



The impact of transcatheter aortic valve implantation on quality of life: A mixed methods study



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ARTICLE INFO

Article history:

Received 11 March 2017

Received in revised form

14 August 2017

Accepted 15 August 2017

Available online 3 October 2017

Keywords:

Aortic stenosis

Transcatheter aortic valve implantation

Quality of life

Mixed methods

Rehabilitation, interview, qualitative

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.

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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 1992⁵ 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

Funding source: This paper presents independent research funded by the National Institute for Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number PB-PG-1208-18173). The views expressed are those of the authors and not necessarily those of the National Health Service, the NIHR or the Department of Health. This report contains anonymised excerpts from interviews and discussions conducted during the research.

Disclosures: Nothing to disclose.

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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 ICF¹⁹ 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 Examination²² (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 disagreement 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-5D²⁸ (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

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