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Original Study

Telehealth Management and Risk Stratification of Older Patients With Chronic Heart Failure During COVID-19 Pandemic: Prognostic Evaluation of the TeleHFCovid19-Score

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ABSTRACT

Objectives: To evaluate 6-month risk stratification capacity of the newly developed TeleHFCovid19-Score for remote management of older patients with heart failure (HF) during the coronavirus disease 2019 pandemic.

Design: Monocentric observational prospective study.

Setting and Participants: Older HF outpatients remotely managed during the first pandemic wave.

Methods: The TeleHFCovid19-Score (0-29) was obtained by an ad hoc developed multiparametric standardized questionnaire administered during telephone visits to older HF patients (and/or caregivers) followed at our HF clinic. Questions were weighed on the basis of clinical judgment and review of current HF literature. According to the score, patients were divided in progressively increasing risk groups: green (0-3), yellow (4-8), and red (>9).

Results: A total of 146 patients composed our study population: at baseline, 112, 21, and 13 were classified as green, yellow, and red, respectively. Mean age was 81±9 years, and women were 40%. Compared to patients of red and yellow groups, those in the green group had a lower use of high-dose loop diuretics (P < .001) or thiazide-like diuretics (P = .027) and had reported less frequently dyspnea at rest or for basic activities, new or worsening extremity edema, or weight increase (all P < .001). At 6 months, compared with red (62.2%) and yellow patients (33.3%), green patients (8.9%) presented a significantly lower rate of the composite outcome of cardiovascular death and/or HF hospitalization (P < .001). Moreover, receiver operating characteristic curve analysis showed a high sensibility and specificity of our score at 6 months (area under the curve = 0.789, 95% CI 0.682-0.896, P < .001) with a score <4.5 (very close to green group cutoff) that identified lower-risk subjects.

Conclusions and Implications: The TeleHFCovid19-Score was able to correctly identify patients with midterm favorable outcome. Therefore, our questionnaire might be used to identify low-risk chronic HF patients who could be temporarily managed remotely, allowing to devote more efforts to the care of higher-risk patients who need closer and on-site clinical evaluations.

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The authors declare no conflicts of interest.

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### HF - OUTPATIENT CLINIC TELEPHONIC CONSULTING

| Date Interviewed: | Patient | Caregiver | Both | Date of birth | Gender: □ F □ M |
|------------------|---------|-----------|------|---------------|------------------|

1. **Living situation:**
   - □ I live alone
   - □ I live with my family
   - □ I live with a caretaker h.24
   - □ I live with part-time caretaker
   - □ I live in a nursing home / rest home

2. **Psychological status: how would you define your mood?**
   - □ Poor
   - □ 1
   - □ 2
   - □ 3
   - □ 4
   - □ 5
   - □ Great

3. **Who takes care of handling medications?**
   - □ I am responsible for taking medication in correct dosages at correct time
   - □ I get help from voluntary association / Civil Protection
   - □ I use home-delivery
   - □ Medications are completely handled by my caregiver

4. **Do you ever forget or voluntary omit to take your medications?**
   - □ Yes (1 point)
   - □ No

5. **Current therapy (check all that apply):**
   - □ Beta-blockers
   - □ ACE-I/ARB
   - □ Sacubitril/Valsartan
   - □ MRA
   - □ DOACs/warfarin
   - □ DAPT
   - □ Diuretics (Furosemide)
   - □ Diuretics high dose (eg. Furosemide ≥250 mg/die)
   - □ Metolazone

6. **Has Diuretic therapy been up-titrated from the last clinical contact/evaluation?**
   - □ Yes (1 point)
   - □ No

7. **Do you control the amount of fluid intake during the day?**
   - □ Yes (1 point)
   - □ No

8. **Are you monitoring regularly SBP, HR and body weight?**
   - □ Yes (1 point)
   - □ No

9. **Systemic blood pressure (mean of last 3 values - mmHg):**
   - □ <100
   - □ 100-130
   - □ 130-160
   - □ >160
   - □ Not applicable

10. **Heart rate (mean of last 3 values - bpm):**
    - □ <60
    - □ 60-69
    - □ 70-100
    - □ >100
    - □ Not applicable

11. **Recommended pharmacological modifications:**
    - □ GDMTs down-titration/withdrawal
    - □ Loop diuretic dose increase
    - □ SNB with Thiazide or Thiazide-like diuretic

12. **Next follow-up (date): ________________________________ Hospitalisation recommended: □ Yes □ No □

### Fig. 1. COVID-19 HF outpatient follow-up questionnaire. ACE-I, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; GDMTs, guideline-directed medical treatments; MRA, mineralocorticoid receptor antagonist; RI, respiratory insufficiency; SBP, systolic blood pressure; SNB, sequential nephron blockade; WRF, Worsening Renal Function.
effectiveness of telemedicine for the management of HF (eg, quality of life improvement with mild or neutral impact on hospitalizations and no significant effect on mortality). 1, 2, 3 Clinicians were forced to organize telephone visits or tele-monitoring, with the purpose of maintaining the delivery of care from remote instead of in-person visits, and this approach was encouraged by international cardiological societies. 3 Therefore, because of the absence of standardized tools, we rapidly developed a multiparametric questionnaire (from which we derived the TeleHFCovid19-Score), suitable for telephone administration to older HF patients and/or their caregivers. 3 This questionnaire was designed to assess the clinical stability and social isolation impact on health status of the nearly 150 patients we were caring for at our outpatient HF clinic by that time. 3 The aim of the present study was to evaluate the 6-month prognostic ability of the TeleHFCovid19-Score during the first months of the coronavirus disease 2019 (COVID-19) pandemic. In a postpandemic setting, where a rational utilization of health care resources is strongly needed, a prognostic score may help to appropriately triage chronic HF patients and, accordingly, manage them in person or remotely.

Methods

The study design, the development of the questionnaire and the derived TeleHFCovid19-Score, as well as the preliminary results of implementation in the first 30 patients, have been previously published in this journal. 3, 5, 6 Briefly, starting from April 2020, we administered the questionnaire to all patients we were taking care of and/or to their caregivers, during scheduled telephone contacts, which were formally recorded through the hospital’s administrative program as teleconsulting evaluations. In accordance with Italian privacy laws, the questionnaire was anonymized, and patients were identified by a numeric code, date of birth, and gender. Selected questions were weighted on the basis of clinical judgment and review of current HF literature, and the final version of the questionnaire was approved after collegial discussion and agreement of all authors using the Delphi method. 30 For the present study, the score was calculated based on data collected during the phone interview. For blood tests, the last evaluations (prior to phone contact) were considered and compared to previous results in order to analyze variations. Figure 1 shows the questionnaire with single questions score assignment, calculation of the TeleHFCovid19-Score and consequent color risk score group designation: green (0–3), yellow (4–8), or red (≥9). The color code also determined the timing of next phone contact at 1, 2, or 4 weeks for the red, yellow, and green groups, respectively. However, all patients were systematically contacted at 1, 3, and 6 months to assess vital status and record potential events (hospitalization and death). The primary study outcome was a composite of death from cardiovascular (CV) causes and/or hospitalization for HF at 6 months, which individually were secondary outcomes. The study conformed to the Declaration of Helsinki 3 and was approved by the local institutional review board.

Statistical analysis was performed using SPSS, version 27 (IBM Corp). Continuous variables were expressed as mean ± SD and categorical variables as percentages. Data were compared across the 3-color code groups using analysis of variance and chi-square test, as appropriate. The sensitivity and specificity of the TeleHFCovid19-Score questionnaire in the prediction of study outcomes was tested with the receiver operating characteristic analysis. A P value <.05 was considered statistically significant.

Results

We enrolled 146 patients. After baseline questionnaire administration, according to the TeleHFCovid19-Score, 112, 21, and 13 patients were assigned to the green, yellow, and red groups, respectively. Demographic and clinical characteristics of the study population, including principal CV and non-CV comorbidities and treatments, are summarized in Table 1. Mean age of the study population was 81 ± 9 years, with a 40% prevalence of females. Almost a third of the study population was represented by patients with HF with reduced ejection fraction, and an ischemic etiology was reported in 50% of patients. Moreover, in keeping with the advanced age of the patients enrolled we found a high prevalence of main CV and non-CV comorbidities. As shown in Table 1, there were no significant differences in terms of demographic and clinical characteristics among the 3-color risk groups. Among pharmacologic treatments, we observed a high prescription rate of oral anticoagulants, as a consequence of the

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Table 1

| Main Demographics and Clinical Characteristics and Treatments in Progress in Study Population, by Baseline Color Code Assignment |
|---------------------------------------------------------------|
| Total Population (n = 146) | Green Code (n = 112) | Yellow Code (n = 21) | Red Code (n = 13) | P Value |
|---------------------------|----------------------|---------------------|------------------|--------|
| **Age, y, mean ± SD**     | 81.3 ± 9.0           | 81.4 ± 8.9          | 79.5 ± 10.9      | 82.7 ± 6.9 | .57    |
| Female                    | 58 (39.7)            | 45 (40.2)           | 10 (47.6)        | 3 (23.1)  | .36    |
| Heart failure with reduced/mid-range/preserved ejection fraction | 35 (63.6) | 41 (36.6) | 9 (42.9) | 3 (23.1) | .60 |
| Heart failure with reduced/mid-range/preserved ejection fraction | 35 (63.6)           | 41 (36.6)           | 9 (42.9)         | 3 (23.1)  | .60 |
| Heart failure with reduced/mid-range/preserved ejection fraction | 35 (63.6) | 41 (36.6) | 9 (42.9) | 3 (23.1) | .60 |

ACE-I, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor neprilysin inhibitor; COPD, chronic obstructive pulmonary disease; DAPT, dual antiplatelet therapy; HFpEF/HFmrEF/HFpEF, heart failure with reduced/mid-range/preserved ejection fraction; MRA, mineral receptors antagonist; OAT, oral anticoagulant treatment.

*Values are n (%) unless otherwise noted. Bold values indicate statistical significance (P < .05).
prevalece of the history of atrial fibrillation, of renin-angiotensin-aldosterone inhibitors (with almost a quarter of the study population treated with sacubitril/valsartan) and beta blockers. Among pharmacologic treatments shown in Table 1, beta blocker prescription was the only one that varied significantly across the 3 groups being less prescribed in the yellow intermediate-risk group.

Answers to the questionnaire regarding clinical condition, blood tests, adherence to recommendations, and treatments are reported in Table 2. We observed a lower rate of previous acute HF hospitalizations as well as of the need to increase diuretic therapy since former clinical evaluation in green than in yellow and red groups (P < .001). In all study populations, a high prevalence of self-reported adherence to pharmacologic treatments including guidelines directed medical treatments and diuretics, as well as behavioral measures (regular assessment of blood pressure, heart rate, body weight, and water restriction) were observed. Moreover, we found significant differences across the 3 groups regarding the use of high dose of loop diuretics (P < .001) and metolazone (P = .027), progressively more frequent from green to yellow and red groups. Similarly, after completing the questionnaire-guided telephone interview, the doses of loop diuretics were increased or thiazide and thiazide-like diuretics for sequential nephron blockade were prescribed more frequently to red-code patients (P < .001). Furthermore, all signs and symptoms potentially related to the severity of HF and/or of heart disease were progressively worse from green to red coding. Higher levels of creatinine and NT-proBNP were also found in the red group than in the green and yellow ones (both P < .002).

At 6-month follow-up, 20 patients (13.7%) had died and 32 (21.9%) had been hospitalized. The 1-, 3-, and 6-month primary composite outcome rates of CV death and/or HF hospitalization were 8.2%, 11%, and 17.8%, respectively. The difference in the primary outcome and its components’ occurrence in the color groups at 1, 3, and 6 months are shown in Figure 2. Patients coded as green had a significantly lower incidence of the primary composite outcome compared to those in the yellow and red groups, thereby confirming the capacity of the Tele-HF Covid19-Score to correctly stratify the risk of serious events. Analyzing in detail the components of the primary outcome, we found a significant difference among the 3 color groups at all follow-up timing intervals both for CV death and HF hospitalizations, being significantly lower in patients coded at baseline as green.

Furthermore, to confirm the clinical predictive validity of the cutoffs used to define the different color-coding risk groups, we used a receiver operating characteristic curve analysis. Our score demonstrated a very good power in predicting the composite of CV mortality and/or hospitalizations for HF, at both the short and medium term, with a high area under the curve at all 3 follow-up intervals (Figure 3); furthermore, a score of 4.5 corresponded to the cutoff with the best sensitivity-specificity relationship for identifying low-risk chronic HF patients at 1, 3, and 6 months.

**Discussion**

The main results of our study may be summarized as follows:

- COVID-19 pandemic has forced health care providers to change their way of managing chronic diseases.
- Our newly developed TeleHF Covid19-Score generated by a phone interview questionnaire at the beginning of the pandemic emergency was able to correctly stratify the risk of adverse events in elderly ambulatory HF patients.
- During the following 6 months, patients identified at baseline as low-risk according to the TeleHF Covid19-Score had a significantly lower risk of the primary composite outcome of CV mortality and/or HF hospitalization.
- In a context of growing HF burden and health care resources sparing, implementation of this methodologic approach may
Fig. 2. Comparison of primary and secondary outcomes in study population. In panels A, B, and C, a comparison of primary (CV death and/or HF hospitalization) and secondary (CV death and HF hospitalization singularly) outcomes between the 3 color groups is respectively shown with the trend at 1, 3, and 6 months.
be used to safely manage low-risk patients in remote and, at the same time, focusing on high-risk patients who require frequent clinical revaluation.

COVID-19 generated a dramatically negative impact on public health not only for the effect of the disease itself and for the health care overload but also by limiting the management of chronic diseases. At present, the SARS-CoV-2 pandemic is still forcing physicians to play out new methods to manage “at a distance” patients affected by chronic diseases such as HF, to limit the accesses to hospital and outpatient clinics.12–14 In Great Britain during the peak of the first pandemic wave, probably as a consequence of social distancing measures or contagion fear, a dramatic reduction of HF hospitalizations has been reported as well as more severe symptoms on admission in hospitalized patients.15 Similar data were observed also in other countries, for example, Italy.16,17 Because of this difficult situation, international societies have invited physicians to play out strategies of virtual or telephone visits for the management of chronic diseases.8 Therefore, we created a standardized questionnaire to be administered during a simple telephone visit (median time of administration 7 minutes), instead of a real virtual visit for the diagnosis in hospitalized patients.15

Similar data were observed also in other countries, for example, Italy.16,17 Because of this difficult situation, international societies have invited physicians to play out strategies of virtual or telephone visits for the management of chronic diseases.8 Therefore, we created a standardized questionnaire to be administered during a simple telephone visit (median time of administration 7 minutes), instead of a real virtual visit for the difficulties that many of our older patients presumably would have had with computer/tablets management. Our TeleHFCovid19-Score generated from the structured questionnaire allowed us to identify low-, intermediate-, and high-risk patients who were then grouped by an easily usable color coding as green, yellow, and red. Based on color group coding, we also modified the intervals of scheduled phone contact at 4, 2, and 1 week, respectively, or we recommended hospital evaluation. To our knowledge, this represents one of the few examples of a telephone visit score for the management of chronic HF patients proposed during the COVID-19 pandemic, especially for older patients.

Through differently scheduled phone contacts, we were able to guarantee continuity of care to our patients and timing adjustments to HF medical therapies by acting both on diuretics and guidelines directed medical treatments. Of note, patients maintained a good adherence to the prescribed treatments and to the nonpharmacologic behavioral recommendations, such as control of weight and vital parameters or water intake restriction, they had been taught during previous in-person visits at our HF clinic.

Our study shows an association of clinical characteristics, typically related with HF prognosis, with a worse outcome also in a “virtual setting,” given the higher rate of some of these variables in red and yellow groups. In fact, for example, the need for high doses of loop diuretics has been associated with unfavorable outcomes in patients with chronic HF,18–20 and, in our study, it was observed more frequently in higher-risk groups. An association of loop diuretic dosage with adverse outcomes was observed also in the ESC HF Long Term Registry.21 A recent meta-analysis highlighted that high doses of loop diuretics are associated with increased adverse outcomes in chronic HF but also concluded that prospective randomized studies are warranted to clarify whether these associations indicate causality or high-dose diuretics are merely a marker of disease severity,22 such as suggested in a small prospective observational study.23

On the other hand, assessment of fluid overload and congestion is of crucial importance in the management of HF, not only because of its correlation with prognosis24–26 but also for symptom relief. To assess the degree of congestion on hospital discharge after HF exacerbation, published scores incorporated different variables such as dyspnea, edema, worsening of renal function, or increased NT-proBNP.24,25 However, few data are available on the evaluation of signs and symptoms of congestion in the context of chronic HF. In a post hoc analysis of the TIME-CHF study, some clinical variables (eg, edema, dyspnea for mild exertion), which we included in our score, were proven to be related with worse outcomes and congestion.20 In light of the known prognostic value of NT-proBNP and renal function assessment, as well as of their variations, to guide diuretic therapy management we have also tried to exploit these laboratory data.24–28 In low-risk patients we found lower levels of NT-proBNP, a more preserved renal function, and a lower rate of other clinical characteristics known to be associated with worse outcomes. Nevertheless, by combining and incorporating these data in our score, we believe we have been able to improve the remote management and risk stratification of our HF patients by objectively identifying global clinical status and its fluctuations during follow-up.

Nevertheless, at 6 months, we observed in our study population a high rate of the composite outcome of CV death and/or HF hospitalization that occurred in nearly one-fifth of our study population. The main finding of our study is that our score was able to correctly identify a low-risk group, patients coded as green, with a significantly lower incidence of the composite endpoint compared to the other 2 higher-risk, yellow and red, groups. Interestingly, the ability of TeleHFCovid19-Score to correctly stratify the risk of adverse events in our patients was evident at 1 month and was maintained up to the 6-month follow-up, when the incidence of the composite outcome was still very low (9%) in the green group compared to the yellow and
red groups (33% and 69%, respectively). Moreover, the cutoff score identified by the receiver operating characteristic analysis as having the highest sensitivity and specificity to identify low-risk patients was 4.5, both at the short and medium term, which is quite close to the cutoff of <4 that we had arbitrarily chosen to assign patients to the green group. The outcome of our population is overall very poor and significantly worse when compared to patients enrolled in randomized clinical trials or cardiologic observational registries. Nevertheless, this comparison requires caution because of the exceptional timing of observation (COVID-19 pandemic) and to the profound epidemiologic and clinical differences in terms of age and comorbidity burden. Our mortality and, mostly, hospitalization rates are in line with those previously reported analyzing specific older HF populations.28

Data in the literature about the effectiveness of telehealth in the management of HF are conflictual. In fact, although telemonitoring in several studies failed to impact prognosis, virtual visits and structured telephone interviews have shown to improve quality of life and reduce the rate of hospitalizations.17 In the DIAL trial, patients who received the telephone intervention were less likely to be admitted for worsening HF or to die, and showed a better quality of life compared with those in the usual care group.21

Therefore, we believe that in a postpandemic era, the TeleHFCovid19-Score, and relative questionnaire, could be used to manage chronic HF patients. For example, it could be applied to remotely confirm patients’ stability (eg, patients in New York Heart Association class I or II at the previous clinical evaluation) or to assess the effects of medical therapy optimization (eg, guidelines directed medical treatment dose adjustments and/or diuretic treatment reduction or withdrawal). Consequently, it will be possible to ease the clinical care burden of HF management, allowing physicians to focus on unstable patients who will benefit from in-person visits.

Some limitations of the present study are to be acknowledged. First, the substantially limited sample size and the selective nature of the study population (older HF patients, with a high prevalence of HF with preserved ejection fraction and comorbidities), which may limit the generalizability of results. Second is the absence of a control group, with preserved ejection fraction and comorbidities), which may limit the generalizability of results.22-23

Conclusions and Implications

The TeleHFCovid19-Score represents one of the few examples of risk stratification for the remote management of HF patients developed during the SARS-CoV-2 pandemic. The questionnaire from which the score was derived was easily and quickly administered to patients and/or their caregivers, providing physicians with a tool able to standardize remote controls. Moreover, the TeleHFCovid19-Score showed a high sensibility and specificity to identify patients at a low risk of adverse events (HF hospitalization and/or CV death). Given the high prevalence of chronic HF and the commitment required for its management, strategies should be studied and implemented to appropriately use clinical resources by directing efforts where most needed. Therefore, the TeleHFCovid19-Score could help to accurately identify those chronic HF patients who, being at a low risk of events, may be managed safely in remote, thereby reserving tighter on-site clinical evaluations for higher-risk patients who, indeed, require more frequent follow-up. Furthermore, we believe that low-risk patients categorized as green by the TeleHFCovid19-Score might be managed by specialized HF nurses with a standardized follow-up in the context of a multidisciplinary HF clinic.

Anyway, the effectiveness of this tool in a postpandemic world should be evaluated in a randomized clinical trial that could verify the effects of our questionnaire and relative TeleHFCovid19-Score in the management of HF patients.

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