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# The Impact of Transthoracic Aortic valve Replacement on Quality of Life: A Mixed Methods Study

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## Abstract

Objective: To provide an in-depth understanding of patients' views about the impact of transcatheter aortic valve implantation on self-reported quality of life. Background: Transcatheter aortic valve implantation is considered to be the gold standard of care for inoperable patients diagnosed with severe symptomatic aortic stenosis. Mid- to long-term clinical outcomes are favourable and questionnaire data indicates improvements in quality of life but an in-depth understanding of how quality of life is altered by the intervention is missing. Methods: A mixed methods study design with a total of 89 in-depth qualitative interviews conducted with participants (39% male; mean age 81.7 years), 1 and 3 months post TAVI, recruited from a regional centre in England. Data were triangulated with questionnaire data (SF-36 and EQ5D-VAS) collected, pre, 1 and 3 months post implantation. Results: Participants' accounts were characterised by four key themes; shortened life, extended life, limited life and changed life. Quality of life was changed through two mechanisms. Most participants reported a reduced symptom burden and all explained that their life expectancy was improved. Questionnaire data supported interview data with gradual improvements in mean EQ-5D scores and SF-36 physical and mental domain scores at 1 and 3 months compared to baseline. Conclusion: Findings suggest that TAVI was of variable benefit, producing considerable improvements in either mental or physical health in many participants, while a smaller proportion continued to deteriorate.

## Introduction

The ageing of the population means that by 2050 one in five people will be over 60 years of age.[1] Acquired aortic stenosis (AS) is typically a disease of ageing which affects up to 12% of people over 75 years of age.[2] If we consider the demographic picture of China as an example, we know that by 2050 about 100 million people will live to be over 80 years old.[3] This would equate with up to 12 million people living with AS which could make a substantial impact on health service provision.

In acquired AS, the narrowed aortic valve causes systolic and diastolic dysfunction with unpleasant symptoms such as dizziness, fainting and chest pain leading to reduced quality (QoL) and quantity of life.[4] Global policy emphasises the importance of 'healthy ageing'; a process in which optimal physical and mental capacity is retained.[1] Therefore interventions that can reduce the AS symptom burden offer an important treatment for what is a growing global population of older adults.

Transcatheter aortic valve implantation (TAVI), first described in 1992[5] and further developed in 2002,[6] offers an alternative and revolutionary treatment option to surgical valve replacement. TAVI involves the placement of a prosthetic valve inside the narrowed aortic valve using a balloon catheter. Trial data comparing SAVR and TAVI shows favourable mid-to-long term outcomes for this innovative treatment.[7-8] Data from several large registry studies reported 30-day, 1-year, and 5-year mortality rates after TAVI as around 6%, 24% and 50% respectively.[9]

Careful assessment of suitable TAVI candidates is required in view of the mortality risk and the potential of TAVI heart valve degeneration. The evaluation of QoL is recognised as an important consideration in identifying patients who might benefit from TAVI.[10] Quantitative data presented in systematic reviews report improvements in self-reported QoL after TAVI.[11,12] Moreover QoL measured pre-TAVI is a predictor of QoL over a 2 year recovery period.[13]

There are a handful of published qualitative studies that describe the patient experience leading up to TAVI treatment but very little information about the recovery experience. Being on the TAVI waiting list is a stressful period as physical function continues to decline and patients reported a sense of 'living on the edge'.[14] One systematic review highlighted a lack of research about AS patients' values, preferences for different treatment options.[15] To make a decision about treatment options it is important that the patients has information about what the recovery pattern might involve and what they might expect. We were unable to identify other qualitative studies that explained how TAVI impacted on self-reported QoL. Understanding the patients' perspective is important as the views of health professionals, patients and their families about QoL do not always match,[16] but health professionals' views typically determine patient access to treatment.[17]

The aim of the study was to provide an in-depth understanding of patients' views about how TAVI impacts upon QoL during early recovery (T1 baseline, T2 1 month post TAVI and T3 3 months post TAVI) through a series of interviews, complemented by quantitative data collected using validated QoL measures.

## Methods

We explored QoL in participants treated with TAVI using a mixed methods design. This study design was chosen to develop a comprehensive and robust knowledge base supported by the triangulation of findings. The qualitative and quantitative studies ran concurrently in a convergent parallel study design[20]. The qualitative study took precedence (QUAL quan), drawing upon the principles of ethnographic research which emphasise the exploration of phenomena. Using this approach we conducted a series of interviews which supported prolonged participant engagement and enabled us to explore participants views of how TAVI influenced their QoL.[21] The quantitative study identified trends in QoL scores to inform the qualitative analysis.

QoL and health-related QoL are terms that are often used interchangeably, but the former is a broader concept than the latter. There are several published QoL models, but no consensus about the most appropriate.[18] We chose the WHO ICF[19] framework to provide us with a theoretical context because it is a biopsychosocial model that can be used across countries; is appropriate for outcome evaluation, and is recognised as a standard for health professionals, policy makers and the public.[18]

**Sample and setting**: All participants scheduled for TAVI at a single regional centre in the North of England servicing a population of over 2 million were invited to participate. The sample comprised English speaking participants with a Mini Mental State Examination[22] (MMSE) score of ≤17 and the capacity to provide informed consent. A maximum variation approach to sampling was adopted in which participants are purposefully selected to capture a variety of participant experiences by gender and age group.

**Procedure**: Eligible patients were identified by clinical staff not directly involved in the study. After providing informed consent participants completed a series of up to two in-depth, face-to-face, semi-structured qualitative interviews conducted in their home setting. Data collection points (1 and 3 months post TAVI) were chosen because cardiac patients and their carers find the early post-discharge period of recovery challenging.[23] All participants were asked open ended questions such as

'Tell us about your experience of the TAVI procedure', 'Have any aspect of your life changed because of TAVI treatment?', 'Do you think having TAVI has influenced your quality of life?', 'If yes then how has this happened and what has changed?'. To support the quality of the data collection, one experienced researcher, trained in qualitative methods, conducted all interviews supplemented by field notes, until data saturation was confirmed.

## Data analysis

### Qualitative interviews

Framework analysis was chosen to explore emerging concepts within the interview data on a case-by-case basis.[24] An initial coding framework was independently developed by three researchers, following the coding of the first five interview transcripts. Themes that are presented represent unifying concepts or statements about the impact of TAVI upon QoL during a 3 month recovery period. Data interpretation was authenticated through a series of audiorecorded team meetings in which decisions about the analytical process were discussed, disconfirming cases reviewed and potential sources of researcher bias considered. The researchers resolved any diagreement in the analytical process by revisiting raw data and reviewing the fit of interpretations. This process of reflexivity with a key audit trail of decision making, along with the triangulation of data and investigators added to the trustworthiness of findings.[25] NVivo (version 9) was used to organise, manage and retrieve data.[26]

### Quantitative measurement

Demographic data were collected on all respondents (age, gender and ethnicity), and health-related QoL as measured by the SF12 instrument (Version 2) (PCS and MCS scales) and the EQ-5D VAS completed. Data were cleaned and entered into SPSS (version 22).

## Measures

### *Quality of Life: Physical and Mental Components*

QoL was measured using the Short Form-12 which is a generic measure that evaluates 8 health-related concepts, with scores being combined into mental and physical component summary scales (Physical Component Score-12 [PCS] and Mental Component Score-12 [MCS]). The general population have a mean score of 50 on these measures, with higher scores representing better health.[27] A general population of a comparable age range to this study reports a mean scores of 38.7 and 50.1 on the PCS and MCS scales respectively[27].

### *Quality of Life: Perceived Health Status*

The visual analogue scale (VAS) of the EQ-5D[28] (EuroQol-5 dimensions) was used to measure perceived health status (100 best imaginable health and 0 worst imaginable health) giving utility scores. A general population of a comparable age range to this study has  a mean score of 79.0 on this measure[28].

The sample was summarised descriptively. Mean and quartile scores (25th percentile, median, and 75th percentile scores) were obtained for each measure at each time point. Values obtained from the study sample were compared against corresponding normative values applicable to a population of similar age range. The number and valid percentage of patients whose scores on each of the three measures matched corresponding age-adjusted population normative scores was obtained for each of time points T1, T2 and T3. For each measure at each time point, the significance of the change from the corresponding population normative scores was also derived. The number and valid percentage of patients who improved between each time point on all outcome measures was also determined. Repeated measures analyses of variance (ANOVAs) were conducted on each measure to assess the significance of the variation in scores on each measure with respect to the time factor. The magnitude of any change observed was quantified using the partial-$\eta^2$ statistic, with Bonferroni-corrected pairwise comparison tests conducted as *post hoc* procedures.

## 3. Results

The final sample composed 53 participants on the waiting list for TAVI. All participants were of Caucasian ethnicity and Table 1 shows sample characteristics. At T1 one patient had died, five had withdrawn and one could not be contacted but participated in later interview.  By three months, a further three patients had withdrawn from the study (see Table 2 for data collection points and recruitment).

Insert Tables 1 and 2 about here please

### 3.1 Interviews

Participants' accounts were characterised by four key themes (shown in Figure 1 with accompanying categories and participants quotes). In summary TAVI impacted on QOL in two ways; most participants reported a reduced symptom burden and all explained that their life expectancy was improved. Some participants explained that TAVI had given them hope as they had access to a treatment that could improve their health and that before there had been no other treatment options.

## Theme 1: Shortened Life

### 1.1 Facing mortality

A key concern for participants, as their AS progressed, was of impending death and the impact of this on their family and significant others. Some participants expressed fear of dying alone or concern about the impact of their death on a spouse. Other participants felt that they had lived their life and that there was little point worrying about events that could not be controlled. Those with extreme breathlessness felt that death might be preferable to their current life. Participants reported feeling scared, lonely and short-tempered as they waited for TAVI. An important part of the pre-TAVI consultation involved candid doctor-patient discussion about the risks, benefits and potential outcomes of TAVI, as well as the likely prognosis should no treatment be given. These discussions acted as a catalyst for reflection about the reality of mortality. Participants were typically in their eighth or ninth decade of life, and many had experienced mortality of family members or friends leading to changes in their personal relationships and social networks. Living with a life limiting condition often increased the emotional closeness between remaining family members.

### 1.2 Deciding to have TAVI

The pre-TAVI consultation was an important part of the overall decision making about agreeing to TAVI. Participants' responses to the consultation varied. Some participants appreciated the candid and honest approach. Others found the information more distressing, and felt that there was more of an emphasis upon risks than benefits. This led to a re-evaluation of their current QoL which was an important influence upon the decision to go ahead with TAVI. All participants recognised that their life expectancy was shortened by their heart condition. For many TAVI offered a source of hope as they had access to a treatment option that could improve their life where they thought there had been none.

## Theme 2: Limited Life

Participants health was severely affected by AS and other co-morbidities. The burden of symptoms limited their opportunity to live what was described as a 'full life' and day-to-day life for many was a 'struggle'.

### 2.1 Symptom burden

Before the procedure, the majority of participants reported moderate to severe breathlessness which led to physical restrictions which had a negative impact upon day-to-day life. The severity of breathlessness had a corresponding effect on energy levels and fatigue. Shortness of breath, dizziness, fainting and falls were common complaints, as were fatigue, pain, sleep disturbance, loss of memory, concentration and appetite. The degree of breathlessness was extreme for some participants who reported being frightened: (Female subject 14, 87 years, NYHA III). One participant was so breathless that she had to sleep in a chair, was unable to talk on the phone to her family and fearful to go anywhere alone. The increased level of dependence on others to manage daily activities of living led some participants to report feeling worthless and burdensome.

### 2.2 Functional and social restrictions

Many aspects of participants' lives were restricted by the symptom burden and associated physical limitations with leisure/social activities being the most affected. Participants often described feeling that they had lost their independence. Many felt unable to leave their homes which led to functional and social restrictions. Being confined to home reduced social contact, leading to feelings of loneliness, isolation, boredom, loss of control and depressive symptoms. Many participants described feeling a loss of pleasure in life and a lack of motivation. Others described restrictions on driving and taking holidays and the inability to participate in the day-to-day activities of normal life; such as attending to hygiene needs, housework, meal preparation, gardening, and caring for other family members such as grandchildren. These activities were either no longer possible, or took much longer than before, which was a source of frustration and misery. Participants' accounts clearly demonstrated the connection between physical functioning and psychological well-being; as physical limitations increased, life became more restricted and psychological well-being declined.

## Theme 3: Extended Life

TAVI was seen as an intervention that could treat a life-threatening heart condition and was preferable to SAVR.

### 3.1 Survival

All participants were aware of their life limiting condition and the potential risks of having TAVI. Participants described their relief at having survived the TAVI procedure and gratitude about having access to this intervention. In addition, participants who had a successful TAVI procedure reported their perception of having a longer life span.

## Theme 4: Changed Life

The reduced symptom burden and the prospect of a longer life was described as 'life changing' for many participants. The availability of a procedure that could offer the potential of a better life, particularly at their advanced age, was very much appreciated. After recovery there was a change evident for many participants in the nature of relationships with 'significant others'. Participants became more focused upon these connections and wanted a change in which they could be 'of use' to others, rather than simply a burden or source of concern.

### 4.1 Symptomatic relief

The mechanism through which TAVI made an impact on QoL was, for most participants, through a reduction in the burden of physical symptoms which were experienced daily. Many participants reported an improvement in their breathing as the best thing about TAVI. The magnitude and pace of improvement varied. Some participants experienced an immediate life changing and transformational improvement in their physical health, whilst others experienced a slower improvement.

The scale of improvement was mediated by the existence of other health conditions. For example, several participants had hoped for a greater improvement in their symptom burden, but other health conditions such as Chronic Obstructive Pulmonary Disease (COPD), or morbid obesity, appeared to counteract improvements after TAVI as the symptoms associated with these non-cardiac conditions were not relieved.  Living with several comorbidities meant that it was sometimes challenging for participants to evaluate the impact of TAVI upon their own symptom burden and QoL. Participants explained that it was difficult to understand which physical symptoms could be attributed to which health condition. The reduction in symptom burden changed some participants' views about the desired length of their life which emphasises the significant impact of symptoms on psychological well-being and QoL. Others experienced a less dramatic change in their symptom burden but still reported some improvement. Many of the participants reported experiencing less fatigue after TAVI. Other reported that they were less short of breath and therefore able to go about their daily activities at a faster pace, which was a positive change. The improvement in their health influenced their mood, with participants and their family explaining that they were less short-tempered. No participants openly expressed regret about their decision to have TAVI, but one participant provided a contrasting view characterised by ambivalence; they acknowledged that the intervention had extended their life but their ongoing symptom burden had not changed to the extent that they had hoped.

For those who did not experience the expected relief of physical symptoms the mechanism of improvement following TAVI was slightly different. For some TAVI functioned as a 'bridge' to other health interventions which had previously been unavailable due to poor health. One example was access to elective surgical procedures, such as a hip replacement, which if successful, would potentially further improve QoL. For others it was the notion that everything possible had been done to try and improve their health. Another participant mentioned that the potential health improvement following TAVI would enable them to continue their role as a carer for their spouse.

TAVI when successful, often enabled recipients to regain a level of functional capacity they had enjoyed at a younger age.  Several participants experienced what they described as the ‘turning back of time’ or a 'new lease of life'.

### 4.2 Feeling safe

Many participants described how TAVI offered them a feeling of ‘being safe’, ‘more confident’ with ‘peace of mind’. The immediate threat of death was removed and their heart was 'repaired' meaning that they could participate more fully in day-to-day activities. The significant reduction in symptoms that most participants experienced signalled a tangible improvement in their heart function which contributed to feelings of security. Even for those who did not experience a significant change in their symptoms there was a perception that everything had been done to try and improve their health. The increase in the level of confidence regarding their physical health enabled participants to return to some of the activities that had been dropped such as taking holidays. This enabled a fuller life and greater participation and engagement in social activities.

## 3.2 Self-Reported Quality of Life SF-12, EQ5-VAS

Tables 3 and 4 show the mean, standard deviation, quartiles scores for the PCS and MCS subscales of the SF12 scale and the EQ-5D VAS instruments; and range scores for the SF12 subscales only. Corresponding population norms are also presented for comparison.

Insert Tables 3, 4 about here please

At T1 (baseline), population normative values were already exceeded in the mean SF-12 PCS scale by 6 out of 45 patients (13.3%); in the SF-12 MCS scale by 16 out of 45 patients (35.6%); and in the EQ5D-VAS scale by 8 out of 45 patients (17.8%). At T2 (1 month post-TAVI), these corresponding proportions had risen to 20 out of 40 patients (50.0%) in the SF-12 PCS scale; to 21 out of 40 patients (52.5%) in the SF-12 MCS scale; and to 15 out of 40 patients (37.6%) in the EQ5D-VAS scale. At T3 (3 months post-TAVI), these corresponding proportions had stabilised to 20 out of 39 patients (51.3%) in the SF-12 PCS scale; to 17 out of 39 patients (43.6%) in the SF-12 MCS scale; and to 15 out of 40 patients (37.6%) in the EQ5D-VAS scale.

Single-sample t-tests show evidence that mean SF-12 PCS, SF-12 MCS and EQ5D-VAS scores were significantly lower than corresponding population normative values at T1 (baseline) (p<0.001 for PCS; p=0.001 for MCS; p<0.001 for EQ5D-VAS). At T2 (1 month post-TAVI), sample scores on the SF-12 PCS and SF-12 MCS scales had recovered to the extent that there was no evidence that they were significantly different from corresponding normative scores (p=0.644 for SF-12 PCS; p=0.924 for SF-12 MCS). This effect was maintained at T3 (3 months post-TAVI) (p=0.710 for SF-12 PCS; p=0.714 for SF-12 MCS).

EQ-5D-VAS scored remained significantly below corresponding normative values at time point 2 (p<0.001) and time point 3 (p=0.026).

Changes in quartile scores followed similar patterns as mean scores; with improvement to normative values in SF-12 PCS and SF-12 MCS quartiles being generally achieved by the 2nd or 3rd time points. EQ-VAS quartile scores did not increase to normative values by time point 3.

Table 5 shows scores on SF-12 and EQ5D VAS and the proportion of improvement at three time points respectively.

Table 5 about here please

These data show that at T3 over two thirds of the sample had improved in the SF12-PCS, SF12 MCS and EQ-5D scores, compared with baseline scores. Repeated measures ANOVAs conducted on all three measures revealed evidence for significant changes in time in SF12-PCS ($F_{1.58,45.8}=5.76$; $p=0.010$); in SF12-MCS ($F_{2,48}=5.98$; $p=0.004$); and in EQ5D-VAS ($F_{1.54,44.6}=7.15$; $p=0.004$). All such effects were moderate in magnitude (partial-$\eta^2=0.166$ for SF12-PCS; partial-$\eta^2=0.171$ for SF12-MCS; partial-$\eta^2=0.198$ for EQ5D-VAS).

The magnitude of mean improvement in QoL was greater between T1 and T2 than between T2 and T3; and more patients showed an improvement of any magnitude between T1 and T2 than between T2 and T3. Bonferroni-adjusted pairwise comparison tests revealed SF-12 PCS scores at T1 to be significantly different from scores at T2 ($p=0.018$). SF-12 MCS scores at T1 were significantly different from scores at T3 ($p=0.005$). EQ5D-VAS scores at T1 were significantly different from scores at T3 ($p=0.005$).

## Discussion

TAVI is set to become a mainstream treatment in many high and middle-income countries  but decisions about who should receive this expensive treatment remain contentious. Whilst it is important to identify the clinical benefits of TAVI, it is equally important to understand the impact of TAVI on self-reported QoL. Most studies,[8-9] report improvements in the average QoL scores recorded after TAVI compared to baseline. However these data do not fully explain how and why changes take place.

To our knowledge this is the first mixed-methods study that provides a detailed account of TAVI patients' perspectives on the impact of TAVI on QoL during the first 3 months of recovery. There is limited published literature for direct comparison,[15] making this study an important first step in understanding patients' views about the impact of TAVI.

Before TAVI consultation, participants had a limited awareness about the likelihood of AS shortening their life-span. A lack of understanding  amongst patients about their diagnosis, and/or prognosis, is not uncommon, as the heart failure trajectory is unpredictable, and conversations about life expectancy are challenging for all those involved.[29]  The pre-TAVI consultation may have been the first time that such information has been shared bringing 'mortality' to the forefront of discussions as. a potential risk associated with TAVI, although  such predictions can only be moderately accurate.[30] The decision to have TAVI was influenced by the participants' perceived QoL. Those with a significant symptom burden felt that they had little choice. This finding is supported by others.[14] Over a third of participants had SF-12 MCS scores, greater than population norms, at baseline which may reflect an improvement in mental health due to TAVI treatment being imminent after several months on the waiting list.

Findings illustrate the considerable symptom burden endured by participants leading up to TAVI. Shortness of breath was experienced by many participants and is reported by other TAVI recipients.[14] The symptom burden restricted functional and social activities leading to a negative impact upon QoL.

Patients perceived TAVI as a treatment option that extended their life.. Many participants expressed their relief at surviving TAVI and viewed it as transforming their QoL. Questionnaire data showed that a large proportion of participants had improved QoL scores post TAVI compared to baseline.

Regardless of the outcome, having the TAVI procedure changed participants' views about their life. Change was mediated through two mechanisms, although not all participants experienced both. Firstly, most participants experienced symptomatic relief, which provided tangible proof of an improvement in their heart health. Participants often reported increased energy levels and mobility leading to greater independence in daily living and leisure activities. Improvements in the QoL scores on the SF-12 and EQ5D VAS supported patients’ accounts. Those patients diagnosed with other co-morbidities did not tend to report a noticeable improvement. This is an important consideration in choosing those who may benefit most from TAVI. Comorbidities in people with AS are especially prevalent, with up to 84% and 59% of patients with AS living with frailty or COPD respectively.[33] Little is known about the impact of comorbidities on survival, QoL, readmission rates and functionality after TAVI. Geriatric syndromes such as frailty, falls, cognitive decline and delirium impact on QoL and recovery following TAVI.[33]

Secondly participants reported feeling 'safe' as they perceived that they no longer faced imminent death. This increased their feelings of confidence and security. This response is understandable as participants had survived both the waiting time, which is known to be anxiety- provoking,[14,31] and a relatively risky medical procedure.[9]

Data from the SF-12 and EQ5D-VAS showed statistically significant improvements across all QoL domains at 3 months compared to baseline, which reflects findings of other studies.[11] The magnitude of improvement is likely to be clinically significant when examined in the context of other studies using the SF-12;[34] however the study was not powered with this in mind, but rather to support the qualitative data set.

As with all studies there are limitations that should be considered. The main one is that the sample was taken from a single regional centre but findings may be transferable across similar contexts. A major strength of the study is the triangulation of research methods which provide a robust account of the TAVI recovery experience with data from longitudinal in-depth interviews and validated outcome measures. Future research should focus upon how the physical and mental components of QoL interact. The development of a disease specific QoL measure for this population is recommended.

There are several clinical implications arising from this study. Health professionals could use the TAVI consultation as a trigger for discussions about advanced care planning and to explore patients' beliefs and preferences concerning quality and quantity of life. A simple survey administered in advance of the TAVI consultation could serve as a mechanism to facilitate such discussions. Patients should have the option of having family or friends present during the TAVI consultation which may be distressing and staff may need additional education about communication skills to support them to broach difficult conversations. The timing of baseline QoL measurement should be carefully considered as being taken off a TAVI waiting list may have an effect upon baseline measurements. Patients' accounts illustrate how TAVI impacts on QoL and may be integrated into information resources to support the TAVI decision making process.

## Conclusion

Findings provide an account of TAVI recipients view about the impact of treatment on their QoL. TAVI was of variable benefit, producing considerable improvements in either mental or physical health in many participants, while a smaller proportion continued to deteriorate. Improvements in either mental or physical health influenced the opportunity and motivation to engage and participate in activities of daily living. The presence of other comorbidities influenced the scope of improvement following TAVI.

## Implications for practice

- The TAVI consultation, which includes the communication of prognostic/diagnostic information, may influence levels of self-reported QoL recorded afterwards.
- Future research should examine how multimorbidity influences TAVI outcomes such as QoL, mortality, morbidity and readmission, to improve understanding of who might benefit most from TAVI.
- Health professionals could use the TAVI consultation as a trigger for discussions about advanced care planning and patients’ beliefs and preferences concerning quality and quantity of life. A simple survey could be administered in advance of TAVI consultation to better understand patients’ views and preferences about quality and length of life.

- Discussions about diagnosis and prognosis are potentially distressing. Patients should have the option of having family or friends to accompany them during the TAVI consultation. Staff may need additional education to support them in such difficult conversations.
- There is evidence that most patients undergoing the TAVI procedure report significant increases in QoL. Physical and mental improvement appear to occur at different rates.

Table 1. Descriptive summary of sample characteristics

| Variable | Mean (SD) |
|---|---|
| Age (years) | 81.7 (7.36) |
| MMSE transformed score | 47.7 (10.5) |
| Variable | Frequency (valid %) |
| Gender | |
| Male | 21 (39.6%) |
| Female | 32 (60.4%) |
| Support level | |
| Carer | 21 (39.6%) |
| No carer | 32 (60.4%) |

| | |
|---|---|
| New York Heart Association Classification | |
| I | 0 |
| II | 10 (18.9%) |
| III | 36 (67.9%) |
| IV | 7 (13.2%) |

**Table 2: Numbers of patients and type of data collected at each time point**

| Data collection | Time points | | |
|---|---|---|---|
| | T1. Pre-TAVI data collected | T2. 1 month post-TAVI data collected | T3. 3 month post-TAVI data collected |
| SF-12 v2 | 45 | 40 | 39 |
| EQ-5D | 45 | 41 | 40 |
| Qualitative interview | n/a | 46 | 43 |

Table 3: Comparison of SF-12 component scores pre and post TAVI with Population

| | SF-12 PCS (Norms 75+) | SF-12 T1 PCS | SF-12 T2 PCS | SF-12 T3 PCS | SF-12 MCS (Norms 75+) | SF-12 T1 MCS | SF-12 T2 MCS | SF-12 T3 MCS |
|---|---|---|---|---|---|---|---|---|
| Mean | 38.68 | 32.06 | 38.04 | 39.28 | 50.06 | 43.09 | 50.22 | 50.70 |
| 25th Percentile | 29.37 | 25.73 | 32.22 | 31.59 | 40.48 | 32.00 | 42.88 | 42.09 |
| 50th Percentile | 38.68 | 31.70 | 38.04 | 38.55 | 53.53 | 41.52 | 51.36 | 49.97 |
| 75th Percentile | 47.77 | 37.96 | 42.87 | 46.02 | 58.89 | 55.28 | 59.13 | 60.12 |
| Standard Deviation | 11.04 | 8.05 | 8.66 | 10.05 | 10.94 | 13.53 | 10.66 | 10.80 |
| Range | 17.0 – 57.0 | 18.8 - 52.2 | 18.9 - 56.7 | 17.8 - 56.7 | 22.0 – 69.0 | 20.5 - 69.6 | 21.8 - 64.5 | 26.1-66.5 |

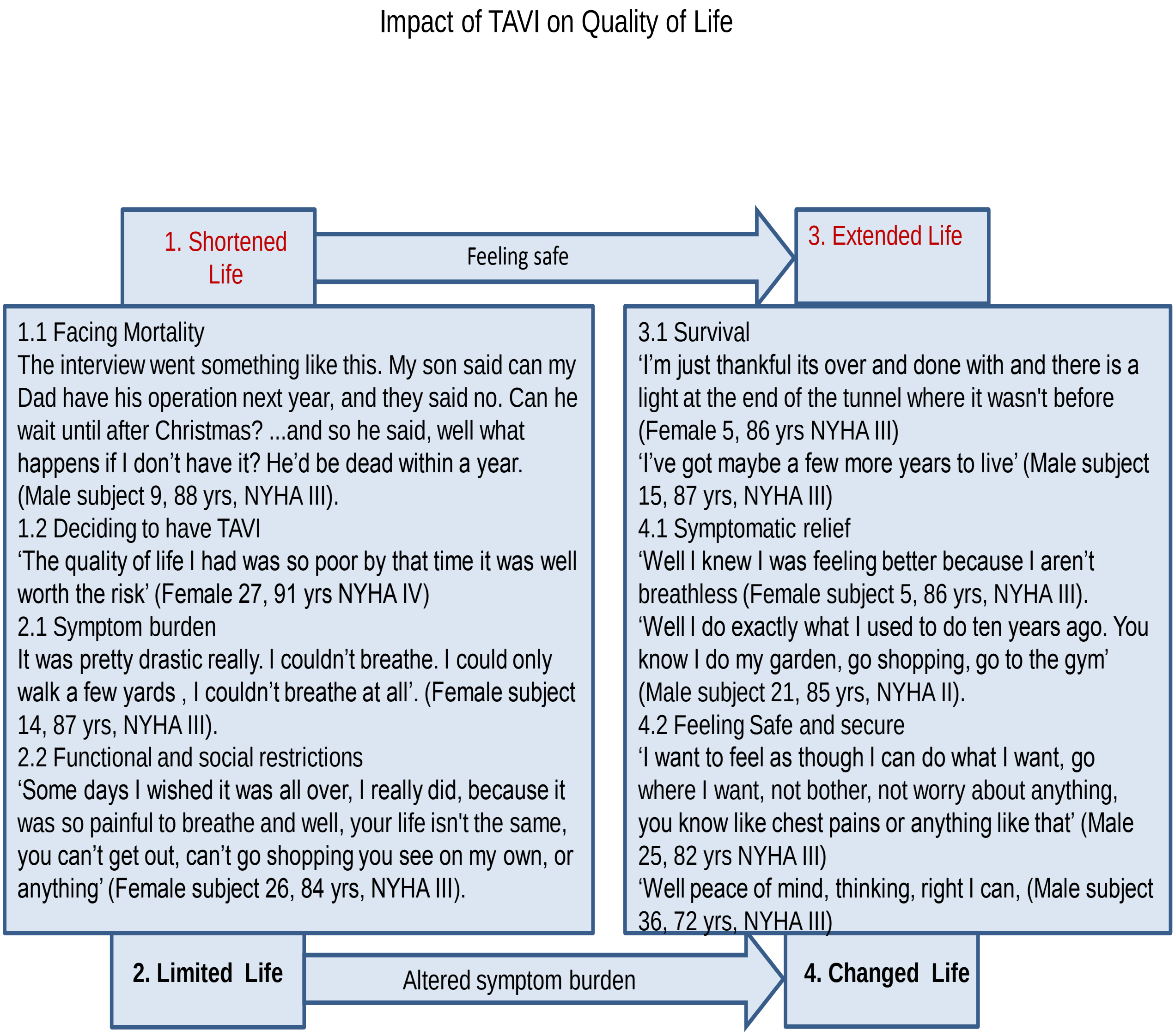
Norms of adults aged 75 years+ (mean age of sample 81.7 years). PCS (Physical Component Scale) MCS (Mental Component Scale)

Table 4: Comparison of EQ5D-VAS component scores pre and post TAVI with Population Norms of adults aged 70 years+ (mean age of sample 81.7 years)

| | EQ5D-VAS (Norms 70+) | EQ5D-VAS T1 | EQ5D-VAS T2 | EQ5D-VAS T3 |
|---|---|---|---|---|
| Mean | 79.0 | 57.2 | 66.3 | 73.3 |
| 25th Percentile | 73.5 | 50.0 | 51.3 | 61.3 |
| 50th Percentile | 80.0 | 50.0 | 62.5 | 75.0 |
| 75th Percentile | 92.0 | 75.0 | 80.0 | 80.0 |
| Standard Deviation | 22.6 | 18.7 | 17.5 | 15.7 |

Table 5. Proportions of patients showing improvement on outcome measures between time points

| Measure | Improvement: T1 – T2 | Improvement: T2 – T3 | Improvement: T1 – T3 |
|---|---|---|---|
| EQ5D-VAS | 20/37 (54.1%) | 19/36 (52.8%) | 24/34 (70.6%) |
| SF12-PCS | 26/37 (70.3%) | 17/36 (47.2%) | 24/34 (70.6%) |
| SF12-MCS | 25/37 (67.6%) | 18/36 (50.0%) | 27/34 (79.4%) |



Impact of TAVI on Quality of Life

1. Shortened Life

Feeling safe

3. Extended Life

1.1 Facing Mortality

The interview went something like this. My son said can my Dad have his operation next year, and they said no. Can he wait until after Christmas? ...and so he said, well what happens if I don't have it? He'd be dead within a year. (Male subject 9, 88 yrs, NYHA III).

1.2 Deciding to have TAVI

'The quality of life I had was so poor by that time it was well worth the risk' (Female 27, 91 yrs NYHA IV)

2.1 Symptom burden

It was pretty drastic really. I couldn't breathe. I could only walk a few yards , I couldn't breathe at all'. (Female subject 14, 87 yrs, NYHA III).

2.2 Functional and social restrictions

'Some days I wished it was all over, I really did, because it was so painful to breathe and well, your life isn't the same, you can't get out, can't go shopping you see on my own, or anything' (Female subject 26, 84 yrs, NYHA III).

3.1 Survival

'I'm just thankful its over and done with and there is a light at the end of the tunnel where it wasn't before (Female 5, 86 yrs NYHA III)

'I've got maybe a few more years to live' (Male subject 15, 87 yrs, NYHA III)

4.1 Symptomatic relief

'Well I knew I was feeling better because I aren't breathless (Female subject 5, 86 yrs, NYHA III).

'Well I do exactly what I used to do ten years ago. You know I do my garden, go shopping, go to the gym' (Male subject 21, 85 yrs, NYHA II).

4.2 Feeling Safe and secure

'I want to feel as though I can do what I want, go where I want, not bother, not worry about anything, you know like chest pains or anything like that' (Male 25, 82 yrs NYHA III)

'Well peace of mind, thinking, right I can, (Male subject 36, 72 yrs, NYHA III)

**2. Limited Life**

Altered symptom burden

**4. Changed Life**

**Figure 1. Patients' perceptions of the impact of TAVI on quality of life**

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