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An Outpatient Management Strategy Using a Coronataxi Digital Early Warning System Reduces Coronavirus Disease 2019 Mortality

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Background. The coronavirus disease 2019 (COVID-19) pandemic has caused sudden, severe strain to healthcare systems. Better outpatient management is required to save lives, manage resources effectively, and prepare for future pandemics.

Methods. The Coronataxi digital early warning (CDEW) system deployed in Rhein-Neckar County and Heidelberg, Germany is an outpatient care system consisting of remote digital monitoring via a mobile application, a medical doctor dashboard, and medical care delivery to COVID-19 patients in home quarantine when indicated. Patients reported their symptoms, temperature, breathing rate, oxygen saturation, and pulse via the app. This single-center cohort study compared outcomes of the population with and without using the CDEW system. The primary outcome was mortality; the secondary outcomes were hospitalization, duration of hospitalization, intensive care therapy, and mechanical ventilation.

Results. Mortality rate was 3- to 4-fold lower and hospitalization rate was higher in the CDEW cohort (459 patients) compared with the cohort without CDEW in the same test area and other regions (Mannheim, Karlsruhe town, Karlsruhe district, and Germany), (mortality rate: 0.65% [95% confidence interval {CI}, .13%–1.90%] versus 2.16%, 2.32%, 2.48%, 2.82% and 2.76%, respectively, $P < .05$ for all; hospitalization rate: 14.81% [95% CI, 11.69%–18.40%] versus 6.89%, 6.93%, 6.59%, 6.15%, and 7.22%, respectively, $P < .001$ for all). The median duration of hospitalization in the CDEW cohort was significantly lower compared with a national sentinel cohort (6 days [interquartile range {IQR}, 4–9.75 days] versus 10 days [IQR, 5–19 days]; $Z = -3.156$; $P = .002$). A total of 1.96% patients needed intensive care and 1.09% were mechanically ventilated.

Conclusions. The CDEW system significantly reduced COVID-19 mortality and duration of hospitalization and can be applied to the management of future pandemics.

Keywords. COVID-19; hospitalization; mortality; outpatient care; remote digital monitoring.

The coronavirus disease 2019 (COVID-19) pandemic has caused and continues to cause great strain to healthcare systems and hospitals globally, where resource allocation is vital to help countries cope with the ongoing pandemic. Improved outpatient management is required to prepare for future global pandemics.

In the last 10 years, the use of telemedicine and nursing staff or nursing practitioners to provide home visits has been increasing to cope with a lack of primary care physicians available to carry out home visits for homebound patients [1]. During the COVID-19 pandemic, patients diagnosed with COVID-19 were also homebound under home quarantine rules to prevent further viral transmission. Because COVID-19 patients often suffer from hypoxemia long before dyspnea is perceived [2], early monitoring of patients' vital parameters allows timely intervention (eg, oxygen and cortisone therapy) to prevent further disease deterioration [3, 4]. Therefore, a structured patient care strategy is important to improve patient outcomes and to reduce pressure on hospitals and healthcare systems by triaging patients and directing them to the appropriate medical care teams early on. However, although some outpatient care and telehealth models for COVID-19 have been proposed and implemented [5–8], there is little evidence available that describes their relative effectiveness in improving patient outcomes or reducing the burden on healthcare systems.

To optimize COVID-19 outpatient management, the University Hospital of Heidelberg cooperated with the local health authorities to design a patient management strategy with the following aims: (1) to reduce mortality; (2) to minimize

unnecessary contact between COVID-19 patients in quarantine and medical personnel and members of the public at emergency departments or public transportation; (3) to monitor patient health indicators at home to identify patient deterioration early; (4) to proactively escalate medical care as needed; (5) to continuously triage patients so that they could remain at home until hospital treatment was necessary; and (6) to reduce patient surges at hospital emergency departments. The Coronataxi digital early warning (CDEW) system was therefore designed and implemented in Rhein-Neckar County and in Heidelberg, Germany. The CDEW consisted of a remote digital monitoring system and a system to deliver medical care to homebound patients.

To measure the effectiveness of the CDEW, this study was conducted to compare the mortality rate, hospitalization rate, and duration of hospitalization between COVID-19 patients included in this CDEW cohort and patients in neighboring areas and in the test area without use of CDEW. We hypothesized that mortality and hospitalization rates, duration of hospitalization, and the need for intensive care would be reduced when COVID-19 patients were monitored remotely in an organized outpatient setting.

METHODS

Study Design and Setting

This is a prospective cohort study approved by the Ethics Committee of the Medical Faculty of Heidelberg University Hospital (number S-324/2020; date of approval May 25, 2020; DRKS00025091). The Heidelberg University Hospital cooperated with the regional health authorities to set up a system for outpatient care and remote monitoring for COVID-19 patients in the region of Rhein-Neckar County and Heidelberg. Rhein-Neckar County has an area of 1061.55 km^2 and a population of 548 233 [9], whereas Heidelberg has an area of 108.33 km^2 and a population of 158 741 [10]. This CDEW system consisted of a call center to obtain the following: patients' medical history and current symptoms at initialization timepoint; a delivery system to bring pulse oximeters to the patients after initial contact with the call center; a mobile application (designed and deployed by the authors in collaboration with Huma-Medopad within 2 weeks) for remote monitoring of self-reported symptoms, vital parameters, and oxygen saturation thrice daily; and a nursing team (Coronataxi) that made additional visits to patients' homes during patient quarantine, if required. Upon COVID-19 diagnosis, patients received a letter from the regional health authority informing them about mandatory quarantine as well as about this voluntary outpatient care program, especially encouraging participation of patients with known risk factors for severe COVID-19. Patients interested in using this system contacted a call center from 8 AM to 4 PM on weekdays, where they were informed about the study and asked for written consent

for participation in this study. This could have led to a voluntary bias in this study. After study consent, a structured survey including medical history, medication, and current symptoms was carried out by a nurse. Information regarding the use and link to initialize the mobile application (Huma-Medopad) as well as detailed instructions on correct use of a pulse oximeter were sent to the patients via email directly after the survey. Pulse oximeters were loaned to the patients and delivered to their homes by a member of the local health authority the next working day after initial contact. After downloading the app, patients keyed in their detailed symptoms, temperature, self-counted breathing-rate, and, after receiving a pulse oximeter, their peripheral oxygen saturation (SpO$_2$) and heart rate into this mobile application thrice daily (Supplementary Material 1–3). Before receiving a pulse oximeter during weekends, patients were still monitored, based on other vital parameters and symptoms. Based on the data obtained from the initial survey and all self-reported app data accessible in the doctors' dashboard, a medical doctor at the university hospital decided whether a visit in home during quarantine by a nurse was indicated and scheduled the visit for the following day. During these home quarantine visits, the visiting nurse performed a clinically oriented physical examination, recorded the patient's vital parameters (temperature, breathing rate, heart rate, and SpO$_2$), and performed blood and urine collection for laboratory analysis. The nursing team consulted the supervising physician as needed. The supervising physician provided consultation to the nursing team, remotely monitored the app data hourly from 8 AM to 10 PM, and made decisions concerning the need for additional home care visits or hospitalization of the patients. Situations that tended to initiate a home care visit were SpO$_2$ <92%, heart rate >100/minute, subjective dyspnea, C-reactive protein >100 mg/dL, or highly pathological blood tests. The decision for escalation of care was made at the discretion of the physician based on all information available. The patients were monitored only for as long as they keyed in data into the app. Technical support for the app was provided by Huma-Medopad, and patients could contact the call center for other questions. Figure 1 shows the workflow of CDEW system.

Other than the efforts that went into planning, collaboration, and execution of this CDEW system, the key staff resources needed for smooth running of the CDEW were a supervising medical doctor, a nurse delivering medical care to patients, nurses to operate the call center, and staff from the local health authority for pulse oximeter delivery to patients' homes and as drivers for the Coronataxi. Because this CDEW was carried out by a hospital, preexisting hospital structures, facilities, and staff could be used.

In general, all patients who contacted the call center at any time point (as outpatients, postdischarge, or postemergency department discharge) were monitored using the CDEW system. For purposes of this study, a clear protocol was used
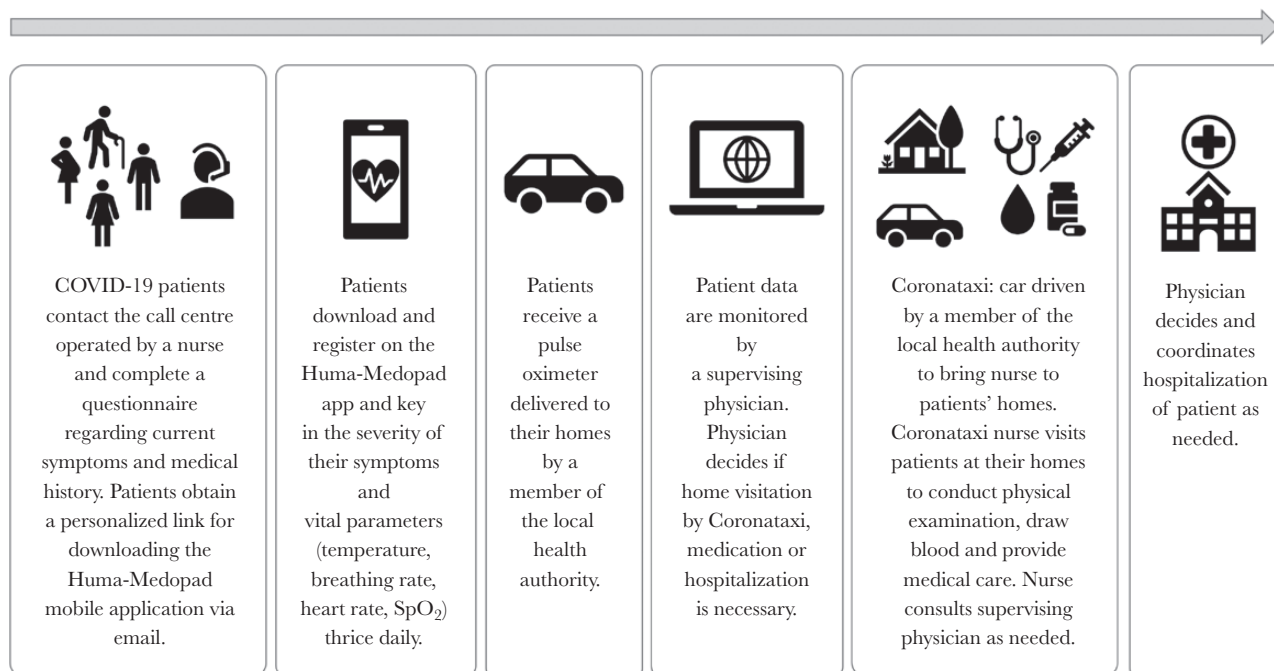
Figure 1. Workflow of the Coronataxi digital early warning system. CDEW, Coronataxi digital early warning system; SpO$_2$, peripheral oxygen saturation.

to decide whether patients were enrolled. Inclusion criteria were laboratory-confirmed COVID-19 diagnosis and keying in information into the Huma-Medopad-App for the first time between September 7, 2020 and March 18, 2021, age ≥18, and written informed consent. Exclusion criteria were age ≤18, inability to operate Huma-Medopad, and absence of informed consent. Patients were excluded from data analysis if they did not have contact with CDEW before hospitalization or treatment in the emergency department or did not report any symptom or vital parameter information in the Huma-Medopad-App.

The primary outcome was mortality; the secondary outcomes were hospitalization, length of hospitalization, intensive care treatment, and need of mechanical ventilation (noninvasive and invasive). The demographic characteristics, medical history, and clinical data (severity of symptoms and vital parameters) were collected by the nurses during initialization call through the call center and also through Huma-Medopad-App.

For survival analysis, the date of inclusion into this study was defined as the earliest date when data were keyed in into the Huma-Medopad-App. A follow-up survey to analyze survival status and gain feedback on the experience of patient care was carried out. This survey comprised 2 parts: a minimal part ("Do you feel healthy again?") and an additional, more detailed, follow-up survey. Patients who did not participate in the follow-up survey were additionally contacted by telephone to confirm survival and to minimize loss to follow-up. On the data closure date (June 12, 2021), all patients (except for the 3 deceased patients) had been successfully contacted to analyze survival status.

The outcomes of the CDEW cohort were compared (1) with the outcomes of the population in the same test area that did not use the CDEW system and (2) with patients in neighboring areas (Mannheim, Karlsruhe town, Karlsruhe district, and Germany as a whole) during the time period between September 7, 2020 and March 21, 2021. Data from the test area and the neighboring areas were obtained from the local health authorities, whereas data for Germany and the total number of patients with positive reverse-transcription polymerase chain reaction (PCR) test for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) were obtained from published data [11–14] from the Robert-Koch Institute, the German federal government agency responsible for disease control and prevention. For some weeks, the number of deaths by age group in the German population was reported as <4. In this study, we applied the same average assumption that was used by the local health authority. The number <4 was considered to be 1 death for patients <30 years old and 3 deaths for patients ≥30 years old. All positive PCR test results were reported to the local health authorities directly from the laboratories. However, hospitalization of patients was reported by hospitals and was underreported, because information on whether patients were hospitalized was only available for 75% of the COVID-19 patients in the German population [12]. The mortality rate in the German population was also underreported. Patients who died of COVID-19 complications were no longer considered as COVID-19-related deaths, once they had a negative SARS-CoV-2 PCR or when mandatory isolation ended. Patients' survival and length of intensive care unit (ICU) stay of the test

cohort were based on initial study inclusion, and follow-up did not end when patients had negative SARS-CoV-2 PCR and mandatory isolation ended.

Statistical Analysis

Descriptive statistics are shown for the CDEW cohort. Continuous variables are reported as median and interquartile range (IQR). Categorical variables are expressed as absolute numbers and percentages. One-sample Wilcoxon signed-rank test was used to compare the median age and median duration of hospitalization for different groups of patients. An exact binomial test was used to compare the mortality and hospitalization rates. Spearman's correlation was used to determine the correlation of subjective dyspnea and SpO_2. All tests were 2-sided and $P \le .05$ was considered significant. All data were analyzed using IBM SPSS Statistics version 27 and Microsoft Excel.

RESULTS

Figure 2 shows the patients included and excluded from this study. Table 1 shows the baseline characteristics and outcomes of 459 patients included in this study as well as the vital parameters and symptoms entered into the monitoring
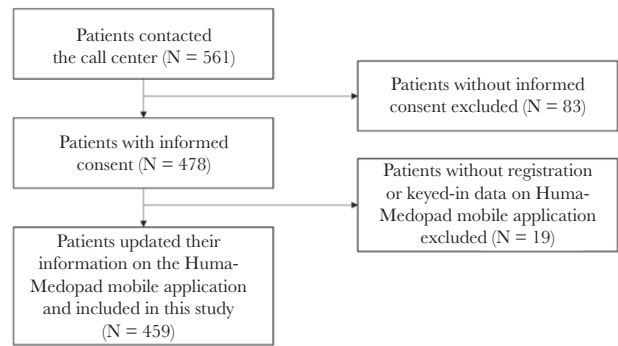

Figure 2. Patient recruitment and number of patients included and excluded.

app by the patients. The patients included in the study were significantly older with a median age of 51 (IQR 40–61) compared with the German national average for COVID-19 patients with an average median age of 42 (Z = 10.985, $P < .001$). There were more patients in the 40–69 age group and fewer patients in the age group younger than 30 years old and over 70 years old in the CDEW cohort compared with other populations (Figure 3a).

Despite an older population in the CDEW cohort, a mortality rate of 0.65% (95% CI, .13%–1.90%) was observed. The

Table 1. Basic Characteristics and Outcomes of the CDEW Cohort

Characteristics	Disease Severity		
	Outpatient (n = 391)	Normal Ward (n = 59)	ICU (n = 9)
Male gender, no. (%)	147 (37.6%)	36 (61.0%)	7 (77.8%)
Age, median (IQR)	50 (39–60)	60 (50–69)	61 (55–70)
BMI, median (IQR)	26.5 (22.8–30.8)	27.0 (24.5–34.3)	29.1 (28.5–30.4)
Arterial hypertension, no. (%)	113 (28.9%)	22 (37.3%)	4 (44.4%)
Diabetes mellitus, no. (%)	35 (9.0%)	11 (18.6%)	2 (22.2%)
Asthma, no. (%)	45 (11.5%)	5 (8.5%)	0 (0%)
COPD, no. (%)	8 (2.0%)	5 (8.5%)	1 (11.1%)
Depression, no. (%)	6 (1.5%)	3 (5.1%)	0 (0%)
Minimum SpO_2, median (IQR)[a]	95 (94–97)	92 (90–94)	91 (86–92)
Maximum heart rate, median (IQR)[a]	90 (80–98)	95 (84–102)	85 (82–96)
Maximum temperature, median (IQR)[a]	37.1 (36.7–37.7)	38.1 (37.2–39.0)	38.2 (37.7–38.8)
Minimum temperature, median (IQR)[a]	36.0 (35.5–36.5)	36.2 (35.8–36.8)	36.9 (36.5–37.6)
Maximum respiratory rate, median (IQR)[a]	18 (16–21)	19 (16–23)	20 (15–33)
Maximum subjective Dyspnea, no. (%)[a]			
0	1 (0.3%)	0 (0%)	0 (0%)
1	220 (58.2%)	24 (43.6%)	3 (37.5%)
2	103 (27.2%)	16 (29.1%)	1 (12.5%)
3	42 (11.1%)	11 (20.0%)	3 (37.5%)
4	12 (3.2%)	3 (5.5%)	1 (12.5%)
5	0 (0%)	1 (1.8%)	0 (0%)
Oxygen therapy, no. (%)	0 (0%)	36 (61%)	9 (100%)
Mechanical ventilation, no. (%)	0 (0%)	0 (0%)	5 (55.6%)
Duration of hospitalization, no. (%)	0 (0%)	5 (5–8)	31 (15–42)
Mortality, no. (%)	1 (0.3%)	1 (1.7%)	1 (11.1%)

Abbreviations: CDEW, Coronataxi digital early warning system; COPD, chronic obstructive pulmonary disease; BMI, body mass index; ICU, intensive care unit; IQR, interquartile range; SpO_2, peripheral oxygen saturation.

[a]Only vital parameters (SpO_2, heart rate, temperature and respiratory rate) and levels of subjective dyspnea before hospital admission (if any) were considered.
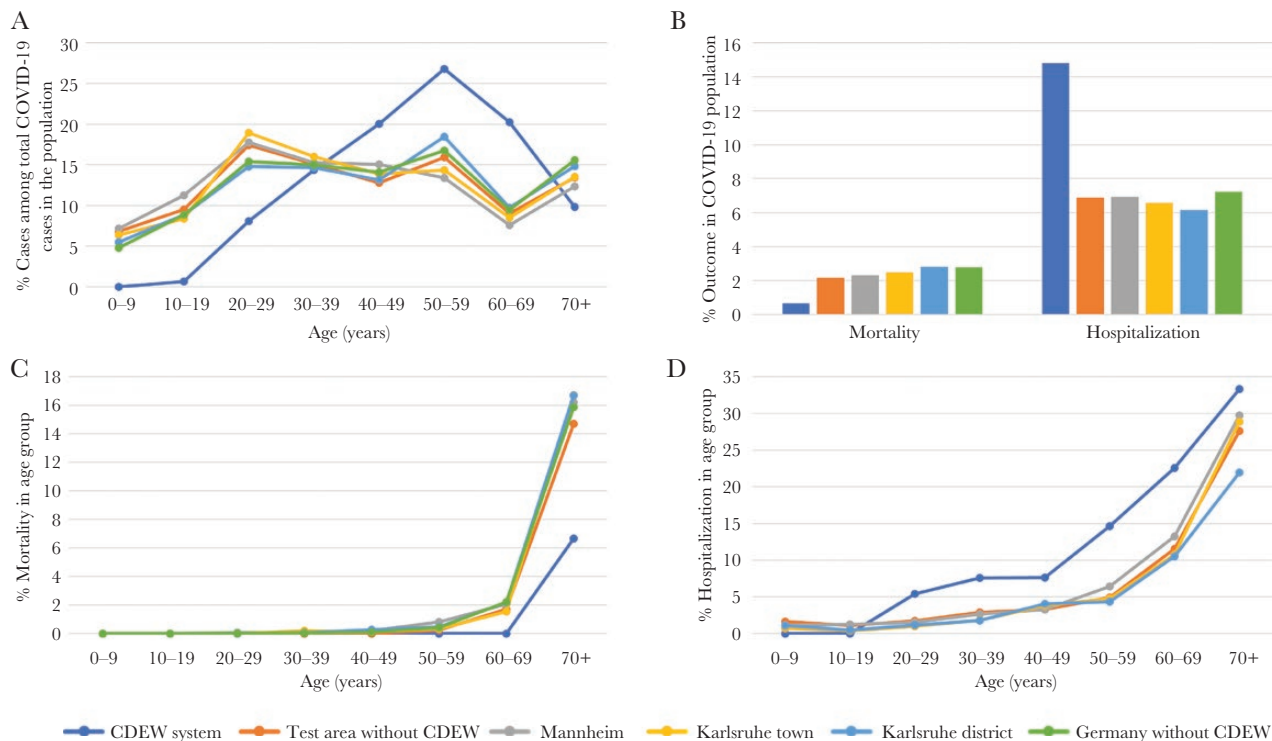
Figure 3. (a) Comparison of age group distribution in the study population, test area without study population, neighboring areas, and Germany nationally. (b) Mortality and hospitalization rates in the Coronataxi digital early warning system (CDEW) cohort, test area excluding the CDEW cohort, neighboring areas, and Germany nationally. (c) Mortality rates in each age group of coronavirus disease 2019 (COVID-19)-positive patients in the CDEW cohort, test area excluding the CDEW cohort, neighboring areas, and Germany nationally. (d) Hospitalization rates in each age group of COVID-19-positive patients in the CDEW cohort, test area excluding the CDEW cohort, neighboring areas, and Germany nationally.

mortality rate was 3- to 4-fold lower than in patients who did not use the app in the same test area and for patients in Mannheim, Karlsruhe town, Karlsruhe district, and the whole of Germany, which had mortality rates of 2.16%, 2.32%, 2.48%, 2.82% and 2.76%, respectively ($P < .05$) (Figure 3b). There was no loss to follow-up. The Kaplan-Meier curve of survival is shown in Supplementary Material 2. Only 1.96% of the CDEW cohort patients were treated at the ICU and 1.09% mechanically were ventilated. All 3 deaths in this CDEW cohort occurred in elderly patients who needed hospitalization, intensive care treatment, or mechanical ventilation but refused it. In fact, no patient in the CDEW cohort who agreed to full-code treatment (maximal therapy, including intubation and resuscitation) died. There were no deaths in the age group <70 years old (Figure 3c). When comparing mortality rates within age groups, the mortality rate in the age group ≥70 years old was lower in the CDEW cohort compared with the cohort of patients of the test area without CDEW (6.67% vs 15.85%, $P < .001$) (Figure 3c).

When comparing the hospitalization rate, this CDEW cohort had a hospitalization rate of 14.81% (95% CI, 11.69%–18.40%), significantly higher (2- to 2.5-fold higher) than in the areas compared as above, with hospitalization rates of 6.89%, 6.93%, 6.59%, 6.15%, and 7.22%, respectively ($P < .001$) (Figure 3b).

For all age groups, a comparatively larger proportion of patients was hospitalized in the CDEW cohort than in the other analyzed populations (Figure 3d).

However, the median duration of hospitalization in the CDEW cohort (6 days; IQR, 4–9.75 days) was significantly lower compared with a sentinel cohort in the whole of Germany during the first wave of COVID-19 pandemic (10 days; IQR, 5–19 days; $Z = -3.156$; $P = .002$). Considering only patients without the need of intensive care, the median duration of hospitalization in this CDEW cohort (5 days; IQR, 4–8 days) was also significantly shorter than that in Germany nationally (7 days; IQR, 5–13 days; $Z = -2.796$; $P = .005$. However, for patients treated at the ICU, the days of hospitalization were not significantly different between these 2 groups: 31 (IQR, 14.5–46.5) vs 16 (IQR, 8–27) ($Z = 1.680$, $P = .093$). There were 6 patients in the CDEW cohort with duration of hospitalization <48 hours.

The Coronataxi made a total of 539 visits to 297 (64.71%) patients, with a median of 1 (IQR, 1–2) visit per visited patient. Using the Coronataxi, 29 (6.4%) patients were treated in an outpatient setting with antibiotics for urinary tract infection or an anticoagulant in case of history of recent thrombotic event.

Among the 362 patients who responded to the detailed follow-up survey, 98.89% believed they were well monitored, 94.44% who had fear of COVID-19 felt more reassured after

using the app, 92.76% found the app easy to use, 14.92% needed help operating the app, and 99.72% found the app useful for monitoring COVID-19 outpatients. There was a small correlation between minimum SpO_2 and maximum degree of reported dyspnea ($r_s = -.238$, $P < .001$, N = 441) (Supplementary Material 3).

DISCUSSION

The key results of this study are that this CDEW outpatient care model resulted in lower mortality rate and higher hospitalization rate with shorter duration of hospitalization. There were no deaths among patients who agreed to full-code medicine without limitations.

In response to COVID-19, technology has been used in many ways to modify patient care and triage. Use of telemedicine to monitor homebound patients [5, 15, 16], provide physician consultation online [7], artificial intelligence to identify patients with disease progression [17], and even providing care to homebound patients [8, 18] are increasing rapidly in hospitals around the world. This CDEW system effectively combines several such aspects of remote monitoring, delivery of medical care, and triaging of patients for hospital admission, which is highly suited to working with infectious patients. This is the first study to quantitively assess the mortality rate, hospitalization rate, and duration of hospitalization in a population with and without the use of an outpatient care system for COVID-19.

The mortality rate in this CDEW cohort (0.65%) was lower than in some cohorts using remote monitoring services in the United Kingdom (1.1%) [19] but higher than in some cohorts with home monitoring and hospital-level care in the United States (0%) [8]. A few factors may have contributed to lower mortality rate in this test cohort. Because subjective dyspnea correlates poorly with hypoxemia in COVID-19 [2] and asymptomatic hypoxemia is related to high mortality [20], early delivery of oxygen therapy and supportive therapy upon onset of hypoxemia has been shown to reduce mortality [3, 21]. Therefore, continuous monitoring of peripheral oxygen saturation using CDEW system allows early warning of moderate or severe disease progression, enabling early intervention and supportive therapy such as oxygen therapy and dexamethasone therapy to be carried out quickly, to slow disease progression [22]. Increased patient awareness [23] regarding signs of disease progression as they keyed in their data into the app could have also contributed to the lower mortality rate, as patients seek medical attention earlier.

Although mortality in patients who require mechanical ventilation is approximately 45% [24], there was no mortality in patients who agreed to full-code medicine in this CDEW cohort. The difference in mortality rates between this CDEW cohort and the populations compared could have been even bigger due to underreporting in the population. Identifying patients quickly at the start of disease progression using the CDEW system results in timely management of these patients to avoid the admission of patients into the ICU in severe respiratory distress without prior therapy. Early therapy reduces pulmonary and systemic damage and may contribute to a reduced mortality, even in patients mechanically ventilated.

The higher rate of hospitalization observed could be explained by the increased care provided and the remote and much more frequent monitoring of patients. However, this may also be the key to reduced duration of hospital stay observed in this cohort, because patients are admitted at the initial stage of deterioration and require shorter treatment. The difference in hospitalization rates between CDEW and the populations compared could be slightly smaller due to underreporting in the populations compared. The CDEW system was also used to monitor patients after discharge from hospital or the emergency department, thus enabling early discharge and further alleviating pressure on hospitals in future pandemics.

The ICU admission rate of all COVID-19-positive patients has been described to be between 5% and 12% in China, South Korea, and Italy [25–27], significantly higher than that in the CDEW cohort (1.9%). This model of patient care, especially when targeting patients at risk of severe disease progression, could therefore be helpful in a pandemic to reduce the burden on intensive care units by optimizing primary and secondary patient care through early monitoring and intervention.

A comparison of the baseline characteristics of the CDEW cohort and the populations compared could not to be carried out due to lack of data. However, the CDEW cohort had either similar or more comorbidities compared with the general German population, except for depression, arterial hypertension (30% vs 31.8% [28]), diabetes mellitus (10.4% vs 7.7% [29]), asthma (10.9% vs 6.2% [30]), chronic obstructive pulmonary disease (3.1% vs 5.8% [31]), and depression (2.0% vs 10.1% [32]). The lower mortality in CDEW cannot be explained by a difference in baseline characteristics.

Compared with other outpatient monitoring systems [33, 34], admission of CDEW patients bypassed the emergency department, which also reduced the burden on the emergency departments during this pandemic. The mortality, hospitalization, intensive care treatment, and ventilation rates were lower compared with other studies using other forms of outpatient monitoring systems [33, 34].

There were no issues reported regarding the use of pulse oximeters. Patient compliance was high without being prompted, because 94.4% also reported feeling reassured using the app. Experiences with this CDEW system have provided valuable experience and knowledge to allow improvements for future use. Functions that prompt patients to key in their data and warning systems for patients could be added in the future. Due to the need of basic technological skills or someone to help with the app or contacting the call center, there may be additional

barriers to accessing CDEW related to age, migrant status, and socioeconomic position.

There are some limitations to this study. The number of patients hospitalized and number of deaths due to COVID-19 from the areas compared were generally underreported and thus underestimated. The decision as to whether a home visit or hospitalization of the patient was required was based on the subjective discretion of a single experienced physician, and although the physician was experienced, this could be a source of bias. Other limitations include a single-center study, lack of validation cohort, and 1-sample comparison. Furthermore, duration of hospitalization was compared using data from the first wave of COVID-19 pandemic in Germany, which may vary slightly from the second wave.

The strengths of this model of outpatient care are that it is a "forward-triage" [6] model, streamlining patients to the appropriate care before they arrive at the admission ward. Because the decision for admission into the hospital was made by the supervising physician, patients did not need to visit the emergency department before admission, therefore further reducing exposure risks and the burden on the emergency department. This process resulted in patients arriving at hospital being less sick than without the CDEW. This decentralized healthcare delivery via the Coronataxi to the patients at their homes was used, because patients were homebound in quarantine. The Coronataxi also logistically minimized movement of patients and viral transmission compared with patients having to needlessly visit primary care clinics or emergency departments. Furthermore, this model optimizes resource allocation, reduces mortality, and duration of hospitalization. Early and close cooperation between the hospital and local health authorities was crucial to the success of the CDEW system. This study has important implications for future pandemics and could be used to improve patient management and optimize resource allocation.

CONCLUSIONS

Early remote digital monitoring of patients using this CDEW system significantly reduces COVID-19 mortality and duration of hospitalization. This model of outpatient care may be applied to other future pandemics, especially those caused by highly infectious diseases.

Supplementary Data

Supplementary materials are available at *Open Forum Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

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