

Assessment of the quality of life of patients after implantation of ventricular long-term assist device LVAD - Heart Mate 3

Streszczenie w języku angielskim

Introduction. Despite breakthroughs in diagnostics, prevention, and therapeutic management, including the emergence of new treatment methods, heart failure (HF) remains the leading cause of death among all circulatory system diseases. In the United States, the number of patients is estimated at nearly 2% of the population. A meta-analysis based on echocardiographic screening in the general population—including previously undiagnosed cases—showed that the prevalence of heart failure of all types in developed countries is approximately 11.8% in people aged 65 and older. In Poland, approximately 1.2 million people suffer from HF, of whom approximately 140,000 die annually. This progressive disease, with exacerbations, often results in repeated hospitalizations and the need for modification of pharmacotherapy. Due to the aging nature of Polish society, studies indicate that the number of patients diagnosed with HF will continue to increase. Therefore, appropriate treatment is essential to improve quality of life and reduce mortality. The prognosis for HF remains unfavorable, and quality of life is significantly reduced. In cases of extremely advanced HF, the only treatment options are heart transplantation (HTX) or long-term mechanical circulatory support (MCS). Long-term MCS, depending on the patient's clinical condition, may be used as a bridge to transplantation, as a target therapy, or as a bridge to regeneration. Besides clinical condition, one of the most important aspects of functioning for patients with MCS is quality of life (QoL). b This therapy often enables a return to normal functioning, but it depends on many factors, such as optimal qualification, lack of complications, individual psychological support, support from loved ones, and patient involvement in the treatment process. Numerous challenges also arise during MCS treatment, both medical (anticoagulation therapy, device care, and device control line management) and psychological (loss of independence,

constant contact with the medical team, depression), often resulting in a deterioration of QoL psychologically. This emphasizes the importance of multidisciplinary support and the importance of assessing the QoL of patients qualified for this therapy and regular treatment evaluation. Health-related QoL in patients with HF is an important outcome because it reflects their daily functioning, while assessment tools enable the exploration of patients' perceptions of the impact of the disease on their daily lives, providing information that cannot be obtained directly from clinical measurements.

Study objective. The aim of the study was to comparatively analyze the quality of life of two groups of patients: those diagnosed with advanced heart failure – patients undergoing only pharmacotherapy and/or qualified and awaiting invasive treatment (heart transplantation / implantation of long-term mechanical circulatory support), and patients after implantation of a LVAD Heart Mate 3.

Material and Methods: The study was cross-sectional and observational. Three research tools were used: (1) a proprietary clinical questionnaire, which included sociodemographic variables (age, gender, education, weight, height, place of residence) and clinical variables in the form of self-report (LVAD pump model, date of implantation, controller parameters, comorbidities, estimated ejection fraction, physical activity); (2) the Minnesota Living with Heart Failure Questionnaire (MLHFQ) – a validated, standardized, and anonymous survey questionnaire translated into Polish, and the Short Form Survey SF-36 - a validated, standardized, and anonymous survey questionnaire translated into Polish after obtaining prior consent from the units distributing the survey (Appendix No. 2 and No. 3). The study was conducted from January 2023 to December 2024 (Appendix No. 4). The study involved 264 people, where the group with LVAD support included 142 patients, while the second group (control, comparative) consisted of 122 people, without MCS support, waiting for the decision to use the surgical method (HTx / LVAD) or to maintain pharmacological therapy.

Results. The analysis showed that individuals treated with MCS demonstrated higher QoL across all analyzed aspects. The effect size for differences was moderate (for pain assessment) or strong (for all other dimensions). The largest percentage of QoL variability was explained by having LVAD support. This determined the QoL assessment in 21.9%. The presence of comorbidities determined 5.1% of the QoL variability, and the remaining variables explained less than 5%. The QoL of the

subjects was higher the younger the subjects were. The presence of comorbidities was negatively associated with QoL – in people who had comorbidities (regardless of their type) and other comorbidities besides the ones mentioned, they showed lower QoL. The strongest association was noted with having LVAD support – this variable explained as much as 35.3% of the QoL variability. Variables: gender, place of residence, cause of HF and comorbidities such as: arterial hypertension, type II diabetes, cardiac arrhythmias, atherosclerosis, as well as the left ventricular ejection fraction were not associated with the assessment of the subjects' quality of life.

The MLHFQ model explained a total of over 30% of the variance in QoL, sk. $R^2 = 0.322$; $F(7) = 18.61$; $p < 0.001$., significant predictors of QoL turned out to be: age, having LVAD support, the presence of comorbidities, and physical activity. The QoL index model assessed according to the SF-36 explained nearly 40% of the variance, sk. $R^2 = 0.387$; $F(9) = 18.89$; $p < 0.001$. Significant predictors of the overall QoL index turned out to be age, having LVAD support, and physical activity. The physical dimension of quality of life in the MLHFQ model explaining the physical dimension of QoL was well fitted to the data and explained 36.3% of the variance in the dependent variable, sk. $R^2 = 0.363$; $F(9) = 17.18$; $p < 0.001$. The model explaining QoL on the mental dimension also fit the data well and explained approximately 36% of the variance in the dependent variable, skew $R^2 = 0.358$; $F(9) = 16.96$; $p < 0.001$.v The analysis confirmed the main effect for having MCS and physical activity. However, the interaction of both factors turned out to be insignificant. The main effects confirm the previous results. People with LVAD support ($M = 31.00$; $SE = 2.12$) have higher QoL than those without support ($M = 46.39$; $SE = 3.87$). Detailed analysis of differences in terms of physical activity showed that non-exercising individuals ($M = 53.15$; $SE = 1.86$) had significantly lower QoL than those exercising 1-2 times a week ($M = 42.96$; $SE = 2.84$; $p = 0.018$), 2-4 times a week ($M = 26.72$; $SE = 5.39$; $p < 0.001$), and daily ($M = 31.94$; $SE = 6.04$; $p = 0.006$). Individuals exercising 2-4 times a week had the highest QoL, which was significantly higher than those exercising 1-2 times a week ($p = 0.048$), and at a similar level to those exercising daily ($p = 1.000$).

Conclusions: Patients with LVAD implantation demonstrate higher QoL compared to those without MCS support. LVAD is a major determinant of QoL. Patients with HHeart Mate 3 assessed their physical and social functioning higher, experienced fewer limitations in role performance due to physical health and emotional issues, and experienced less pain. They demonstrated a greater sense of physical and mental health, as well as higher vitality. MCS use is associated with significantly higher QoL in all analyzed dimensions compared to those without support. The obtained results emphasize the importance of LVAD therapy as an effective method for improving QoL in patients diagnosed with end-stage HF, which is an important argument in making clinical decisions regarding qualification for advanced treatment. These findings underscore the importance of LVAD implantation in improving QoL in patients with HF and indicate the need for an individualized approach to patients, taking into account age and the presence of comorbidities. They also highlight the importance of telemonitoring in the care of patients with long-term MCS.