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Office- versus Home-based Evaluation of Quality of Life in Heart Failure with Reduced Ejection Fraction: A Randomized Study

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ABSTRACT

Background: Heart failure (HF) patients often experience poor health-related quality-of-life (HR-QoL). The Kansas City Cardiomyopathy Questionnaire (KCCQ) is frequently used for assessing HR-QoL in HF. Whether KCCQ scores vary in a clinical meaningful manner according to the setting (home vs office) where patients respond to the questionnaire is currently unknown.

Aims: Assess the differences in the responses to KCCQ-23 questionnaire when completed at home or office.

Methods: Randomized parallel-group study, including patients with HF with reduced ejection fraction (HFrEF). Primary outcome was home vs office comparison of overall summary score (KCCQ-OSS). Main secondary outcomes were clinical summary score (KCCQ-CSS) and total symptom score (KCCQ-TSS).

Results: A total of 100 patients were included in the study: 50 home vs 50 office. Mean age was 71yrs. Most baseline characteristics were well balanced between groups, except male sex, MRA use, and prior HF hospitalizations which were more frequent in the home group. No statistically-significant between-group differences were found regarding KCCQ-OSS (median [percentile₂₅₋₇₅]) scores: home 69.1 (42.0-86.5) vs office 63.1 (44.3-82.3) points, P-value=0.59, or main secondary outcomes: KCCQ-CSS home 62.2 (46.5-79.9) vs office 68.1 (51.9-79.2) points, P-value=0.69, and KCCQ-TSS home 84.7 (59.7-97.2) vs office 76.4 (66.7-94.4) points, P-value=0.85. Results remained similar after adjustment for differences in baseline characteristics and using non-parametric regressions.

Conclusions: No major differences were found in KCCQ-23 scores regardless of whether the questionnaire was completed at home or office. These findings can be useful to make HR-QoL more accessible, allowing patients to respond at home using email or cell-phone applications.

Keywords: KCCQ; Home versus Office; Health Status; Heart Failure.

INTRODUCTION

Heart failure (HF) affects many people across the globe and commonly places a huge burden on patients' physical and psychological health with a poor health-related quality-of-life (HR-QoL) experience.¹⁻³ Functional status is increasingly valued by patients and doctors, and, as a consequence, treatment should not only prolong life and reduce the hospitalizations, but also improve symptoms and HR-QoL.^{4,5}

Physician's assessed symptom severity through New York Heart Association (NYHA) classification does not fully take into account the patient's perspective.^{6,7} Thus, in addition to traditional clinical outcomes, patient-reported outcomes (PROs), which function as a measure of HR-QoL, have been proved useful in assessing the functionality, symptoms and outcomes of patients with HF. The U.S. Food and Drug Administration (FDA) has qualified the Kansas City Cardiomyopathy Questionnaire (KCCQ) as a potential tool for drug and device approval, which can be also used as a performance measure to evaluate quality of care.³

Usually, KCCQ questionnaires are completed at the doctor's office, in the presence of a health professional, which can influence patients' responses. Whether KCCQ scores vary in a clinical meaningful manner according to the setting (home or office) where patients respond to the questionnaire is currently unknown. Given the increase in the use of electronic-based PRO measures which can be filled-in at home, knowing whether such measures vary according to the setting where they are filled-in (i.e., home vs office) is clinically relevant.

With this study, we sought to explore if differences in KCCQ score may occur when the KCCQ-23 questionnaire is completed at home or at the doctor's office. Answering this question is clinically relevant in the context of a growing use of HR-QoL questionnaires sent by email or phone apps for the patients to fill-in at home.

METHODS

Study Population

Patients with chronic stable HF and reduced or mildly reduced ejection fraction (HFrEF/HFmrEF) and attending HF clinics appointments at the *Centro Hospitalar Universitário São João, Porto, Portugal* were included in this study between January 2022 and December 2023. The inclusion criteria were: age ≥ 18 years, diagnosis of HFrEF/HFmrEF (with an ejection fraction of 40% or less at the time of patient's referral to the HF clinic), and informed consent signed. Exclusion criteria were: dementia, active cancer, and being unable to understand or complete the questionnaire. All patients provided written informed consent to participate in this study. The study was approved by the local ethics committee with evaluation number 112/21.

Sample Size and Statistical Power

This is a non-inferiority trial. Assuming a null-hypothesis of no difference between home or office responses with a standard deviation of the outcome of 10 points and a non-inferiority limit of 5 points in the study primary outcome of KCCQ-Overall Symptom Score (OSS),⁸ we calculated that 100 patients (50 per group) would be required to provide 80% power with a lower limit of a one-sided 95% confidence interval (or equivalently a 90% two-sided confidence interval).

Data Collection

Patients' information, including medical history, medication, and the results of complementary diagnostic tests, was collected prospectively through electronic health records (EHRs).

The KCCQ is a 23-item self-administered instrument that assesses physical and social function, symptoms and QoL. It takes an average of 5 minutes to complete the questionnaire. Scores range from 0-100, where lower scores suggest worse symptoms and function. The questionnaire is divided into: physical limitations (question 1); symptom frequency (questions 3, 5, 7 and 9); symptom burden (questions 4, 6 and 8); clinical stability (question 2); self-efficacy (questions 10 and 11); QoL (questions 12, 13 and 14); and social limitation (question 15).⁶ The total symptom score (TSS) results from combining the symptom frequency and symptom burden scores. The clinical summary score (CSS) results from combining the physical limitation and total symptom

scores. The self-efficacy score, QoL score, and social limitation score were also assessed.

The physical limitation, symptoms, social limitation, and QoL scores combined result in an OSS – the study primary outcome. TSS and CSS were defined as the main secondary outcomes.

When carried out at the office, the questionnaires were administered before the face-to-face clinical appointment with the doctor, whereas patients randomized to the home group were given an envelope with the questionnaire in paper format to be completed at home and then (once completed) sent by standard mail.

Study Design

We performed a cross-sectional randomized parallel-group study. We randomized the days of the appointments using randomly generated numbers (even numbers =home and odd numbers =office), so that on the same day all patients filled in the questionnaire at home or at the office. In this way, by randomizing the appointment days and not the patients, we avoided possible interference in the answers, since patients could talk to each other in the waiting room and influence the way the questionnaires were filled in.

We opted for a parallel group study rather than a cross-over study, since patients, regardless of whether they answered the KCCQ at home or in hospital, could memorize and remember the questions and answers, which could influence future answers.

Statistical analysis

Descriptive statistics were performed to compare home vs hospital response allocation using parametric or non-parametric tests for continuous variables (as appropriate) and frequencies for categorical variables. Despite the randomized nature of this study, we decided to report P-values for home vs office differences on *Table 1*, to adjust on such statistically significant differences in adjusted models. Non-parametric tests, linear and non-parametric regressions (using spline variable transformation with 3-knots) were performed to compare home vs office KCCQ scores. The primary analyses were carried out using non-adjusted non-parametric tests. Additionally, we performed (parametric and non-

parametric) regressions adjusted on all the statistically significant differences detected on the baseline characteristics to assess the influence of such differences in the KCCQ scores as well as to evaluate the consistency of the results. P-values <0.05 were considered statistically significant. All analyses were performed using Stata® (StataCorp. 2023. Stata Statistical Software: Release 18. College Station, TX: StataCorp LLC).

RESULTS

Patients' Characteristics

A total of 100 HFrEF outpatients were included in the study: 50 in the home group and 50 in the office group. The baseline characteristics of the patients are described in *Table 1*. The mean age was 71 years. Most baseline were well balanced between groups, except for sex with a more frequent allocation to the home group of men (home 34 [68%] vs office 24 [48%], P-value=0.043), patients using MRAs (home 37 [74%] vs office 23 [46%], P-value=0.004), and patients with history of HF hospitalizations (home 21 [42%] vs office 7 [14%], P-value=0.002). Most patients were clinically stable in NYHA I/II class.

Home vs Office KCCQ Comparison

No statistically significant between-group (home vs office) differences were found regarding the primary outcome of KCCQ-OSS (median [percentile₂₅₋₇₅]) scores: home 69.1 (42.0-86.5) vs office 63.1 (44.3-82.3) points, P-value=0.59; and no significant differences were found in the main secondary outcomes scores: KCCQ-CSS: home 62.2 (46.5-79.9) vs office 68.1 (51.9-79.2) points, P-value=0.69, and KCCQ-TSS: home 84.7 (59.7-97.2) vs office 76.4 (66.7-94.4) points, P-value=0.85. Results remained similar after adjustment for differences in baseline characteristics and using non-parametric regressions. *Table 2 (including legend), Figure 1 & Supplementary Table 1*.

Quality of life, social limitation, physical limitation, symptom stability, symptom frequency and symptom burden scores, showed no significant differences between home and office groups. The self-efficacy score had a P-value <0.05, but this was due to a rightward distribution shift in the office group with >25% of patients having a score of 100 despite a similar median of 75 points. *Table 2*.

DISCUSSION

Given the increasing use of remote PRO assessments in clinical practice, we assessed the comparability of home vs. office-based completions of the KCCQ in patients with HF_{rEF}. In the present randomized study, no differences were found in the primary outcome (KCCQ-OSS), nor in the main secondary outcomes (KCCQ-CSS and KCCQ-TSS) between the home and office groups, which suggests that the setting where patients complete the KCCQ-23 questionnaire does not influence their answers in a significant manner.

Although it is extremely important for doctors to assess HR-QoL and take the patients' perspective into account, sometimes it is difficult to apply questionnaires, such as the KCCQ-23, in clinical practice. Mainly because of the amount of time it takes to complete the questionnaires, when doctors often have several appointments with strict time-limits and many patients in the waiting room. Therefore, providing there are no significant differences, patients can read and complete the KCCQ-23 questionnaire comfortably at home, and then send the completed questionnaires via email or mobile phone applications, for example.

Prior studies have shown that HF patients are receptive to smartphone apps that allow them to monitor their disease, particularly symptoms.⁹⁻¹¹ For example, telemonitoring of vital parameters via mobile phone was associated with a reduction in the frequency and duration of hospitalizations following an episode of acute HF decompensation.¹² Moreover, monitoring patients' symptoms and their perspective on their health status was associated with better HR-QoL in HF.¹³ Therefore, the KCCQ-23 questionnaire could be integrated into mobile health apps (mHealth) to monitor patients' health status over time, even outside the clinical appointments. The mHealth KCCQ monitoring can also be important in HF clinical trials, where PROs are increasingly being used as main outcomes of interest.¹⁴⁻¹⁶

Another potential advantage of filling the KCCQ questionnaires at home while storing the information "online" is allowing doctors to assess patients' health status remotely, which permits to monitor the progression of the disease and identify early health status deteriorations that may require clinical action.¹⁷

In summary, this study shows that completing the KCCQ-23 questionnaire at home is likely not different from completing it at the doctor's office, supporting the use of mHealth apps to monitor health status over time without the strict time, scheduling and space constraints of a doctor's office.

Limitations

Our study has some limitations. The office group has more women than the home group, which could be a limitation, since it is known that women have a worse QoL than men.¹⁸ Additionally, the home group had more prior HF hospitalization than the office group and HF hospitalizations have been associated with worse KCCQ scores.¹⁹ However, despite such differences, the scores were similar and statistical adjustment for such differences did not change the results. The median KCCQ-TSS for both the home and office groups is above 75, which represents a good-to-excellent health status. The KCCQ-OSS and KCCQ-CSS, were between 50 and 74 in both groups, showing a fair-to-good health status.³ Additionally, most patients (in both groups) were on NYHA class I as assessed by the doctor. Therefore, the population enrolled in the study had a relatively good QoL (regardless of it being assessed at home or office), and these findings cannot be generalized to "sicker" and more symptomatic HF_rEF/HF_mrEF patients i.e. these findings only apply to stable HF_rEF/HF_mrEF outpatients. It should also be noted that patients had a LVEF <40% at the time of HF clinic referral; however, after optimization of guideline-directed medical therapy LVEF increased on average, leading to a median LVEF just above 40% at the time this study was conducted. Still, most patients had LVEF <50%. We assumed a 5-point between-group difference as being clinically meaningful. However, due to limitations in our recruitment capacity we assumed a 80% power in the sample size calculation; therefore, this study might have been underpowered to detect smaller differences in KCCQ scores that could also have clinical significance. Lastly, patients who filled the questionnaires at home, did so after the appointment which could have led to a better health status in these patients (e.g., related to adjustment in HF medications); still, no significant differences were observed between home and office.

CONCLUSIONS

In mostly asymptomatic stable outpatients with HFrEF/HFmrEF, no major differences were found in KCCQ-23 scores when the questionnaire was completed at home or at the office. These findings can be useful to make HR-QoL more accessible, allowing patients to respond at home using email or cell-phone applications. However, these findings cannot be applied to more symptomatic patients.

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None.

DISCLOSURES

None related to the content of this work.

DATA SHARING STATEMENT

Data of this work can be shared upon reasonable request to the corresponding author.

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Table 1. Baseline Characteristics by randomization group

Characteristic	Home N = 50	Office N = 50	P-value
Age (years)	71.1 ± 11.1	71.4 ± 9.9	0.89
Male sex	34 (68%)	24 (48%)	0.043
BMI (Kg/m ²)	28 ± 4.7	28.0 ± 4.9	0.98
PREVIOUS MEDICAL HISTORY			
Stroke	4 (8%)	4 (8%)	1.00
Chronic Kidney Disease	8 (16%)	13 (26%)	0.22
Smoking	22 (44%)	17 (34%)	0.31
Atrial Fibrillation	23 (46%)	17 (34%)	0.22
OSA	15 (30%)	14 (28%)	0.83
Diabetes Mellitus	23 (46%)	20 (40%)	0.54
Insulin	5 (10%)	8 (16%)	0.37
Hypertension	35 (70%)	35 (70%)	1.00
COPD	6 (12%)	3 (6%)	0.29
Previous Malignancy	5 (10%)	4 (8%)	0.73
Device therapy	9 (18%)	5 (10%)	0.25
MEDICATION			
Beta-blocker	49 (98%)	44 (88%)	0.050
ACEi or ARB	13 (26%)	20 (40%)	0.14
ARNI	25 (50%)	19 (38%)	0.23
MRA	37 (74%)	23 (46%)	0.004
SGLT2 inhibitors	39 (78%)	35 (70%)	0.36
Loop diuretics	24 (48%)	24 (48%)	1
Statins	43 (86%)	46 (92%)	0.34
CLINICAL PRESENTATION AND HOSPITAL STAY			
Systolic blood pressure (mmHg)	119.6 ± 21	125.3±21.5	0.18
Diastolic blood pressure (mmHg)	66.4 ± 11.9	68.4 ± 9.6	0.35
Heart rate (bpm)	69.8 ± 13.9	69 ± 15.3	0.77
Pulmonary Congestion	6 (12%)	4 (8%)	0.50
Peripheral edema	5 (10%)	5 (10%)	1
NYHA I	33 (66%)	27 (56%)	0.59
NYHA II/III	17 (34%)	21 (44%)	
Time HF diagnosis (years)	2.0 (1.0, 6.0)	2.0 (1.0, 4.0)	0.82
HF ischemic aethiology	17 (35%)	16 (33%)	0.83
Previous HF hospitalizations	21 (42%)	7 (14%)	0.002
ADMISSION ANALYTICAL EVALUATION			
Hemoglobin (g/dL)	13.8±2.2	13.6 ± 1.7	0.62
eGFR (mL/min/1.73m ²)	61.9 ± 24.3	63.1 ±25.8	0.82

Characteristic	Home N = 50	Office N = 50	P-value
Transferrin Saturation (%)	23.8 ± 7.6	22.9 ± 7.8	0.64
Ferritin (ng/mL)	217 (131, 365)	177 (109, 233)	0.22
Sodium (mEq/L)	139.3±2.4	139.9±2.8	0.28
Potassium (mEq/L)	4.5 ± 0.6	4.6 ± 0.4	1
BNP (pg/mL)	99 (54, 222)	152 (70, 331)	0.099
<u>ECHOCARDIOGRAPHIC PARAMETERS</u>			
Ejection Fraction (%)	41 (27, 47)	43 (35, 52)	0.067
LAVI (mL/m ²)	43.8 ± 13.8	40.7 ± 14.3	0.34

* Normally distributed continuous variables are presented as mean ± SD and variables with skewed distribution are presented as median (percentile 25-75). Abbreviations: BMI – body mass index; OSA - obstructive sleep apnea; COPD - chronic obstructive pulmonary disease; ACEi or ARB - Angiotensin-converting-enzyme inhibitors or angiotensin receptor blockers; ARNI - angiotensin receptor/neprilysin inhibitor; MRA – aldosterone receptor antagonists; SglT-2 – SGLT2 inhibitor; NYHA – New York Heart Association; Time diagnosis – time since diagnosis; LAVI - Left Atrial Volume Index.

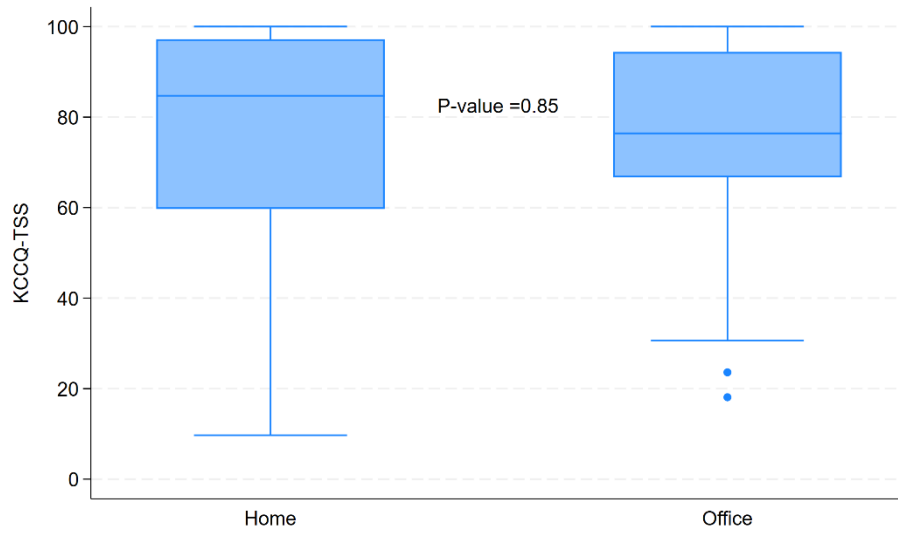
Table 2. Home vs Office KCCQ comparison

KCCQ parameter	Home ¹	Office ¹	Office vs Home (crude) ²	Office vs Home (Adjusted) ^{*2}	P-value**
Overall Summary Score*	69.1 (42, 86.5)	63.05 (44.3, 82.3)	-1.79 (-11.6, 8.03)	4.25 (-6.60, 15.11)	0.59
Clinical Summary Score	62.2 (46.5, 79.9)	68.1 (51.9, 79.2)	1.98 (-5.97, 9.93)	7.64 (-1.29, 16.58)	0.69
Total Symptom Score	84.7 (59.7, 97.2)	76.4 (66.7, 94.4)	0.33 (-9.02, 9.68)	4.54 (-6.27, 15.34)	0.85
Quality of Life Score	58.3 (33.3, 83.3)	58.3 (41.7, 83.3)	-0.66 (-11.5, 10.2)	4.26 (-8.07, 16.58)	0.89
Social Limitation Score	60.4 (33.3, 83.3)	66.7 (41.7, 83.3)	0.47 (-11.1, 12.1)	8.19 (-4.74, 21.12)	0.94
Physical Limitation Score	62.5 (41.7, 87.5)	50 (29.2, 79.2)	-7.31 (-18.9, 4.29)	0.01 (-12.3, 12.3)	0.21
Symptom Stability Score	50 (50, 50)	50 (50, 50)	-0.50 (-7.51, 6.51)	1.72 (-6.64, 10.10)	0.87
Symptom Frequency Score	83.3 (50, 100)	77.8 (66.7, 94.4)	1.50 (-8.80, 11.8)	5.27 (-6.78, 17.32)	0.78
Symptom Burden Score	83.3 (58.3, 100)	75 (66.7, 100)	-0.83 (-9.81, 8.14)	3.81 (-6.42, 14.05)	0.61
Self-Efficacy Score	75 (50, 87.5)	75 (62.5, 100)	10.7 (1.92, 19.6)	16.31 (5.93, 26.70)	0.027

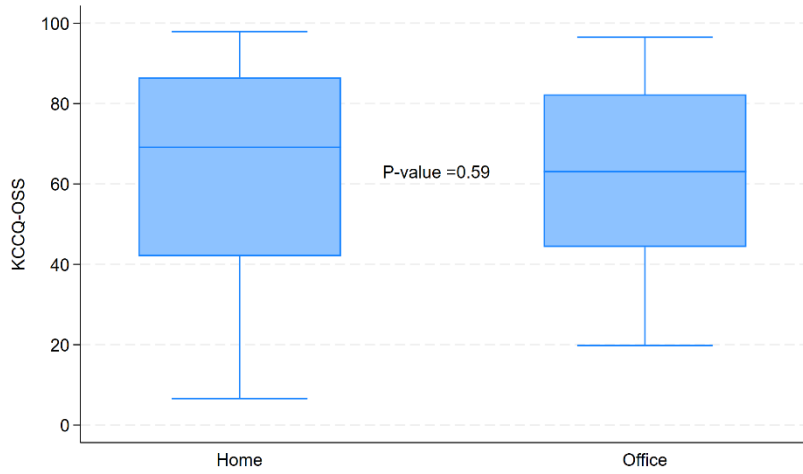
Legend: *Primary outcome; ¹Median (percentile 25-75); ²Parametric regression results presented with their 95% confidence interval. ^{*2}Parametric regression model adjusted for variables with a P-value <0.05 in Table 1. **P-values for unadjusted comparisons. The corresponding P-values for the adjusted comparisons (*2) are: OSS P-value=0.44; CSS P-value=0.10; TSS P-value=0.41; QLS P-value=0.49; SLS P-value=0.21; PLS P-value=0.99; SSS P-value=0.68; SFS P-value=0.39; SBS P-value=0.46; SES P-value=0.002.

Figure 1. Home vs Office KCCQ comparison

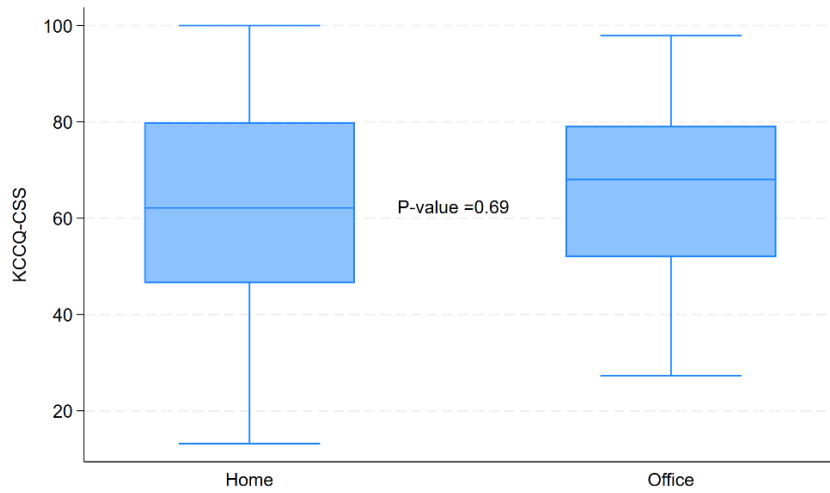
A) KCCQ-TSS



B) KCCQ-OSS



C) KCCQ-CSS



Legend: KCCQ, Kansas City Cardiomyopathy Questionnaire; TSS, Total Symptom Score; OSS, Overall Summary Score; CSS, Clinical Summary Score.