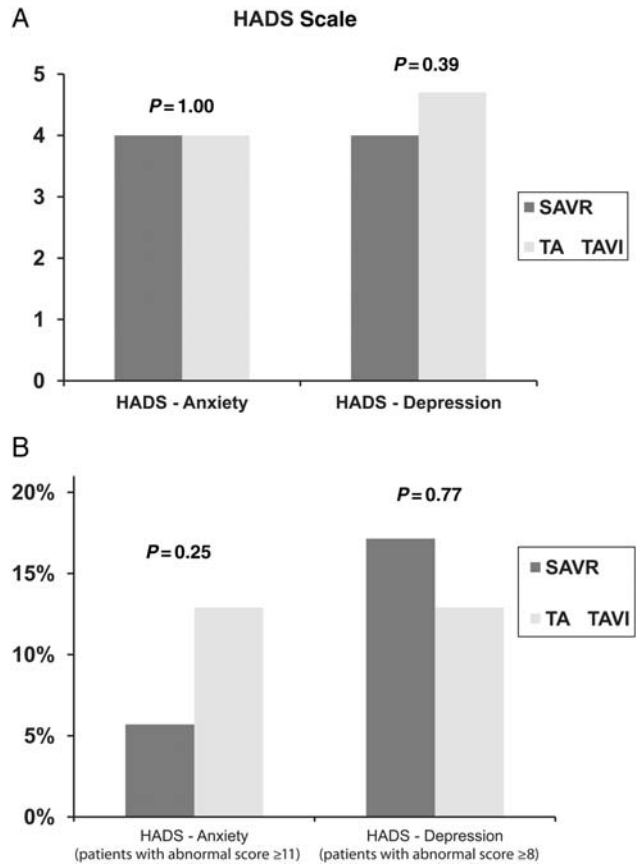

Figure 5: (**A**) Total Anxiety (A) and Depression (D) mean scores in the TA TAVI ($n = 31$) and SAVR group ($n = 70$). (**B**) Percentage of patients with scores suggestive of or indicating a depressive or anxiety disorder.

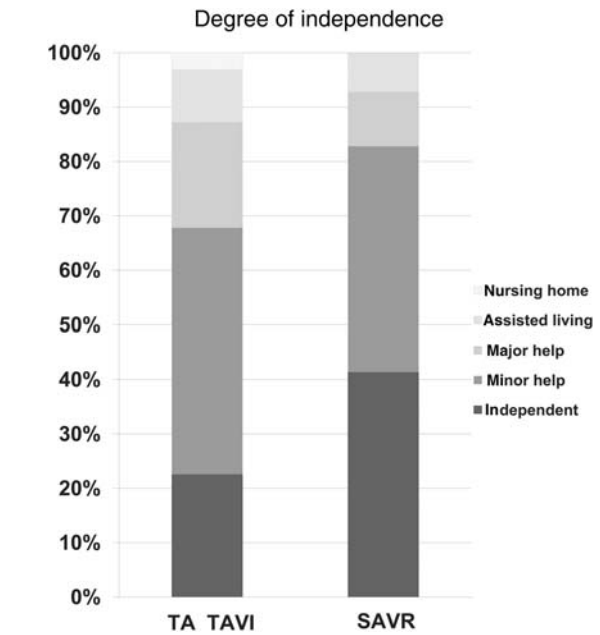

Figure 6: Living conditions of patients after TA TAVI or after SAVR at the time of follow-up (15 ± 10 months).

assess and quantify the degree of anxiety and depression, was used in all patients. No previous TAVI study has evaluated follow-up outcomes by the HADS so far. The results of this specific emotional assessment with the HADS did not show significant differences between TA TAVI and SAVR patients, neither on the depression nor on the anxiety scale (Fig. 5) at the 15-month follow-up.

The fact that more than 80% of surviving patients indicated an improvement in the QoL due to the assigned treatment and 90% reaffirmed their decision to undergo the same procedure again may also add special value on the individual improvement with regard to the QoL after the procedure.

However, although our study population presented with advanced age and had multiple comorbid conditions at baseline, a surprisingly high proportion were able to care for themselves and live alone with only minor assistance after the intervention (68% in the transapical TAVI group, 83% in the SAVR group). After all, two-thirds of the patients could fill in the questionnaires without external help, which indirectly points to the adequate cognitive skills of most of these octogenarians.

Limitations

The present study has several limitations. As with any single-centre experience, our findings may not be generalized. The relatively small sample size, although well within the range of comparable studies on TAVI, may limit statistical significance in some aspects. All patients in this study were evaluated by an interdisciplinary heart team and, according to their risk, allocated to either conventional SAVR or TA TAVI. A randomized comparison would have been preferable in this situation to create a non-biased statement. The highest risk patients were assigned to TA TAVI, which might result in a selection bias, and therefore postoperative QoL values in SAVR and TA TAVI patients need to be interpreted with caution. There could also be a potential bias due to the relatively high number of patients who died in either group before assessment of their QoL. QoL is influenced by several daily living circumstances and therefore, a generic tool like the SF-36 reflects not just the cardiac causes of poor QoL. On the other hand, the SF-36 is a validated tool and this study explicitly addressed the general QoL in this elderly patient population.

CONCLUSION

This study adds to the growing body of evidence that elderly patients undergoing transapical TAVI achieve similar clinical outcomes as well as the health-related QoL compared with patients undergoing SAVR. This effect was maintained over time and was still present beyond a year after the intervention. There is a significant correlation between the STS score and the QoL. Every added point in the STS score decreased the SF-36 physical health dimension by 2 raw points at the follow-up assessment.

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APPENDIX. CONFERENCE DISCUSSION

Dr C. Schlensak *(Tübingen, Germany)*: TAVI was introduced for patients with aortic stenosis who are not eligible for conventional aortic valve replacement. Due to the high costs and the potential complications of the TAVI procedure itself, analysis of the quality of life after TAVI is crucial. Since you could not identify any differences in quality of life between the groups, transapical TAVI vs. conventional aortic valve replacement, does this have any impact on the treatment strategy at your centre?

Dr Huber: I am sorry, what do you mean?

Dr Schlensak: The TAVI patients were the much sicker patients compared to the conventional aortic replacement patients. However, in comparing the two groups there was no difference in outcome. Did I understand that correctly?

Dr Huber: Yes, that is correct in terms of quality of life.

Dr Schlensak: Therefore I wonder, does this have any impact on your treatment protocol, whether you treat patients with TAVI or a conventional surgical procedure?

Dr Huber: Well, there is a patient group where there certainly is an ambiguity about selecting the kind of procedure which is best for that patient. We have that kind of patient, not the patients included in this study now, but those that are referred for TAVI. But, on the other hand, we have patients that are beyond 80 years of age, let's say 83 for example, who might be in quite good shape but who nevertheless demand transcatheter valve replacement. And I think in those patients, even more so with the kind of information coming from the data, I start more and more to agree with doing TAVI in those patients, even though they might also be candidates for surgery, as long as they are old enough, because their life expectancy still is limited just by the nature of their age itself. So I think it would be worth those patients being included as TAVI patients if they understand what the risks are and understand the durability issues of the valve, et cetera.

Dr Schlensak: Coming back to the demand of patients, if I understood that correctly, you have demonstrated (after taking into account the complexity and comorbidities) that the outcome of both patient groups is the same. Bearing in mind that the TAVI procedure is very costly and associated with a higher complication rate, I wonder why not do conventional aortic valve surgery in these patients?

Dr Huber: Well, this is a fair enough question. In this study there were still patients that were referred for TAVI evaluation. In those patients we split apart those that we thought were better suited for surgery and those in whom we didn't want to do surgery.

But your first question asked whether the patients sent for surgery in this study would be candidates to go for TAVI next time, and I think I would answer that question with 'yes'. In terms of the issues facing the patient, such as advanced age, three months of sternal healing, etc., I think if we can shorten the recovery time, and we will certainly do that with TAVI, it is a benefit we can add to our patients in the older age population, yes.

Dr N. Moat *(London, UK)*: I am trying to work out why you decided to choose a subgroup of TAVI, that is to say transapical TAVI, to compare with surgical AVR rather than your whole TAVI population.

Dr Huber: I'm sorry, why we didn't include transfemorals?

Dr Moat: Why did you choose a subgroup of patients having TAVI, i.e., the transapical group, rather than the whole population? Was there some reason for that?

Dr Huber: Well, the bunch of the transapical patient population has been included. All our transapical patients underwent multidisciplinary screening, and then we went backwards, and then the quality of life was retrospectively assessed in all the patients by phone interview. So this information comes from all the patients.

Dr Moat: A second question. I wouldn't pretend to be an expert on assessing quality of life. It is quite a complicated issue and, as I am sure, as you know, there are very many instruments to assess it. So you could interpret your results in two ways: one is that there is no difference in quality of life; the other is that the instruments that you used, the SF-36 and the HADS score, are not very good instruments in this patient population. Would you like to comment on that?

Dr Huber: Well, the SF-36 is a quite standardized instrument. It has also been partly used in the PARTNER trials, even though the shorter version, and it has been validated. It certainly is an instrument that has this validation. You can use other scores. That will be the subject of another study.

Now, just to get back to your first question regarding the number of transapical patients, obviously those patients have to have a long enough follow-up. So the ones that are more recent were not included in the study. That is why the number is smaller than the overall number of patients in whom we would have performed transapical TAVI.

Dr O. Wendler *(London, UK)*: I have one more question, and that is, have you ever looked in the past into the quality of life of your surgical patients? If you have done so, would you say that the introduction of TAVI has improved the outcome in terms of quality of life of the surgical cohort because you take the high-risk, maybe less fortunate patients in terms of outcome, out of the surgical group?

Dr Huber: From 2001 to 2002, we performed a study in 166 octogenarians that underwent surgery. Of those, I showed on one of the first slides a glimpse of the aortic valve replacement. But those patients had been investigated before TAVI was introduced at our centre. So I wouldn't be able to give you a well-defined answer to that.

Dr Wendler: Well, that was exactly the reason why I was asking, because you can make a point out of the fact that TAVI, and one would hope so, would improve the outcomes after conventional surgery, and that would also include quality of life. So that is maybe a point to look at in the future.

Dr Huber: I would certainly think so, but I don't have data to support it.