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Original paper

Quality of life after transcatheter edge-to-edge mitral valve repair – prospective observational cohort study

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ABSTRACT

Introduction: In patients with heart failure (HF), left ventricular remodeling can lead to secondary mitral regurgitation (SMR), which exacerbates HF symptoms and reduces quality of life (QoL). Transcatheter edge-to-edge repair (TEER), an interventional therapy for patients with SMR and high surgical risk, allows effective reduction of mitral regurgitation, leading to improved survival and quality of life. However, data on QoL outcomes post-TEER in the Polish population remain limited.

Material and methods: Aim of the study was to assess changes in QoL, measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ-12), in patients with severe SMR undergoing TEER. This prospective, single-center, observational study included 42 consecutive patients with severe SMR who underwent TEER. Main outcome was QoL change after 3 months.

Results: TEER was performed successfully in all cases without any major complications. An improvement in KCCQ-12 was observed in 38/42 (90.5%) of patients, mean KCCQ-12 score before and after 3-month was 41.9 ± 15.5 vs 61.4 ± 16.9, respectively ($p < 0.001$). The most significant improvement was observed among patients with lower initial QoL ($r = -0.462$; $p = 0.002$) and among patients without co-existing severe tricuspid regurgitation (Δ +21.7 vs +5.5; $p = 0.04$). During the follow-up period, only one patient required unplanned hospitalization.

Conclusions: TEER is associated with a significant improvement in QoL at 3-month follow-up in patients with severe SMR. These findings support TEER as a valuable treatment strategy, providing important data for clinical practice in Poland.

KEYWORDS

secondary mitral regurgitation, transcatheter edge-to-edge repair, heart failure, quality of life

STRESZCZENIE

Wstęp: U pacjentów z niewydolnością serca przebudowa lewej komory prowadzi do wtórnej niedomykalności mitralnej, co nasila objawy niewydolności serca i obniża jakość życia. Przezcewnikowa naprawa metodą brzeg-do-brzegu (*transcatheter edge-to-edge repair* – TEER), będąca metodą leczenia interwencyjnego u pacjentów z wysokim ryzykiem operacyjnym, umożliwia skuteczną redukcję niedomykalności mitralnej, prowadząc do poprawy przeżywalności oraz jakości życia. Jednak dane dotyczące jakości życia po TEER w populacji polskiej są nadal ograniczone.

Materiał i metody: Celem badania była ocena zmiany jakości życia, mierzonej za pomocą KCCQ-12 (Kansas City Cardiomyopathy Questionnaire), u pacjentów z ciężką wtórną niedomykalnością

mitralną, poddanych TEER. Badanie zostało zaprojektowane jako prospektywne, jednoośrodkowe badanie obserwacyjne i objęło dane 42 kolejnych pacjentów, u których wykonano TEER. Głównym punktem końcowym była zmiana jakości życia po 3 miesiącach obserwacji.

Wyniki: TEER przeprowadzono skutecznie we wszystkich przypadkach, bez poważniejszych powikłań. Poprawę wyniku KCCQ-12 zaobserwowano u 38 z 42 pacjentów (90,5%). Średni wynik KCCQ-12 przed zabiegiem i po 3 miesiącach wynosił odpowiednio 41,9 ± 15,5 oraz 61,4 ± 16,9 punktu ($p < 0,001$). Największą poprawę stwierdzono u pacjentów z niższą wyjściową jakością życia ($r = -0,462$; $p = 0,002$) oraz u chorych bez współistniejącej ciężkiej niedomykalności trójdzielnej (Δ +21,7 vs +5,5; $p = 0,04$). W okresie obserwacji tylko jeden pacjent wymagał nieplanowanej hospitalizacji.

Wnioski: Zabieg wiązał się z istotną poprawą jakości życia w 3-miesięcznej obserwacji u pacjentów z ciężką wtórną niedomykalnością mitralną. Uzyskane wyniki potwierdzają, że TEER jest skuteczną strategią terapeutyczną, i dostarczają istotnych danych dla praktyki klinicznej w Polsce.

SŁOWA KLUCZOWE

niedomykalność mitralna, przezcewnikowa naprawa zastawki mitralnej metodą brzeg-do-brzegu, niewydolność serca, jakość życia

INTRODUCTION

Secondary mitral regurgitation (SMR) is a prevalent cardiovascular disorder characterized by dysfunction of the mitral valve due to left ventricular remodeling, commonly seen in patients with heart failure (HF). Moderate to severe SMR affects up to 6% of individuals over the age of 65 [1]. Patients with SMR experience deterioration in the quality of life (QoL) due to HF symptoms (such as shortness of breath, orthopnea, fatigue or oedema), higher risk of HF decompensation and higher risk of death [2]. EVEREST II study published in 2011 proved safety and efficacy of percutaneous treatment compared to surgical treatment [3], and since then transcatheter edge-to-edge repair (TEER) started to be widely investigated. In 2018 COAPT study demonstrated that TEER not only reduces the severity of mitral regurgitation but also significantly improves survival and heart failure hospitalization rates among patients with SMR [4]. Based on those data, and ESC guidelines from 2021 and 2025, TEER is indicated for selected subgroups, especially in those patients with ventricular SMR and preferable anatomy.

Nowadays TEER is known as a safe and efficient method of treatment of SMR. There is an increasing amount of scientific evidence that TEER is associated with improvement in quality of life (QoL), worldwide, however data in Polish population remain limited. QoL is a complex and multifactorial parameter, which remains extremely important for individual patients, as it represents

not only lack of disease, but also is determined by possibility to achieve life goals and live in social and personal relations. QoL is considered so essential that one of the fundamental parameters used in cost-utility analyses is the quality-adjusted life year (QALY), which integrates both the quantity and quality of survival [5]. Data suggest that lower QoL is associated with higher mortality and highlight it's clinical utility [6]. There are numerous dedicated questionnaires assessing QoL; however, among patients with HF, the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) is most popular. It is reliable, validated, reproducible and relatively effortless for patients to complete [7]. Moreover, the KCCQ-12 is available in a validated Polish language version, making it an ideal questionnaire for use in this study. Due to its construction KCCQ-12 assesses main area of life affected by symptoms of HF. KCCQ-12 evaluates 4 key domains: physical limitations (PL), symptoms frequency (SF), self-reported quality of life (SL-QoL), and social limitations (SL). Since first human experiments, over 150 000 patients were treated with TEER [8]. In Poland as well, the number of TEER procedures has been steadily increasing, with 256 procedures performed in 2021 and 520 in 2023 [9,10]. Given the increasing use of TEER in clinical practice, including in Poland, it is essential to assess the real-world impact of this intervention on QoL among Polish patients. This study aims to evaluate the effects of TEER on patient-centered outcomes, focusing on symptom relief and quality of life improvement, thereby providing valuable data to guide future therapeutic decisions in this population.

Aim of the study

This work is a part of a study, which received opinion of Bioethics Commission of Silesian Medical University BNW/NWN/0052/KB/138/23. This study was designed a prospective, single-center, observational study. Main aim was to assess the QoL in patients with severe SMR undergoing TEER in Department of Cardiology and Structural Heart Diseases in Katowice.

Study design

Study population includes consecutive patients diagnosed with SMR and treated in the Department of Cardiology and Structural Heart Disease who fulfilled the inclusion criteria: age > 18 years old, significant mitral regurgitation with valve morphology appropriate for TEER (we included both COAPT-like patients and COAPT not-eligible, but with anatomy suitable for percutaneous treatment) based on COAPT criteria [11,12], symptoms of heart failure at least New York Heart Association (NYHA) class II. Main exclusion criteria covered comorbidities (including dementia) affecting QoL assessment, co-existing severe tricuspid regurgitation, qualified for both M-TEER and T-TEER, failure of the M-TEER procedure, and the need for cardiac surgery. The assessment of quality of life was conducted at two time points: prior to the procedure and three months afterward. The primary endpoint was the change in health status as measured by the KCCQ-12 questionnaire. In each part of KCCQ-12 (PL, SF, SL-QoL) patient got from 0 to 100% (the higher

score means the higher QoL), and the whole questionnaire result is given also as percentage from 0 to 100%. The secondary outcome was the incidence of major adverse cardiovascular events (MACE), including death, myocardial infarction, stroke or hospitalization due to heart failure.

Statistical analysis

In statistical analysis normality Shapiro-Wilk test was performed before analysis to confirm normal distribution. Paired t-tests were used to compare pre- and post-procedural values of KCCQ-12 results. Linear correlation was calculated using Spearman's equation. A p-value of <0.05 was considered statistically significant. The Statistica 13.3 software was used.

MATERIAL AND METHODS

This study remains part of a larger research project investigating long-term results in patients undergoing TEER of mitral regurgitation. The minimum sample size, statistically calculated for that study, based on a pilot study, was at least 41 patients. Between 04.2023 and 10.2024. Fifty-five patients were included in analysis. Due to prospective design, some patients were lost from follow-up. Detailed flow chart was presented in Figure 1.

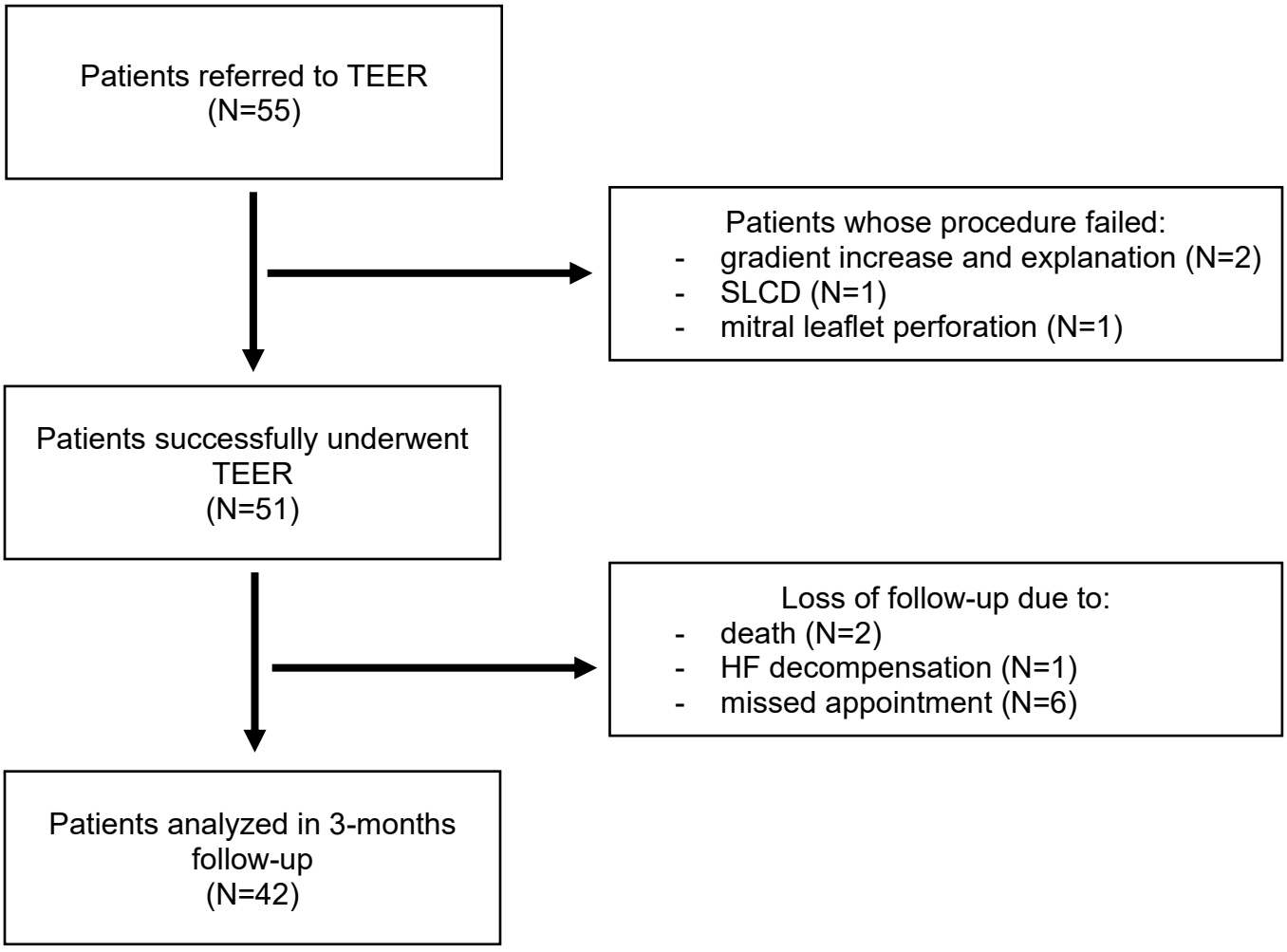


Fig. 1. Patient's flow chart

TEER – transcatheter edge-to-edge repair, HF – heart failure, SLCD – single leaflet clip detachment

Procedure success was defined as MR reduction to mild or trivial with normalization of pulmonic veins inflow – assessed intraprocedural using TOE. Fifty-one of 55 patients (93%) underwent TEER successfully without complications. In perioperative period there were 2 major adverse events requiring surgical treatment (3.6%), and in 2 patients (3.6%) the procedure was aborted due to elevated transmitral gradient. Three months mortality was 3.6% (2 of 55 individuals). One patient missed follow-up appointment due to hospitalization, because of HF decompensation. Other 6 patients who missed the appointments were contacted by phone; all patients survived and experienced no hospitalizations during the 3-month period.

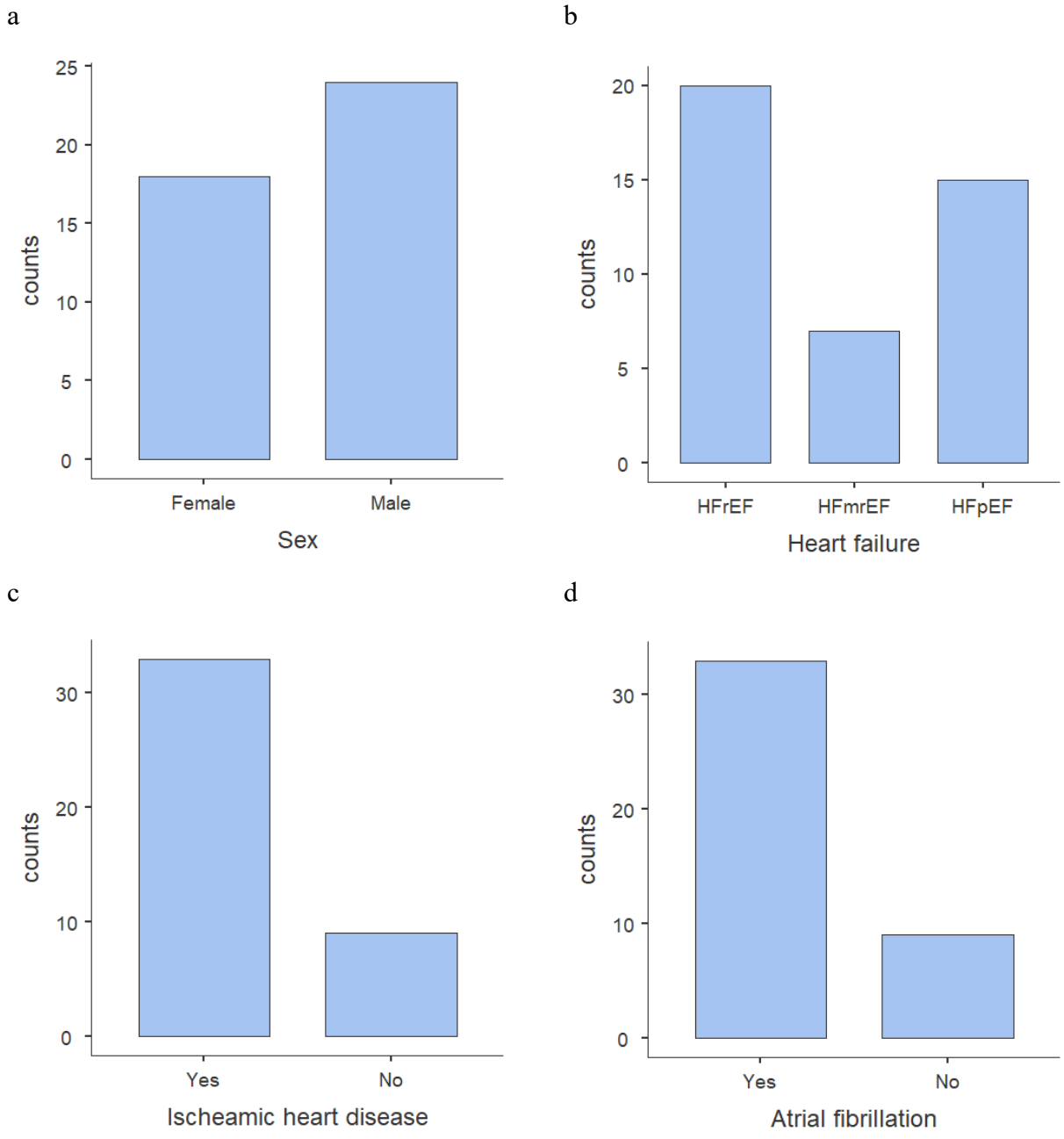
Population characteristics

Analyzed group consists of 42 patients. The mean age was 76.4 ± 6.6 year (age range from 63 to 89 years), 24 patients were male, and 18 were female. Mean BMI was 27.9 kg/m2 ± 4.6 kg/m2. There was high comorbidity prevalence in studied population – 42 (100%) patients were diagnosed with heart failure (mean EF was 39.6±13.9%; 20patients (48%) had reduced ejection fraction – HfrEF, 7 patients (17%) mildly reduced ejection fraction – HFmrEF and 15 patients (36%) preserved ejection fraction HFpEF), majority of patients (32 patients; 76%) were in NYHA functional class III, 9 patients (21%) in class II and 1 patient (2%) in class IV. Moreover 39 patients (93%) suffered from hypertension, 33 patients (79%) from atrial fibrillation, 32 (76%) from ischemic heart disease [19 (45%) after MI, 28 after PCI, 6 after CABG]. Twenty-nine patients (69%) were diagnosed with chronic kidney disease, 18 (42%) with type 2 diabetes and 6 (14%) with chronic obstructive pulmonary disease (COPD). All patients received guidelines-directed medical therapy (GDMT) before the procedure, unless contraindicated. During the study period, SGLT2 inhibitors were not included in GDMT for HFpEF yet. Summary of demographic data and baseline echocardiographic characteristics of this population was given in Table I and Figure 2. Post-procedural echocardiographic evaluation revealed significant reduction in MR in all patients. Additionally, none of these 42 patients required urgent /emergency hospitalization for any reason during the 3-month follow-up period (except the one patient excluded from analysis).

Table I. Echocardiographic characteristic of studied population

Parameter	Mean	SD	Min	Max
EF [%]	39.6	13.9	20	60
EDD [mm]	61	10.3	42	81
ESD [mm}	46.4	10.3	27	73
EDV [ml]	178.4	77.3	62	346
ESV [ml]	111.8	67.9	28	278

EF – ejection fraction, GLS – global longitudinal strain, EDD – end diastolic diameter, ESD – end systolic diameter, EDV – end diastolic volume, ESD – end systolic volume



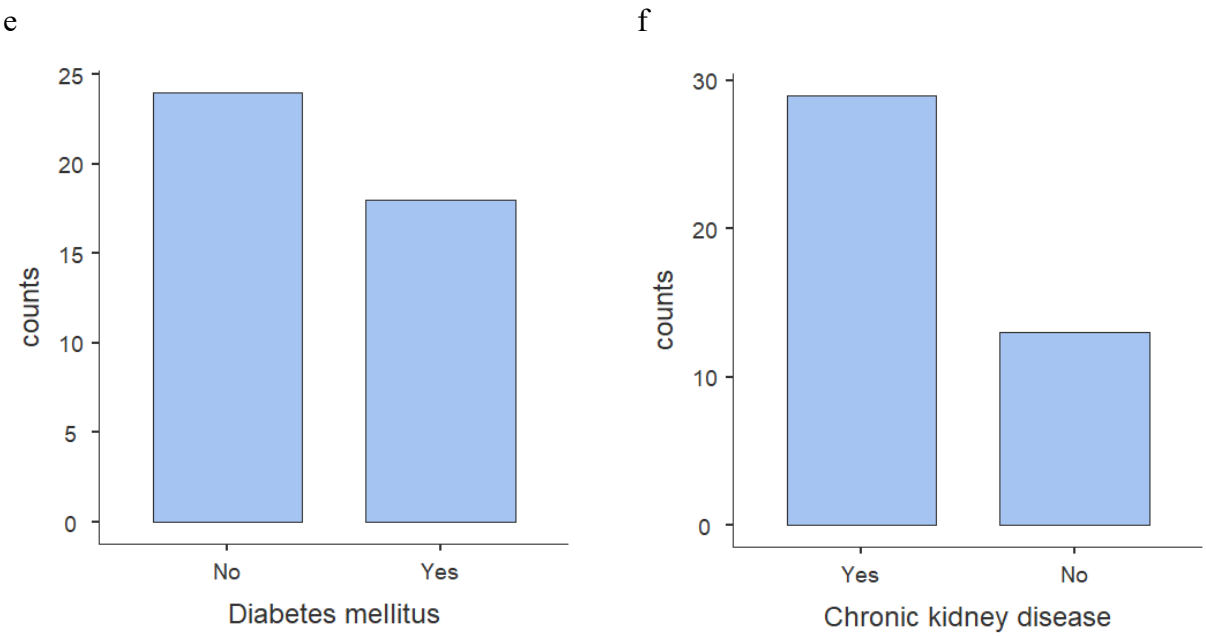


Fig. 2. Characteristic of studied population. Graphs present: sex differentiate (a), prevalence of heart failure, depend on ejection fraction (b), ischemic heart disease (c), atrial fibrillation (d), diabetes mellitus (e) and chronic kidney disease (f), respectively.

RESULTS

There was a significant improvement in QoL as measured by KCCQ-12 before and 3 months after TEER – 41.9 ± 15.5 vs 61.4 ± 16.9 ($p < 0.001$), respectively. In addition to overall improvement of KCCQ-12 result, significant improvement was observed in each part of KCCQ-12 questionnaire. Results in each component of the KCCQ-12 are presented in Figure 3.

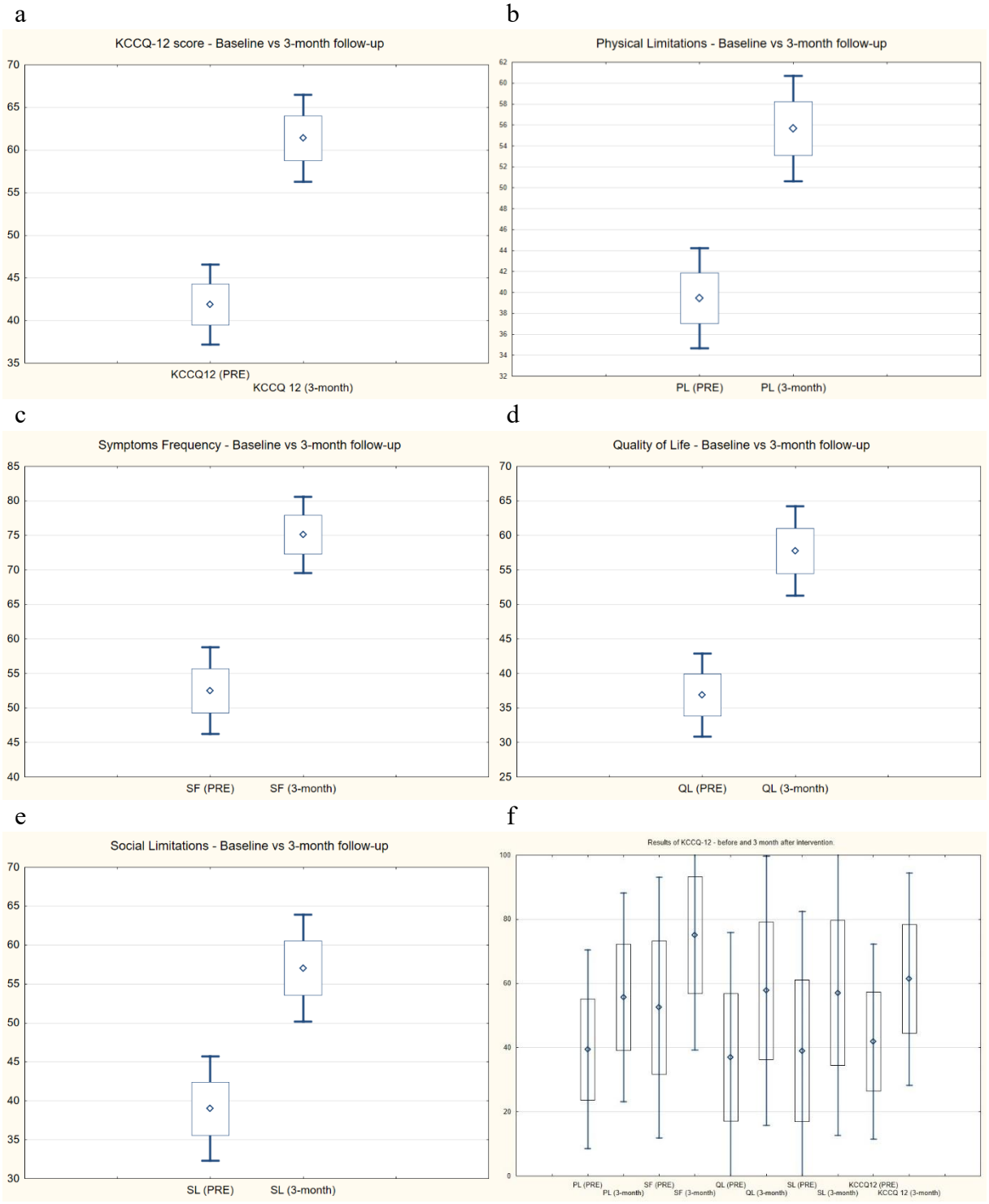
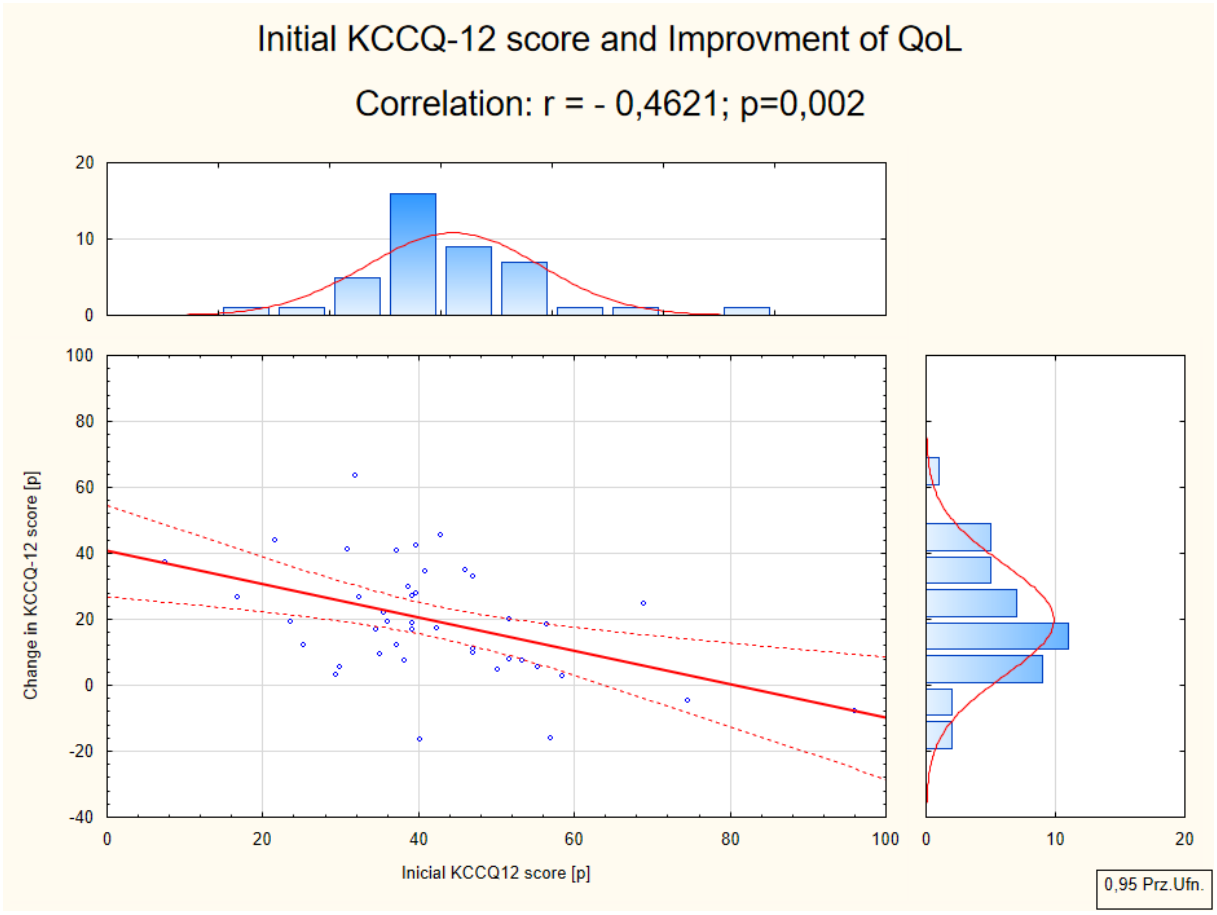


Fig. 3. Results of KCCQ-12 questionnaire. Each part of figure presented results before procedure (PRE) and at 3-month follow-up (3-month), respectively. a) summary score of KCCQ-12 questionnaire, b) score of physical limitations part, c) score of symptoms frequency part, d) score of self-reported quality of life part, e) score of social limitations part, f) summary of all parts in one graph

Indicators of QoL improvement

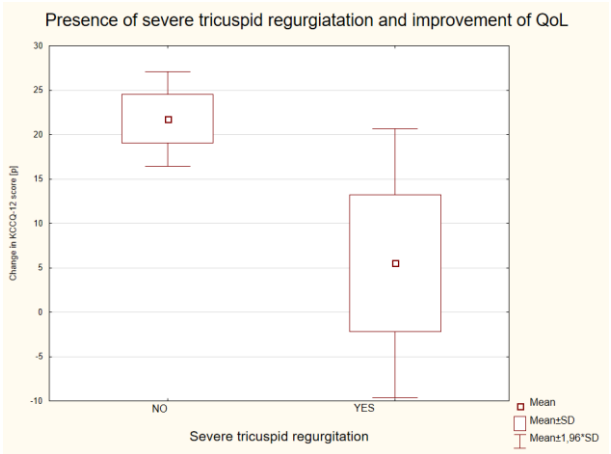
Further analysis was performed to determine factors influencing changes in QoL. Especially demographic data, comorbidities and echocardiographic parameters were analyzed. The highest improvement of QoL was observed in patients with initially lower baseline QoL. Spearman's correlation shown significant moderate impact with r = -0.462, p = 0,002, however when NYHA classification was used there was no significant differences between NYHA II (9/42, 21%) and

NYHA III+IV (33/42, 79%) patients (16.4 vs 20.3, respectively p = 0.547). (Figure 4). Moreover, patients with significant tricuspid regurgitation (TR), despite no significant differences in preprocedural QoL (58.3 vs 62.2, respectively p = 0.635) presented significantly lower improvement compared with patients without significant TR (Δ +5.5 vs +21.7, respectively p = 0.04). Other demographic and clinical factors (age, BMI, and comorbidities) did not significantly affect improvements in QoL. Other echocardiographic parameters, such us EF, GLS, size of left ventricle or atrium, did not significantly affect changes in quality of life.



a

b



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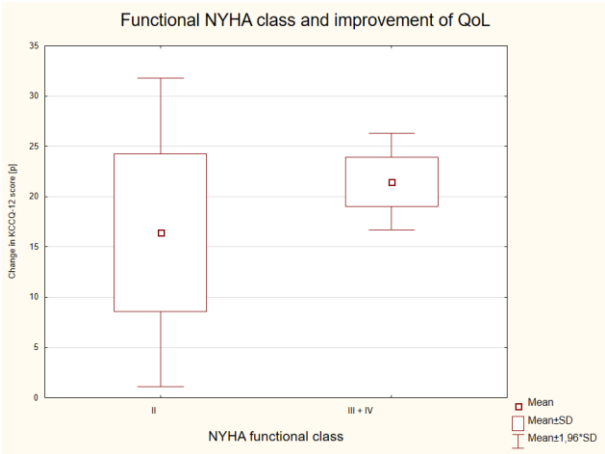

Fig. 4. Indicators of QoL improvement. The graphs present the influence of initial QoL (a), the presence of severe tricuspid regurgitation (b), and NYHA functional class (c) on QoL improvement.

Non-respondents – Is TEER beneficial for everyone?

Among studied population 9.5% (4 of 42) patients declared decrease in QoL during follow-up appointment compared to the pre-procedural period. In the "non-respondens" group a decrease in KCC-12 score of -10.8 ± 6 points was noted, whereas the rest of the study population showed an increase of +22.7 ± 14.4 points. In the subgroup without QoL improvement the initial KCCQ-12 score was significantly higher than in the rest of study population (66.8 ± 23.9 vs 39.2 ± 12.1; $p < 0.001$). There was no significant difference between EF and co-existing illnesses. A non-significant trend suggested that "non-responders" were older than responders (81.7 ± 3.4 +-vs 75.8 ± 6.7 years; $p = 0.09$).

DISCUSSION

The main finding of this study – that QoL improves significantly after the TEER procedure – remains in line with findings reported in both original clinical trial assessing the efficacy of TEER and real-world reports following its implementation in widespread clinical practice [4,13]. This study, like most of the previous studies, used KCCQ-12 questionnaire. KCCQ-12 is widely used, starting from COAPT study, where QoL was assessed before and 24-month after procedure [4]. Other studies assessing short-term influence of TEER usually evaluated QoL after 1 month after procedure [13] however studies investigating positive remodeling of LV used even 6-month follow-up period [14,15]. Based on those data, 3-months follow-up was chosen, as optimal period to assess impact of TEER procedure on QoL.

COAPT study reported improvement in KCCQ-12 score from 45.2 to 70.9 points over 24 months. Our results in KCCQ-12 score improved from 41.9 to 61.4 over 3 months. However mean age of patients in COAPT study was lower (72 vs 76.4 years), in our study more patients suffered from arterial hypertension, ischemic heart disease, diabetes mellitus or atrial fibrillation. Prevalence of CKD was similar, and of COPD was lower among our study population. In 2023 Goel et al. [13] presented data from 5000 consecutive patients treated with TEER in US after presentation of COAPT results. This study, named COAPT-PAS, reported increase of KCCQ-OS from 41.1 to 68.1 within 30 days.

In 2025 study conduct by Brooks et al. [16] was presented. They assessed QoL improvement in a registry of 1838 individuals and observed an improvement in KCCQ-12 from 43 to 68.9 over 30 days. Our study group was of similar age (76.4 vs 77.2 years) but had a higher burden of comorbidities. The authors also analyzed QoL change regarding stage of TR and found no significant correlation between improvement of QoL and grade of TR, however they combined patients with moderate to severe tricuspid regurgitation in one group, whereas we analyzed only the impact of severe TR. Our results support these benefits, and highlight their relevance in the Polish healthcare setting, where data on QoL outcomes post-TEER have been limited until now.

Furthermore, the significant improvement across all KCCQ-12 domains, indicates a broad impact of TEER on patients' daily live. This holistic improvement reflects benefits of the procedure on both physical and psychosocial aspects of health, a finding similarly reported in prior studies evaluating QoL in TEER-treated patients [1,7]. The largest improvement of QoL was noted among patients with lower initial QoL that may on the one hand, reflect the significant impact of psychological expectations and a placebo-like effect related to belief in the procedure. On the other hand, it may indicate that the greatest benefit is observed in patients with more severe symptoms, in whom the treatment induces a substantial improvement in left ventricular hemodynamics. Moreover, an interesting phenomenon was observed: a lower initial KCCQ-12 score predicted greater QoL improvement at follow-up, whereas a higher NYHA class was not significantly associated with such improvement. This may result from simplified assessment using NYHA classification, where KCCQ-12 is multi-faceted questionnaire. Our study also highlights the high comorbidity burden in this population, including both cardiac comorbidities (such as heart failure, ischemic heart disease or atrial fibrillation) and non-cardiac illness (especially diabetes mellitus and chronic kidney disease). High comorbidities rate was also reported in previous studies [17]. None of the above co-existing conditions showed significant differences in baseline QoL or in the degree of QoL improvement. Severe tricuspid regurgitation was the only echocardiographic finding associated with poor clinical response. It is important to note that all patients included in this dataset were disqualified from one-step tricuspid valve TEER (T-TEER). This study did not assess patients undergoing combined mitral and tricuspid TEER (M-TEER and T-TEER). It was impossible to assess the influence of other significant valvular diseases on M-TEER outcomes due to a lack of relevant data. In the study group, apart from severe tricuspid regurgitation, no patients had clinically significant multi-valve disease. During the study period, only one patient undergoing M-TEER had also undergone TAVI six months earlier; however, this individual was excluded from the study due to the significant impact of aortic stenosis on quality of life assessment, which remains one of the exclusion criteria. Although many patients presented with significant comorbidities, only two major adverse events were recorded during the 3-month follow-up: one patient died prior to follow-up, and another was hospitalized due to heart failure decompensation. These findings are consistent with the safety profile reported in previous studies. Echocardiographic analysis demonstrated significant reduction in mitral regurgitation severity post-procedure, which is a core factor contributing to symptomatic relief and improved QoL [18].

Limitations and future directions

Despite the promising findings, this study has limitations. The limited sample size and single-center nature of the study may restrict the relevance of the results to other populations. Additionally, the 3-month follow-up period, though sufficient to capture early QoL improvements, does not provide

insights into long-term outcomes. Future studies should aim to include larger cohorts and extend follow-up durations to better assess the durability of TEER's benefits.

CONCLUSIONS

This study confirms that TEER significantly improves quality of life in patients with severe SMR, including those with substantial comorbidities. Our findings reinforce the role of TEER as a transformative therapy for SMR and provide valuable data for guiding clinical practice in Poland.

Authors' contribution: TG – study design, investigation data curation, statistical analysis, data interpretation, writing – original draft; MM – data curation; MJ – statistical analysis, writing – original draft; GS – writing – review & editing, supervision; WW – data interpretation, writing – review & editing, supervision; EPP – conceptualization, investigation, data interpretation, writing – review & editing, supervision

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