Protocol Study

Optimizing Self-Care in Cardiovascular Patients Undergoing Transcatheter Aortic Valve Implantation: A Systematic Review Protocol

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Abstract

Introduction. Optimizing a self-care approach to support health maintenance in patients with aortic valve stenosis (AVS) who require minimally invasive transcatheter aortic valve implantation (TAVI) before and after the procedure could promote faster and more effective recovery. Additionally, this methodology may improve the perceived health-related quality of life (HRQoL) in the patients undergoing treatment, contributing to better overall outcomes through health promotion practices and disease management. This review's primary objective is to investigate self-care's effectiveness in enhancing quality of life.

Methods and materials. The literature review protocol follows PRISMA guidelines and uses the PIO framework for search terms. Studies will be identified through significant databases (PubMed, Scopus, CINAHL, Web of Science, and Cochrane Library). Methodological quality and bias risk will be assessed with JBI Critical Appraisal Tools. This review protocol has been registred on PROSPERO (No. CRD420250655531).

Results. The emerging findings could potentially contribute to refining current theories on the indications for using self-care

interventions to improve the HRQoL of patients undergoing TAVI.

Discussion and conclusions. Future implications for research and clinical practice should adopt an increasingly targeted and focused approach in using self-care interventions to enhance the health-related quality of life of patients undergoing TAVI, both in terms of symptom recognition and disease management pre- and post-procedure. This systematic review will comprehensively examine the effects of the implementation of self-care methodologies on improving the quality of life in post-TAVI patients.

Keywords: Self-Care, Transcatheter Aortic Valve Intervention, Health-Related Quality Of Life, Systematic Review, Aortic Valve Stenosis.

Introduction

Aortic stenosis (AS) is a condition where the aortic valve narrows, causing hemodynamic issues and severe clinical effects. Due to increased life expectancy, AS is a significant global health challenge, especially in high-income countries. It affects around 2.3% of the global population.[1,2] In Europe and North America, AS is the most common valvular heart disease, affecting 2% to 7% of people aged 65 and older.[1] Symptoms like angina, dizziness, dyspnea, and fatigue severely impact functional capacity and quality of life impacting mobility, work productivity, and daily activities.[3,4] Until the early 21st century, surgical aortic valve replacement (SAVR) was the standard treatment for AS.[2] However, standard treatment cannot be a viable option for a considerable proportion of patients due to advanced age, frailty, and multiple comorbidities, which increased operative risk.[5] In response to these limitations, TAVI was introduced in 2002 as a less invasive alternative for individuals deemed ineligible for SAVR. This innovative approach marked a paradigm shift in the treatment of high-risk patients suffering AS, offering a viable solution with reduced procedural morbidity. Multiple clinical trials have demonstrated that TAVI is associated with decreased all-cause mortality, reduced cardiovascular morbidity, and lower hospital readmission rates.[6-8] Recent evidence supports not only the non-inferiority but, the superiority of TAVI compared to SAVR, even in patients with a lower surgical risk profile, including younger individuals with longer life expectancy.[9,10] TAVI has largely replaced SAVR for AS treatment due to quicker recovery. Self-care strategies, including a healthy lifestyle, balanced diet, avoiding harmful habits, and symptom monitoring, are crucial for improving outcomes. These strategies can reduce healthcare use before the procedure, enhance readiness for TAVI, and improve recovery, leading to fewer complications and better long-term quality of life. However, the use of this strategy in patients undergoing TAVI remains limited and has been insufficiently studied. Therefore, this review is necessary to provide a theoretical foundation for further research.

The aim of this protocol is to conduct a systematic review to investigate the effectiveness of self-care maintenance, self-care monitoring e self-care management in improving the quality of life in patients with severe aortic stenosis undergoing TAVI.

Our research question is: Does implementing self-care strategies in patients undergoing TAVI improve their quality of life?

We hypothesize that adopting self-care approaches both before and after the procedure in patients eligible for and treated with TAVI may enhance their self-management capabilities and overall well-being.

Methods and Materials

Eligibility Criteria

This preliminary review protocol will ensure that the selected articles align with the objectives of the systematic review. The results will be presented to provide a clear and useful message

to the scientific community. The systematic review will follow the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines. Specifically, the Preferred Reporting Items for Systematic reviews protocols and Meta-Analyses (PRISMA-P) guidelines[11,12] were used to develop the review protocol [see the PRISMA checklist in the supplementary files], while PRISMA guidelines will be applied in the final review manuscript.

The inclusion criteria for this systematic review will include all studies published in peer-reviewed journals that address the self-care question in patients undergoing TAVI (primary studies such as observational, cohort, cross-sectional, quasi-experimental, randomized controlled trials (RCTs), non-randomized controlled trials, and intervention studies). Only studies published in English and Italian will be included in this review. This decision will be made to ensure consistency in data interpretation, address resource constraints related to translation, and focus on the primary language of high-impact academic publications in the field. The exclusion criteria will outline the parameters to maintain the focus and integrity of the review. Studies investigating TAVI patients that do not address self-care, self-management, self-monitoring, compliance or adherence will be excluded. Unpublished studies, including conference abstracts, theses, and study protocols, will also be excluded. Similarly, editorials and opinion articles lacking primary data, animal studies, and experimental or laboratory models will be excluded from the scope of this review. Additionally, studies focused exclusively on pediatric populations (<18 years) will not be considered. Unpublished studies and theses generally do not undergo rigorous peer-review evaluation, raising concerns about their reliability and scientific validity. Conference abstracts, although useful for initial insights, are typically brief and fail to provide the depth of analysis or complete data necessary for solid conclusions. Experimentation protocols, on the other hand, outline planned methodologies but do not offer actual results or evidence, limiting their relevance for evidence-based assessments. Studies published in languages other than English and Italian will be excluded.

We acknowledge that the exclusion of non-English studies and unpublished or grey literature may introduce some degree of language and publication bias. However, this approach will be adopted to prioritize methodological rigor and feasibility. These criteria will be carefully applied to ensure that the review includes a comprehensive range of relevant studies.

Information Sources

This review protocol used the PIO (Population-Intervention-Outcome) framework to ensure a robust methodological approach that directly addresses our research question. To conduct a comprehensive review, carefully designed search terms will be identified and applied across multiple databases. This approach will enable a broad exploration of resources, including MEDLINE (via PubMed), CINAHL (via EBSCO), the Cochrane Library (via Embase), Web of Science, Scopus, and Embase. All relevant studies up to the extraction date will be included. Given the relevance of our research question, the PIO framework will allow us to clearly define the study area (Table 1). Supplementary Material 1 presents the key terms used in the PubMed database to conduct the search. This search string will then be adapted for the other selected databases. Subsequently, we will use Rayyan software (Rayyan Enterprise, Cambridge, MA, USA, https://www.rayyan.ai/ (accessed on February 8, 2024)) to eliminate duplicates.[13]

Table 1. Framework PIO.

Problem	Patients with severe aortic stenosis who require aortic valve replacement through the minimally invasive TAVI (transcatheter aortic valve intervention) technique.
Intervention	Adoption of self-care strategies, including structured therapeutic education, self-monitoring of symptoms, adherence to pharmacological treatment, lifestyle modifications and pre- and post-procedure educational support programs.
Outcome	Improvement of quality of life. Secondary outcomes include: increased self-efficacy, reduced symptoms, improved medication adherence, lower incidence of rehospitalizations, and faster functional recovery.

Search Strategy

The systematic search was developed following the PIO framework described in Table 1.

The quality of the included studies will be assessed using the Joanna Briggs Institute (JBI) Critical Appraisal Tools, including those for Case-Control Studies, Case Reports, Cohort Studies, Case Series, Quasi-Experimental Studies and Randomized Controlled Trials.[14] Different checklists will be used depending on the study design. They consist of multiple questions; for each question, only one response can be selected from the available options: yes, no, unclear, or not applicable. The manuscript will adhere to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA) guidelines.[12,15] Data extraction and analysis will be conducted in two phases. Initially, two authors will independently screen the titles and abstracts of the retrieved literature using the Rayyan software to identify potential articles for inclusion in the systematic review.[16] Any discrepancies will be resolved through discussion among the authors, with the involvement of a third author if conflicts persist. Subsequently, the same three authors will independently read the full texts of the selected articles and perform data extraction. To ensure high quality and reliability in the systematic review, a rigorous evaluation process will be implemented. This process will carefully assess each included study's methodological robustness and relevance. Two independent researchers will extract the following variables:

- Author(s)
- Year and country of study
- Study type
- Population
- Setting
- Intervention(s)
- Primary and secondary outcomes
- Results

Data Collection Process

A PRISMA-based flow diagram will be included to visually summarize the review process, including the selection and exclusion of studies. This review will adopt a systematic approach to data extraction, utilizing a standardized data extraction tool. Relevant data, including study design, participant demographics, interventions, and outcome measures, will be collected from

each included study. For quantitative data, results will be synthesized through a narrative summary. For qualitative data, thematic synthesis will be employed to identify recurring patterns and insights. Studies will be categorized based on their respective levels of evidence, facilitating a comparative assessment of the strength and reliability of their findings. This mixed-methods synthesis approach will integrate qualitative and quantitative results to provide a comprehensive understanding of the impact of the use of self-care strategies to improve the quality of life of patients with AS and who are undergoing TAVI.

Study Risk of Bias Assessment

The risk of bias assessment will be conducted comprehensively for each study by two or more independent reviewers using the Risk Of Bias In Non-Randomized Studies of Exposures (ROBINS-E) tool specifically designed for observational studies. Any discrepancies arising during the assessment will be resolved through discussion to reach a consensus among reviewers, with the involvement of a third reviewer if necessary. The ROBINS-E tool evaluates seven domains of bias, including confounding factors, bias in the measurement of exposures, selection bias, post-exposure intervention bias, bias due to missing data, bias in outcome measurement, and bias in the selection of reported results. Each domain will be assessed individually, and the cumulative evaluations will contribute to an overall judgment regarding the study's risk of bias, classified as low, some concerns, high, or critical.

Synthesis methods

In accordance with the JBI data extraction model, two or more independent reviewers will conduct data extraction for all full-text articles included in the review, ensuring comprehensive data acquisition for each study. Extracted information will include: (I) author(s) and year of publication, (II) country of origin, (III) study objective, (IV) sample characteristics (e.g., population and sample size), (V) study methodology and design, (VI) type of intervention, (VII) outcomes, and (VIII) main results. All the information will be recorded in a Microsoft Excel® spreadsheet for the creation of summary tables. The study results will be summarized narratively, focusing on identifying patterns

and themes within the data. This summary will also be used to highlight areas for future research. Quantitative data, where available, will be presented descriptively, while qualitative findings will undergo thematic analysis to identify recurring insights. The narrative synthesis will follow a structured framework, exploring relationships within and across studies and mapping the results to identify key themes and patterns. The included studies will then be grouped based on intervention type, population characteristics, and measured outcomes. If sufficiently homogeneous data are available, we will attempt to perform a meta-analysis using the RevMan 5.3 software. For the meta-analysis, a random-effects model will account for potential variability across studies, including differences in study design, intervention types, and populations. Heterogeneity will be assessed using the I2 statistic, with thresholds of 25%, 50%, and 75% indicating low, moderate, and high heterogeneity, respectively. Sensitivity analyses will also be conducted to assess the robustness of the aggregated results. By combining a structured narrative synthesis with a potential meta-analysis, this systematic review aims to provide a comprehensive and transparent evaluation of the available evidence while addressing the inherent variability among the included studies.

Measures and Outcomes

To ensure a comprehensive assessment of self-care optimization in patients undergoing TAVI, this review will consider the primary outcome of interest: health-related quality of life (HRQoL) through adopting self-care, adherence, and management and compliance strategies.

Expected Results: Impact of the Review

This systematic review will include original studies on cardiac patients (≥18 years old) post-TAVI. The impact of self-care interventions will be evaluated to assess HRQoL. To ensure a structured and transparent approach to the systematic review process, this review will follow the conceptual framework "The Situation-Specific Theory of Heart Failure Self-care".[17] This framework provides a robust guide for synthesizing evidence across studies, allowing for a comprehensive evaluation of the use of self-care, self-management, self-monitoring,

and adherence strategies to improve quality of life. If optimising self-care strategies effectively improves HRQoL, it could represent a relatively low-cost and highly accessible intervention strategy to enhance overall healthcare for cardiac patients. Furthermore, our findings could be used to support healthcare professionals in planning targeted interventions for managing patients undergoing TAVI.

Discussion: Outcome and Prioritization

The systematic review protocol primarily aims to assess health-related quality of life (HRQoL) among patients undergoing TAVI, emphasizing the integration of self-care strategies in the pre- and post-procedure phases.[18] HRQoL has been prioritized for its comprehensive reflection of physical, psychological, and social well-being, closely aligning with patient-centered clinical practice.[19] The review will specifically examine whether structured, educational, and behavioural self-care interventions can effectively improve patient autonomy, adherence to treatment regimens, and overall quality of life. These improvements may also positively impact family well-being. Given the increasing implementation of digital health technologies, remote monitoring and digitally supported educational programs offer promising avenues to improve patient engagement in self-care.[20,21] Secondary outcomes will be the assessment of adherence to self-care interventions, assessing the consistency with which patients adopt and maintain recommended self-care behaviors. The insights from this the systematic review will help healthcare professionals, particularly nurses, to integrate effective self-care interventions into routine clinical practice, thereby optimising both patient outcomes and healthcare delivery models.[22,23] Overall, the findings from this the systematic review will provide valuable information for healthcare professionals, particularly nurses, highlighting how structured self-care education can be effectively integrated into clinical routines, improving patient outcomes and contributing to the development of new care delivery models in patients undergoing TAVI.

Implications for Clinical Practice

Patients and caregivers must be educated on self-care strategies for promoting patient-

centered care. This education empowers individuals to effectively manage symptoms before and after the TAVI procedure, which is essential for improving overall health outcomes. Furthermore, it plays a significant role in reducing the need for unnecessary hospital admissions, as patients are better equipped to handle their condition independently. Implementing self-care methodologies is particularly beneficial in facilitating a faster post-procedural recovery. By encouraging early mobilization and harnessing the patient's strengths, these strategies help avoid prolonged hospital stays, which are often caused by complications such as immobility. Moreover, these interventions allow patients to regain their autonomy more quickly, contributing to their physical and emotional well-being. The positive effects extend beyond physical recovery as patients become more independent and engaged in managing their health. Self-care strategies foster a sense of empowerment, leading to a gradual but significant improvement in quality of life. This ongoing progress enhances the patient's overall well-being and reduces the burden on healthcare systems, as it lowers the likelihood of readmissions and the need for intensive medical interventions. Ultimately, education on self-care strategies is a key factor in ensuring the long-term success of TAVI and supporting patients in achieving optimal recovery and quality of life.

Limitations

Although the inclusion of only English-language studies may introduce a linguistic bias, this choice was made to facilitate a more accessible and coherent review of the relevant literature, given that a substantial proportion of high-quality evidence on the topic is published in English. The inclusion of studies in Italian was also considered important to capture contributions from local research that may be pertinent to the subject. While Italian-language literature may not offer the same broad international scope or consistently high standards as English-language publications, its inclusion aimed to ensure a more comprehensive evaluation of the available evidence within the selected linguistic framework. Nonetheless, it is recognized that this approach may have excluded valuable studies published in other languages, which could have added further depth to the review. Furthermore, the variability in self-care protocols and outcome measures across the included studies reflects the dynamic and heterogeneous nature of practices in this field. Although such heterogeneity presents challenges for direct comparison of results, it also underscores the flexibility and adaptability of interventions across diverse contexts. While this variability may limit the extent to which findings can be generalized, it nonetheless allows for the identification of meaningful patterns and insights that can inform future research and clinical application.

Meta-Bias

This systematic review will account for potential meta-biases, including a tendency to favour studies with positive findings and linguistic bias due to including studies solely in English and Italian. Moreover, selection bias and heterogeneity in self-care protocols may influence the results. However, a highly sensitive method will be employed to critically select and analyze the included articles, ensuring an accurate and comprehensive assessment of the available evidence.

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