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REVIEW

Survival, Functional Capacity and Quality of Life after Transcatheter Aortic Valve Implantation: Present Considerations and Future Perspectives

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ABSTRACT

Severe aortic stenosis (AS) is the most common valvular heart disease, with an increasing prevalence due to age-related degenerative modifications of the valve. Once AS becomes symptomatic, the survival of patients is significantly reduced with an annual mortality rate of 25%. Depending on surgical risk, anatomical and technical aspects, and the patient's option, correction can be made either by surgical valve replacement (SAVR) or by transcatheter aortic valve implantation (TAVI). Although aortic valve implantation brings relief of symptoms, there is little data on the quality of life (QoL) of patients undergoing TAVI and the factors that directly influence it. Even if age and comorbidities are known modifiers of survival, there is no specific tool to assess the impact of AS and to determine the appropriate treatment strategy.

Keywords: aortic stenosis, transcatheter aortic valve implantation, quality of life, mortality, frailty.

REZUMAT

Stenoza aortică (SA) strânsă reprezintă cea mai frecventă valvulopatie, cu o prevalență în creștere la pacienții vârstnici prin modificările valvulare degenerative. Apariția simptomatologiei se asociază cu prognostic prost, cu o mortalitate anuală de aproximativ 25%. În funcție de riscul chirurgical calculat, particularitățile anatomice și tehnice, dar și de dorința pacientului, corecția se poate face prin protezare valvulară chirurgicala sau prin implantare transcateter de valvă aortica (TAVI). Deși protezarea valvulară aduce beneficii în ceea ce privește simptomele asociate, există relativ puține date legate de modificarea calității vieții după TAVI și de factorii determinanți ai acesteia. Vârsta și comorbiditățile asociate modifică atât supraviețuirea, cât și calitatea vieții pacienților, însă este nevoie de instrumente specifice de evaluare a impactului bolii asupra pacienților pentru stabilirea tratamentului potrivit.

Cuvinte cheie: stenoză aortică, implantare transcateter de valvă aortică, calitatea vieții, mortalitate, fragilitate.

INTRODUCTION

Aortic stenosis (AS) is an important health burden, representing the most common valvular heart disease which affects up to 5% of patients over 75 years of age[1]. The prevalence of degenerative AS is increasing due to ageing of population and better access to proper diagnosis and treatment. At the time of AS related symptoms start to develop, survival of patients without treatment ranges from 15% to 50% at 5 years[2], with an estimated annual mortality of 25%, making AS also the most common valve disease with an indication for surgical or percutaneous intervention[1]. Surgical aortic valve replacement (SAVR) has been the gold standard treatment for patients with symptomatic AS, with transcatheter aortic valve implantation (TAVI) being initially considered only for those patients at high operative risk, but recent randomized controlled trials have shown that TAVI is a good alternative to the surgical treatment even in low-risk patients[3,4]. TAVI now has clear indication in the European and American guidelines for the treatment of AS[2], but there are still questions on the survival and the quality of life (QoL) of patients who undergo TAVI compared with age- and sex- matched general population[4,5]. These are important issues considering that patients referred for TAVI tend to be older and have more comorbidities than

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those undergoing SAVR which clearly affects both survival and QOL. Long-term mortality profile of these patients is rather difficult to assess because older age and multiple comorbid conditions make them more likely to die from other causes[4]. Nevertheless, based on evidence emerging from large clinical trials, indication for TAVI is extending beyond moderate- and high-risk patients and is also expanding to younger patients.

SURVIVAL AFTER TAVI

The important PARTNER (Placement of Aortic Transcatheter Valves) trial proved survival benefit of TAVI compared with standard therapy, including balloon aortic valvuloplasty which was performed in 83,8% of the patients in the standard-therapy group, in a high-risk population considered unsuited for surgical treatment[6]. The primary end point – death of any cause, death from cardiovascular causes and hospitalizations were significantly lower in the TAVI group. When first compared with SAVR in high-risk patients, TAVI patients had comparable mortality at 1 year and 5 years[7] but progress made in terms of procedural risk due to technical improvements and novel delivery systems leads to further reduction of mortality. The results of the recent published PARTNER3 trial[8] showed better outcomes (mortality and quality of life) of patients with low-risk who underwent TAVI compared with SAVR. QoL reported in PARTNER3 was improved in the TAVI group compared with medical treatment and assessment at 1 year after intervention showed no difference between TAVI and SAVR.

Having these data in mind, it is predictable that an increasing number of patients with severe AS will be treated by TAVI, which leads to the question of proper selection considering that some patients benefit more from TAVI than others.

The Netherlands Heart Registration (NHR) compared data from a large TAVI cohort (5489 patients, 2013-2017) with information from the national Dutch population in order to determine differences in survival and quality of life between patients treated by TAVI and age-matched general population[4]. Patients in the TAVI cohort had a mean age of 80 ± 7 years and were followed for 1,95 years. The younger patients (<65 years) had more often renal disease, lower left ventricular ejection fraction and chronic lung disease. The results of this long-term study showed that in the group of over 80 years and older survival was equal to the matched general population, but the groups of less than 65 years and between 65-85 years did worse than their matched population[4]. This outcome was predictable since younger patients than 75 years were referred for SAVR according to the current guidelines and those unsuited for surgery had significant comorbidities which led to reduced survival rate. Another aspect assessed was the QoL 1 year after TAVI which was comparable to the general population in age groups 65-75 and over 75 years[4]. These are interesting results because they prove that younger patients eligible for TAVI have greater benefit from the intervention.

Because in older patients with important associated conditions it is difficult to establish the benefit of a certain procedure such as TAVI, data from registries were analyzed in the United Kingdom between 2007-2014[5]. Their aim was to determine relative survival (RS) after TAVI. RS adjusts the observed mortality to the expected within a matched general population[9]. Results showed that even if mortality hazard was high relative to that of general population early after TAVI, it had declined significant at 1 year follow-up and even more by 3 years, reaching mortality hazards of general population[5]. Moreover, significant RS was observed between 2011-2014 as compared to 2007-2010, proving the important role of perfecting procedural techniques in clinical outcomes. The authors concluded that the initial mortality excess due to index AS and TAVI decreased within the first year and returned to the expected within the general population by 3 years (Martin et al., 2017). This demonstrates that short term mortality is related to cardiovascular and procedure related events, but that beyond 24 months non-cardiovascular causes become leading cause of death.

SPECIFIC TOOLS FOR ASSESSING QOL IN TAVI PATIENTS

More than survival, one very important aspect in patients with severe AS is the reduced QoL. There are many scales to evaluate QoL of patients with cardiovascular diseases, such as the Kansas City Cardiomyopathy Questionnaire (KCCQ)[10], the Seattle Angina Questionnaire (SAQ)[11], and the Minnesota Living with Heart Failure questionnaire (MLHF)[12]. Nevertheless, these are all generic tools, mainly useful for assessing QoL in patients with heart failure (HF), but since the treatment of AS differs to that of HF, it became necessary to develop a specific AS questionnaire that detects AS related symptoms and how they influence the patient's physical and mental well-being, as well as their general health[13]. There are also some generic health-related QoL questionnaires such as the Illness

Intrusiveness Rating Scale (IIRS)[14] or the Short Form (SF)-12[15].

Up to the present, the KCCQ is the most used instrument to quantify physical function, symptoms, social function, self-efficacy and QoL in patients with HF[10], but it has been widely used to assess QoL in TAVI patients. The KCCQ is a 23-item self-report measure of health status that scores from 0 to 100 with high scores representing high QoL[16,17]. Most of the items are related to HF related symptoms: symptom burden, symptom frequency, symptom stability[16].

The TASQ is a 16-item self-administered questionnaire that has 4 subscales: physical symptoms, physical limitations, social limitations and emotional impact and sums up a maximum of 112 (each question has a maximum score of 7) (Table 1 – after Styra et al., 2020). A difference between the KCCQ which is more symptom directed is that the TASQ tried to capture the emotional picture of the disease which is crucial in assessing QoL[17]. There is great need for a specific tool to assess QoL since this is patient perspective, and not physician perspective, like the *New York Heart Association* (NYHA) classification.

The goal of the TASQ was to provide a more specific option to measure QoL for patients with severe AS considering that this population is different from those with HF, assessed by the KCCQ or the MLHF questionnaires[17]. For validation, the TASQ was assessed by comparison with the KCCQ and IIRS. The questionnaire was developed by a multidisciplinary team for patients with AS who were considered for TAVI[13]. 333 patients were interviewed to determine their current QoL and their expectations for the procedure. They were asked to identify those factors that were most important for them in terms of QoL. 211 patients underwent TAVI, 89 were declined for TAVI and 38 were waiting for TAVI at the time of review[13]. The participants completed the questionnaire before TAVI and at discharge (100%), 1 month (81%) and 3 months (69%)[17]. The TASQ demonstrated sensitivity to change from baseline to each of the three reevaluations. The symptoms and physical limitations correlated well with the KCCQ and the QoL domains with the IIRS[17]. During follow-up, limited by fewer responders at 3 months, the emotional impact and health expectations were sensitive in terms of detecting changes in QoL that occurred after correction of AS itself. Important conclusions can be drawn early after intervention to assess changes in QoL from TAVI and the 3 months evaluation will provide possible indications of long-term outlook after TAVI[13].

As a practical approach, comprehensive evaluation of these patients should include cardiological evaluation of the functional capacity, symptoms and comor-

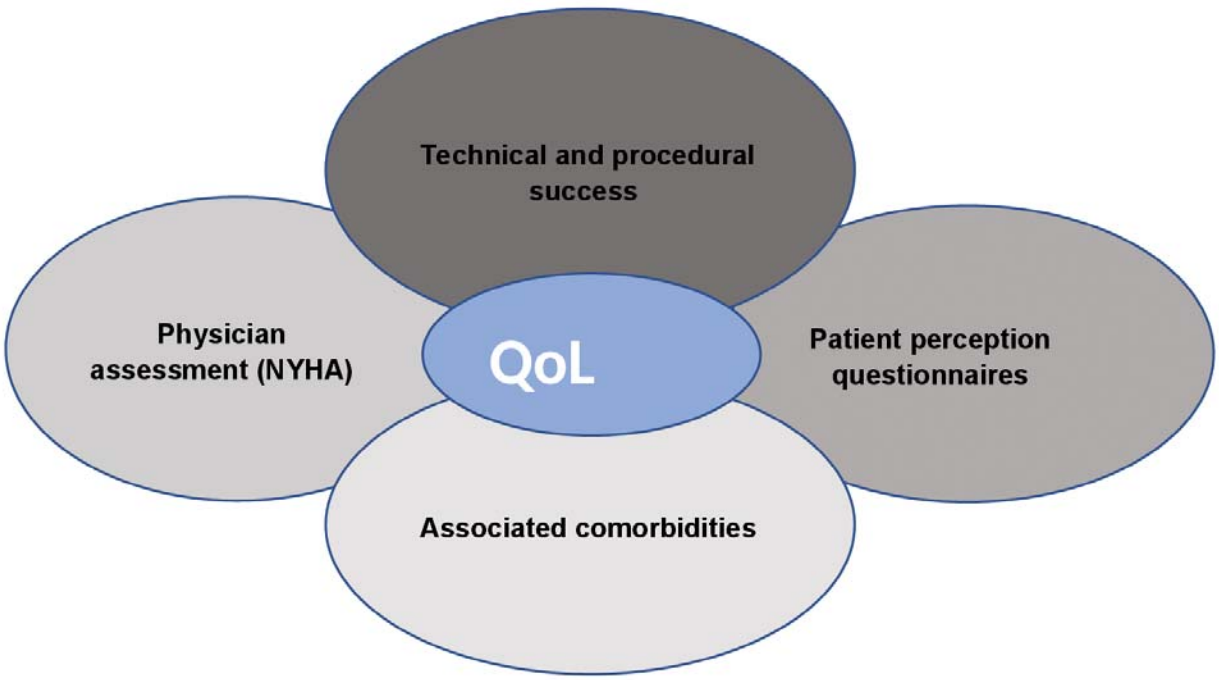


Figure 1. Interdependence of main determinants that influence quality of life.

Table 1 - Summary of the TASQ, Toronto Aortic Stenosis Quality of Life Questionnaire

Domain	Questions	Maximum points
Physical symptoms	1, 14	14
Physical limitations	3, 6, 7, 15	28
Emotional impact and expectations	16	7
Emotional impact	2,8, 9, 10, 11, 12, 13	49
Social limitations	4,5	14
		Total score=112

bidities, technical aspects of the procedure and an attentive assessment of patients' perception (Figure 1).

IMPACT OF FRAILTY ON QOL IN TAVI PATIENTS

Probably one of the main concerns in all invasive interventions is to avoid futility. It is established that TAVI brings symptom relief, increased functional capacity and improvement in QoL in the majority of patients with severe AS, but there is a consistent subgroup of patients that do not benefit[18].

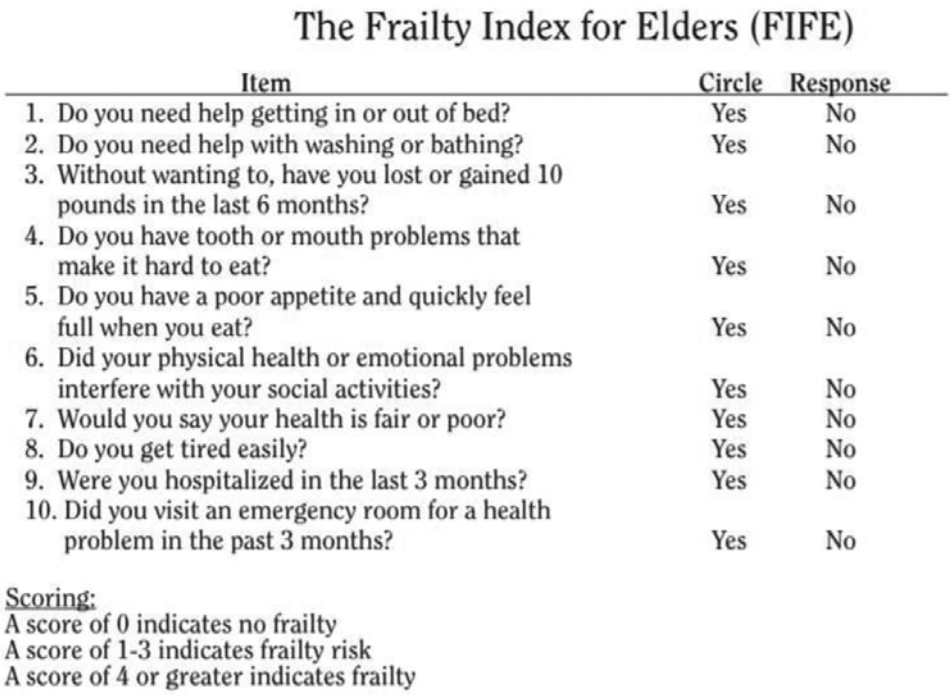
Most patients still referred for TAVI are older, have associated comorbidities and high-risk for SAVR, but there is a distinct category of frail patients, not very well defined but included in current guidelines as an indication for TAVI. Frailty is generally described as a reduction in physical, psychological and social functions that comes along with aging and overall health deterioration[19]. Even if frailty is not equivalent with chronological aging, the prevalence of frailty increases from approximately 10% in people over 65 years old to almost 50% in those over 85 years old[20]. Frailty is not clearly defined but is considered a geriatric clinical syndrome affecting older patients with multiple comorbidities[21]. The hallmark of frailty is it's dynamic condition with progressive decline in physical capacity, increased risk of falls, slowing of illness recovery, more frequent and longer hospitalizations and increased mortality[22]. There are multiple instruments available to assess frailty, one of the most used and validated being The Frailty Index for Elders (FIFE)[23]. The FIFE is a friendly, easy to use questionnaire that uses a 10-item assessment and offers practical approach to physicians (Figure 2 – after Tocchi, 2016).

Moreover, identifying frail patients becomes crucial when it comes to procedures with implications for both the patients and the use of health services. A previous study suggested that if the indication for TAVI was frailty, the risk of not having benefit in QoL was twice as high compared with patients that had technical indications for the interventional approach[24]. Frailty needs better understanding and a comprehensive geriatric assessment because frailty is an independent predictor of poor QoL and outcome 1 year after TAVI[25,26]. Studies on the impact of frailty are still limited[27].

The Erasmus University Medical Center conducted an observational study – The TAVI Care & Cure Program, including 239 patients between 2013-2017[18]. Patients had baseline cardiologic assessment, using the NYHA classification, comprehensive geriatric assessment (CGA) and QoL measurement using the EuroQoL5 dimensions questionnaire (EQ-5D-5L)[28]. In the CGA, some frailty domains were evaluated: cognition, strength, (mal)nutrition, inactivity and limitation of mobility. The EQ-5D-5L questionnaire use for QoL consists of 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Frailty was defined by the Erasmus Frailty Score (EFS) which was corelated with postoperative delirium and 1-year mortality, significant being EFS >3%[25].

Patients enrolled had a mean age of approximately 80 years and 29,3% of them had EFS >3%; during follow-up 27,1% of frail patients died compared with 13,3% non-frail patients[18]. Clinical improvement measured by the NYHA functional classification was noticed more in non-frail patients and improvement in QoL at 1 year after TAVI was seen more often in non-frail patients. Interestingly, in frail patients, the EQ-5D-5L index decreased from baseline, whereas in non-frail patients, the EQ-5D-5L index did not change from baseline to 1 year follow-up. Frailty was an independent predictor of deterioration of QoL 1 year after TAVI, along with current smoking, renal dysfunction and limited mobility (Table 2) after (Goudzwaard et al., 2020).

The results of this study showed that even if NYHA functional class had improved in both frail and non-frail patients, deterioration of QoL and self-rated



The Frailty Index for Elders (FIFE)

Item	Circle	Response
1. Do you need help getting in or out of bed?	Yes	No
2. Do you need help with washing or bathing?	Yes	No
3. Without wanting to, have you lost or gained 10 pounds in the last 6 months?	Yes	No
4. Do you have tooth or mouth problems that make it hard to eat?	Yes	No
5. Do you have a poor appetite and quickly feel full when you eat?	Yes	No
6. Did your physical health or emotional problems interfere with your social activities?	Yes	No
7. Would you say your health is fair or poor?	Yes	No
8. Do you get tired easily?	Yes	No
9. Were you hospitalized in the last 3 months?	Yes	No
10. Did you visit an emergency room for a health problem in the past 3 months?	Yes	No

Scoring:
A score of 0 indicates no frailty
A score of 1-3 indicates frailty risk
A score of 4 or greater indicates frailty

Figure 2.

health status unchanged was noticed significantly more in frail patients. Nevertheless, among frail patients, the absence of peripheral artery disease (PAD) and of renal dysfunction[29] was corelated with improved QoL.

The technical aspects of TAVI have evolved, with shorter duration of the procedure that can be performed under general anesthesia or sedation, less complications and faster recovery. This is extremely important in frail patients (Figure 3).

GAPS IN KNOWLEDGE

There is scarce data on why some patients have clear benefit after TAVI and others do not (there are only pathophysiological suppositions) since we don't have any clinical studies targeting QoL after TAVI as major end-point. Further research with prospective studies aimed to investigate the relationship between hemodynamic ang biological status and the change in QoL after TAVI may help to understand the critical points associated to clinical and functional benefit in TAVI patients. Another gap in evidence so far is related to predicting changes in QoL according to the risk stratification of the patients – there is not enough data if there are distinct predictors of improving QoL in high, intermediate or low-risk AS.

An important aspect that also needs better discrimination is the difference between physician evaluations and what is considered important by the pati-

Table 2 - Predictors of deterioration of quality of life 1 year after TAVI (from Goudzwaard et al., 2020)

Variable	OR	95%CI	P-value
Age	1.01	0.96-1.07	0.647
Gender	1.13	0.56-2.27	0.737
Eq5D-5L index on baseline	10.62	2.32-48.52	0.002
Current smoker	3.21	1.06-9.77	0.040
Peripheral artery disease	1.40	0.73-2.66	0.312
Renal dysfunction	2.12	1.11-4.04	0.023
Limitation of mobility (5mGST)	2.29	1.35-6.17	0.006
Frailty (EFS)	2.25	1.07-4.70	0.003

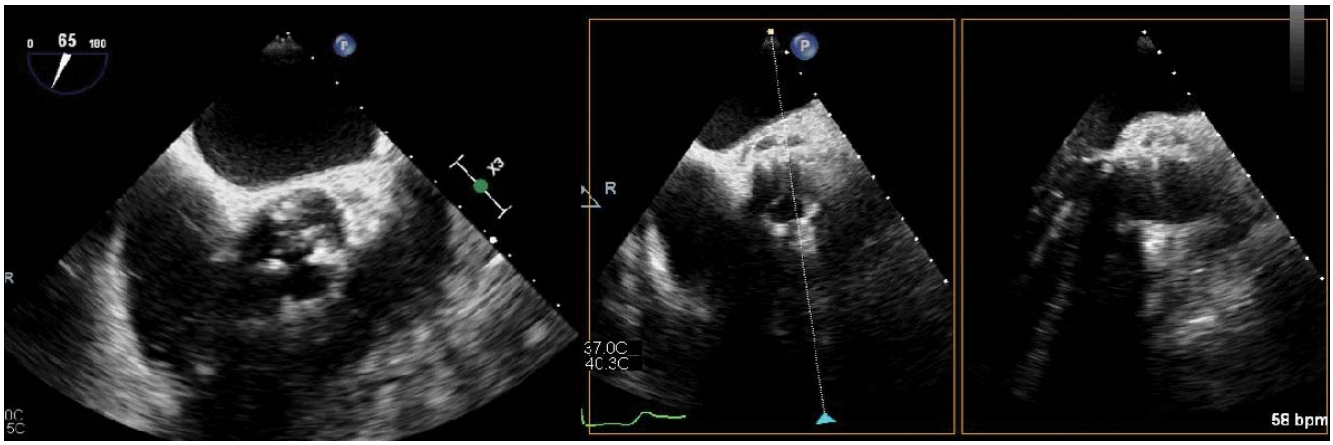


Figure 3. Intraprocedural transesophageal echocardiography. Short axis view of calcified aortic valve with severe aortic stenosis; short and long axis view by X-plane after de implantation of a biological valve (Edwards Sapien 3, no. 26).

ents in terms of health related QoL. How patients feel about their condition and their perception is not yet well defined in current scales, but it seems extremely important in assessing QoL after procedures such as TAVI.

CONCLUSIONS

Although TAVI is increasingly becoming an important choice of intervention in selected patients with severe, symptomatic AS – over 80 years of age TAVI is first option and in the group between 65-80 years old the decision for TAVI or SAVR is guided by specific criteria and considering the durability of the valve[30] – there are still gaps in evidence on determining QoL of patients following TAVI. The technique in TAVI has improved significantly, with very low procedural mortality, reported between 1-2,5%[31,32]. Most of the patients undergoing TAVI experience improvement in QoL, but some of them do not and this may be a result of factors such as multiple comorbidities and frailty. Measuring QoL is challenging because even if frailty is an independent predictor of deterioration in QoL, frail patients with no renal dysfunction or peripheral artery disease had clear benefit[18].

Usually, evaluations are mainly physician assessment, such as the NYHA classification, echocardiographic parameters or determining biomarkers related to HF, which represents an approach that ignores how patients perceive symptoms and how AS affects their well-being. Awareness to quantify QoL has led to the development of more specific tools, such as the TASQ, especially considering that most of the questionnaires are rather HF symptom oriented. The TASQ outlines that what may be regarded as a good result and favorable outcome by the physician may be different from the patient's perspective and what matters to them.

The complexity of these patients, usually older, frail and with significant associated comorbidities and the importance of a good health related QoL make it essential to develop a holistic approach for better understanding and managing TAVI patients.

Compliance with ethics requirements:

The authors declare no conflict of interest regarding this article. The authors declare that all the procedures and experiments of this study respect the ethical standards in the Helsinki Declaration of 1975, as revised in 2008(5), as well as the national law. Informed consent was obtained from all the patients included in the study.

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