

# Quality of life of patients with cardiomyopathy treated with sacubitril/valsartan vs. standard therapy during or after COVID-19 in Kazakhstan

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## Abstract

The objective of this study is to evaluate the quality of life (QoL) of hospitalised patients with cardiomyopathy (CM) treated with a fixed dose combination (FDC) of sacubitril/valsartan, or standard therapy in Kazakhstan during or after COVID-19.

This is an observational study of patients with incidents of CM that require hospitalisation during or after a COVID-19 infection. QoL was evaluated with the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) during admission. Demographic and other characteristics of the patients were analysed for both patient groups: on standard therapy and on FDC therapy with sacubitril/valsartan.

Patients on standard therapy tended to be older and had a higher relative share of previous cardiac surgery. The vaccination rate is low in general and was lower in the group on standard therapy. The QoL between the two groups was significantly higher in the group on FDC therapy. No statistically significant difference in the QoL between males and females was found. The vaccination status also does not influence the QoL. Patients with prior surgery possess a higher quality of life. QoL in younger patients is higher. There is a statistically significant negative correlation between age and QoL, and with the increase in age over one year, the quality of life will decrease by 0.3622 points.

Sacubitril/valsartan is associated with higher QoL in hospitalised patients with CM during or after COVID-19. QoL is correlated with age. Vaccination does not affect QoL, but patients with prior cardiac surgeries possess a higher QoL.

## Keywords

cardiomyopathy, quality of life, pharmacotherapy, sacubitril/valsartan, COVID-19, Kansas City cardiomyopathy questionnaire

## Introduction

The health-related quality of life (QoL) of patients with chronic diseases is an important indicator of their health

status and treatment results. Health status and disease-specific measures of QoL quantify medically relevant aspects of the diseases and are considered to be more sensitive to clinical state (Green et al. 2000). The Kansas City

cardiomyopathy questionnaire (KCCQ) is a disease-specific measure of the QoL of patients with cardiomyopathies (Arnold et al. 2013). It has been extensively tested to evaluate the QoL of patients with heart failure and a variety of other cardiomyopathies (Green et al. 2001). It could also be used for mortality and healthcare cost prediction in such patients (Soto et al. 2004; Pettersen et al. 2005; Speratus et al. 2008). The KCCQ-12 measures four domains of the QoL: physical limitations domain, symptoms frequency domain, social limitations domain, and quality of life domain, and summarises them in an overall average score.

Cardiomyopathies (CMs) are a heterogeneous group of diseases with structural and functional changes of the heart. The American College of Cardiology/American Heart Association stage and the New York Heart Association describe all probable morpho-functional, genetic, etiological, and functional status changes in patients with CMs in their MOGE(S) classification (Ciarambino et al. 2021).

CM therapy involves a variety of therapeutic classes, and among them are fixed dose combinations (FDC), such as sacubitril and valsartan, which is one of the most recommended choices. The therapy could also be performed with a mix of mono products such as ACE inhibitors, diuretics, Ca-channel antagonists, sartans, and beta-blockers (Cooper et al. 2023). Sacubitril/valsartan has only recently become widely used in Kazakhstan. Before its introduction in the therapy, the standard approach involved a mix of mono products from the above-listed classes.

The Centre for Disease Control (CDC) in the United States has published a list of concomitant diseases associated with severe COVID-19 infections. Among them, cardiovascular diseases (coronary heart disease, heart failure, and/or cardiomyopathy) take a leading role when talking about the complications and worsening of patients' states after COVID-19 infection (CDC 2023). A systematic review of the relationship between CM and COVID-19 concluded that cardiac injury and cardiomyopathy were common conditions in patients with COVID-19 (Omidi et al. 2021). Based on these recommendations, the medication treatment of CM during and after COVID-19 should be as effective as possible to prevent further patient deterioration.

To date, there have not been studies of the QoL of patients with cardiomyopathy during and after COVID-19 in Kazakhstan, which provoked our interest in this study (Schreiber et al. 2022).

The objective of this study is to evaluate the QoL of hospitalised patients with CM treated with FDC of sacubitril, valsartan, or standard therapy in Kazakhstan during or after COVID-19.

## Materials and methods

### Design of the study

This is an observational, non-interventional study of patients with incidents of CM that required hospitalisation during or after a COVID-19 infection. Patients were

admitted between 2020 and 2022 to the City Cardiology Centre in Almaty, Kazakhstan. Inclusion criteria were a clinically proven diagnosis of CM, ongoing COVID-19 or complaints after infection, and hospitalised patients in the centre. No other limitations were set for the recruitment.

Information for patient demographics, pharmacotherapy, vaccination, previous cardiac surgery, and subjective feelings of worsening of their heart status was collected.

Records of selected patients were separated into two groups: those on standard therapy and those on FDC therapy with sacubitril/valsartan, with physicians having full freedom of choice. All patients sign informed consent before answering the QoL questionnaire.

The standard therapy was previously explained in detail and includes captopril, ramipril, carvedilol, bisoprolol, spironolactone, digoxin, and furosemide in different combinations. The FDC therapy includes sacubitril/valsartan combined with either carvedilol, bisoprolol, spironolactone, digoxin, or furosemide (Dadanbekova et al. 2024).

### Quality of life analysis

Patients were interviewed with the Kansas City Cardiomyopathy Questionnaire-12 (KCCQ-12) after their admission (Annex 1). The questionnaire is a multidimensional QoL instrument that assesses on a 5-point Likert scale the following QoL domains: physical limitations, symptom frequency, social limitations, and the overall quality of life. It contains 12 items to assess the QoL. By using the electronic calculator, we calculated the QoL score for every individual patient and for every domain of the questionnaire. A higher score is related to better QoL.

Subgroup analysis was developed for patients QoL on different pharmacotherapies, age groups, vaccinations, previous surgeries, and other characteristics.

### Statistical analysis

A descriptive statistical analysis was performed. The sample distribution was tested with the Kruskal-Wallis test. Both samples were not normally distributed. The Mann-Whitney test was used to test statistical differences in both samples for different variables. We explored several relationships between patients' demographics, heart state, and QoL. Spearman correlation analysis explored the correlation between age and QoL, and linear regression analysis examined their dependence. We used Medcalc v. 22.023 as one of the most widely used healthcare software programmes.

## Results

### Demographic characteristics

The active FDC group was numerically larger than the standard therapy group, probably due to physicians' choices and attempts to better control the disease (Table 1). Both groups had a higher percentage share of

**Table 1.** Patient demographics.

Characteristic	FDC group	Standard therapy group
N (%)	207 (87.34%)	30 (12.66%)
Male - n (%)	137 (66.2%)	22 (73.3%)
Female - n (%)	70 (33.8%)	8 (26.7%)
Average age (SD)	58 (13.6)	66 (17.5)
Clinically proven COVID-19 n (%)	25 (12%)	9 (29%)
Vaccination against COVID-19 n (%)	62 (30%)	7 (23.3%)
Surgery (n %)	76 (36.7%)	14 (46.6%)
Worsening of heart status – n (%)		
Yes	60 (28.9%)	7 (23.3%)
No	75 (36.2%)	12 (40%)
Do not know	72 (34.9%)	11 (36.7%)

males, corresponding to world statistical data. Almost one-third of the patients reported subjective feelings of a worsening of their heart status. Patients on standard therapy tended to be older and had a higher relative share of previous cardiac surgery. The vaccination rate was low in general and lower in the standard therapy group. Although at the time of hospitalisation a majority of patients declared they had the COVID-19 infection, only 12% to 29% presented clinical proof during that time.

## Quality of life

The average QoL between the two groups was higher in the FDC therapy group, which was confirmed to be statistically significant (Mann-Whitney test,  $p > 0.0124$ ) (Table 2).

We compared the QoL in both gender groups and found that there is no statistically significant difference in the QoL between males and females ( $p = 0.4374$ ). The vaccination status also appeared to not influence the QoL ( $p = 0.1788$ ). The group of patients with prior cardiac surgery possessed a higher quality of life, and this difference was statistically significant ( $p = 0.0287$ ).

Comparing the QoL of patients in different age groups, we found a statistically significant difference ( $P = 0.00020$ ).

**Table 3.** Subgroup analysis per age group.

Characteristic	n (%)	Physical limitation (SD)	Symptoms frequency (SD)	Social limitations (SD)	Quality of life (SD)	Average QoL (SD)
<b>FCD therapy</b>						
30–50 years old	78 (38%)	34.19 (11.16)	29.56 (15.28)	43.75 (16.35)	45.51 (13.44)	38.24 (9.54)
50–60 years old	44 (21%)	22.91 (5.03)	21.87 (13.35)	33.81 (24.26)	39.58 (12.97)	29.55 (7.65)
60–70 years old	30 (14%)	20.83 (5.8)	25.90 (15.1)	30.42 (14.2)	41.11 (12.89)	29.57 (7.31)
70–80 years old	39 (19%)	17.0 (5.74)	22.59 (10.8)	32.69 (14.4)	33.12 (15.2)	26.38 (7.56)
Above 80	16 (8%)	15.105 (5.28)	23.7 (8.43)	27.34 (13.57)	31.77 (10.94)	24.48 (6.19)
<b>Standard therapy</b>						
30–50 years old	9 (30%)	28.85 (12.14)	26.35 (14.38)	33.02 (17.87)	41.67 (18.52)	31.95 (14.77)
50–60 years old	4 (13%)	22.92 (3.1)	8.51 (9.6)	12.5 (12.5)	41.67 (8.3)	21.35 (6.77)
60–70 years old	4 (13%)	12.5 (8.3)	28.65 (14.06)	37.5 (6.25)	29.17 (14.58)	25.39 (5.8)
70–80 years old	3 (11%)	11.11 (3.7)	4.17 (5.56)	29.17 (13.89)	27.78 (9.21)	18.06 (6.7)
Above 80	10 (33%)	9.55 (3.44)	21.15 (13.98)	27.05 (9.18)	20.8 (10.04)	19.64 (4.7)

**Table 2.** QoL of patients.

QoL domain	FDC group	Standard therapy group
physical limitation (SD)	25.16 (12.48)	16.81 (12.88)
symptoms frequency (SD)	25.63 (17.32)	17.44 (19.26)
social limitations (SD)	36.35 (19.19)	27.07 (19.45)
quality of life (SD)	40.22 (16.96)	31.39 (19.28)
Average QoL (SD)	31.84 (11.51)	21.17 (13.23)

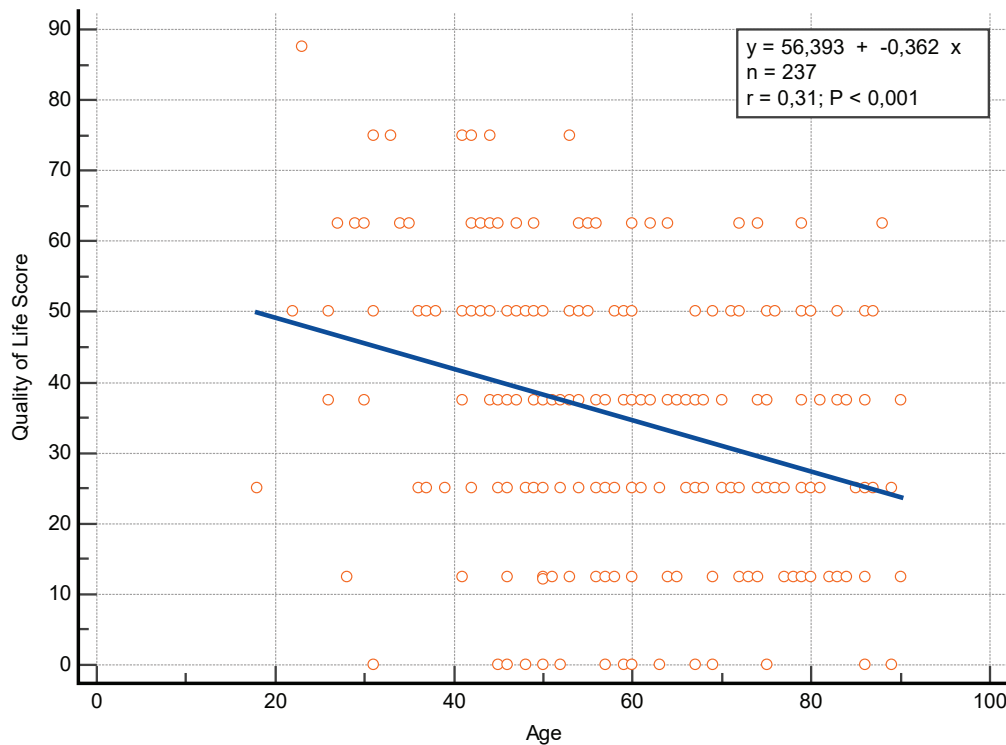
Logically and evidently from Table 3, younger patients have a higher quality of life than older ones. The lowest QoL values were recorded for the symptom's severity domain, suggesting that during or after COVID-19, CM symptoms had worsened.

A deeper analysis of the correlation between age and QoL for the whole sample shows that the Spearman rank coefficient is  $-0.314$  (95% CI  $-0.425$ – $0.195$ ;  $p < 0.0001$ ), meaning that there is a statistically significant negative correlation between age and QoL. Linear regression analysis reveals moderate correlation dependence between both variables ( $R^2 = 0.09523$ ). We might expect that with the increase in age over one year, the quality of life will decrease by 0.3622 points (Table 4, Fig. 1).

## Discussion

In this study, we attempt to analyse the QoL of patients with CM treated with FDC sacubitril/valsartan or standard therapy during or after COVID-19 by using the KCCQ-12. To the best of our knowledge, this is the first such study in Kazakhstan and even worldwide.

A systematic review explores cardiac complications after COVID-19 vaccination (Fazlollahi et al. 2022). The authors found out that myocarditis, myopericarditis, and pericarditis were the most common adverse events among the 243 reported cardiac complications after the COVID-19 vaccination. The other systematic review, following cardiovascular disease and COVID-19 vaccines, found that ultimately, cardiovascular complications after



**Figure 1.** Graphical presentation of the linear regression analysis.

**Table 4.** Linear regression analysis.

Dependent Y	Quality of life score				
Independent X	Age				
<b>Least squares regression</b>					
Sample size	237				
Coefficient of determination R <sup>2</sup>	0.09523				
Residual standard deviation	18.5164				
<b>Regression equation</b>					
$y = 56.3927 + -0.3622 x$					
<b>Parameter</b>	<b>Coefficient</b>	<b>Std. error</b>	<b>95% CI</b>	<b>t</b>	<b>P</b>
Intercept	56,3927	4,4320	47,6611 to 65,1242	12,7240	<0.0001
Slope	-0.3622	0.07284	-0.5057 to -0.2187	-4.9734	<0.0001
<b>Analysis of variance</b>					
<b>Source</b>	<b>DF</b>	<b>Sum of Squares</b>	<b>Mean Square</b>		
Regression	1	8480,4481	8480,4481		
Residual	235	80571,6781	342,8582		
F-ratio	24,7346				
Significance level	P < 0.0001				
<b>Residuals</b>					
Shapiro-Wilk test for Normal distribution	W = 0.9890 accept Normality (P = 0.0677)				

COVID-19 vaccination include myocarditis, myopericarditis, ischaemic heart disease, and arrhythmia, and that younger populations could be more vulnerable to myocarditis (Khaity et al. 2023). In contrast to these studies, we did not find a correlation between the vaccination status and cardiac functioning in any one of the observed patients, although it is worth noting that vaccination rates were low for the country. This result is supported by Kornowski and

Witberg, who concluded that the risk for pericarditis and myocarditis is overall “very rare” (~1 in 10 000 vaccinated people) (Kornowski and Witberg 2022). It is well described that COVID-19 affects a variety of organ systems and that its main sequelae include post-infectious fatigue, persistent reduced lung function, and carditis; therefore, patients with CM need careful follow-up post-COVID-19 to minimise the risk of further complications (Willi et al. 2021).

The other study we found exploring the quality of life with KCCQ and functional capacity outcomes in patients with surgery due to CM found that gains in QoL and functional capacity were similar early after different implants and that serious adverse events did not change QoL (Cowger et al. 2018). We found that QoL is higher in patients with previous cardiac surgery.

Several studies explored the QoL of patients treated with sacubitril/valsartan with KCCQ. In the first study, the control group was on valsartan monotherapy, with the active on sacubitril/valsartan showing a borderline benefit on KCCQ-CSS at 8 months in patients with heart failure with preserved ejection fraction (Chandra et al. 2022). The second study described that changes in KCCQ clinical summary scores and KCCQ overall summary scores are better in patients treated with sacubitril/valsartan compared with those treated with enalapril in all domains (Lewis et al. 2018). Improvement in QoL was reported by Rubio Campal et al. in all domains of KCCQ-12 for patients treated with sacubitril/valsartan (Campal et al. 2021). Similar results are reported for other domains in the QoL measure with KCCQ-12 for patients with CM treated with sacubitril/valsartan (Dattilo et al. 2022; Mapelli et al. 2023; Yang et al. 2023). Our study reveals that sacubitril/valsartan therapy is related to higher QoL in patients

with CM during or after COVID-19 infection and that it is more effective for patients admitted to the hospital.

The benefits of the study are in its object of evaluation in the post-COVID environment, when we need to collect more data based on real-world therapeutic practice to evaluate the long-term impact of the infection of patients with different chronic diseases and the effectiveness of different therapeutic strategies. Our manuscript highlights the crucial aspects of the quality of life for patients with cardiomyopathy who are hospitalised during or after COVID-19. It is essential to gather more information from real-world therapeutic practices and to address the uncertainties for people with chronic diseases and the efficacy of various therapeutic strategies.

One limitation of the study is the fact that only a single QoL assessment was conducted without follow-up, which means we were not able to measure change over time. A second point to consider is the low number of patients in the control group, which hindered our ability to conduct more statistical analyses; however, this was due to the study design, where physicians had the freedom to

decide therapy. Initially, we posited that younger patients would be more eligible for monotherapy, which could bias results, but the current patient distribution compensates for this limitation.

## Conclusion

Sacubitril/valsartan is associated with higher QoL in hospitalised patients with CM during or after COVID-19. QoL is correlated with age. Vaccination does not affect QoL, but patients with previous cardiac surgeries possess a higher QoL.

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## Supplementary material 1

### Kansas City Cardiomyopathy Questionnaire (KCCQ-12)

Authors: C. Patrick Green, Charles B. Porter, Dennis R. Bresnahan, Johan A. Spertus

Data type: pdf

Explanation note: Reference: Green CP, Porter CB, Bresnahan DR, Spertus JA (2000) Development and evaluation of the Kansas City Cardiomyopathy Questionnaire: a new health status measure for heart failure. *Journal of the American College of Cardiology* 35: 1245–1255.

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