RESPINOS Remote Monitoring Device to Observe the Vital Signs of Mild – Moderate COVID-19 Patients

Hafif – Orta Derecede COVID-19 Hastalarının Hayati Belirtilerini Gözlemlemek İçin RESPINOS Uzaktan İzleme Cihazı

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ABSTRACT

Objective: To assess the validity of RESPINOS, a remote monitoring device, to measure the vital signs of patients with mild – moderate COVID-19.
Methods: A cross sectional study was conducted in Dr. Soetomo Hospital, Surabaya, Indonesia. All patients with mild – moderate COVID-19 were enrolled to our study, and patients with unable to cooperate in operating the tool were excluded. The implementation of RESPINOS was considered the predictor covariate, and the vital signs were considered the outcome, compared to the measurement of standard device. A t test and kappa agreement were used to assess the similarity between the measurement of RESPINOS and the standard device.
Results: A total of 180 participants was employed to our study. Of them, we found that the measurements of respiratory rate, heart rate, and oxygen saturation had similarity between RESPINOS and the standard device ($p > 0.05$). Moreover, our analysis in kappa agreement also found that the coefficient of kappa agreement was higher in respiratory rate, heart rate, and oxygen saturation, suggesting that the measurement either by using RESPINOS or standard device provided similar findings.
Conclusion: RESPINOS offers the benefits for a remote monitoring in patients with mild – moderate COVID-19.

Keywords: COVID-19; RESPINOS; remote monitoring; medical device.

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ÖZET

Amaç: Hafif-orta şiddette COVID-19'lu hastaların hayati belirtilerini ölçmek için bir uzaktan izleme cihazı olan RESPINOS'un geçerliliğini değerlendirmek.
Yöntem: Bu kesitsel çalışma Endonezya, Surabaya'daki Dr. Soetomo Hastanesinde yürütülmüştür. Hafif-orta şiddette COVID-19'u olan tüm hastalar çalışmamıza dahil edildi ve aracı çalıştırmada işbirliği yapamayan hastalar dışlandı. RESPINOS'un uygulanması, öngörücü ortak değişken olarak kabul edildi ve yaşamsal belirtiler, standart cihazın ölçümüne kıyasla sonuç olarak kabul edildi. RESPINOS ölçümü ile standart cihaz arasındaki benzerliği değerlendirmek için t testi ve kappa anlaşması kullanıldı.
Bulgular: Çalışmamıza toplam 180 katılımcı alındı. Bunlardan solunum hızı, kalp hızı ve oksijen satürasyonu ölçümlerinin RESPINOS ile standart cihaz arasında benzerlik gösterdiğini bulduk ($p > 0.05$). Ayrıca, kappa uyumundaki analizimiz de kappa uyumu katsayısının solunum hızı, kalp hızı ve oksijen satürasyonunda daha yüksek olduğunu bulmuştur, bu da RESPINOS veya standart cihaz kullanılarak yapılan ölçümün benzer bulgular sağladığını düşündürmektedir.
Sonuç: RESPINOS, hafif – orta şiddette COVID-19 hastalarında uzaktan izlemenin faydalarını sunar.

Anahtar Sözcükler: COVID-19; RESPİNOS; uzaktan gözlemleme; Tıbbi cihaz.

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INTRODUCTION

Since declared as a global pandemic, COVID-19 has caused multisectoral disruption, and the aggressive action has been recommended to take to against the pandemic.(1) The World Health Organization (WHO) has published the living guideline for the management of COVID-19, (2) and the periodical update has been taken. (3,4) However, the guideline may have several important limitations such as: unavailable definitive proven drugs, the challenging of treatment response measurement, the challenging of follow up of quarantine COVID-19 patients.(5,6) Of them, the management of COVID-19 patients in quarantine has been a primary concern, especially for the monitoring of vital signs. The report revealed that the mortality of COVID-19 patients in quarantine was occurred in 5-7% of all COVID-19 mortality.(7) The data suggested that the management of COVID-19 patients in quarantine needed an exclusive strategy.

The concept of technology - based patient care have been developed since the last decade.(8) To resolve the monitoring of COVID-19 patients in quarantine, a remote monitoring device might be required. Since introduced in the last decade, a remote monitoring device was believed to concert a patient care progress, and it appeared to maximize the effectiveness of patient monitoring and the treatment response.(9) Previously, the concept of remote monitoring device has been applied in the case of automated peritoneal dialysis,(10) cardiovascular disease, chronic obstructive pulmonary disease,(11) end stage renal disease, diabetes mellitus, and hypertension,(12) and the positive outcome was found. Moreover, a study also revealed that the implementation of a remote monitoring device provided the cost effectiveness compared to the conventional monitoring.(13) However, to date, no standardized device for remote monitoring in COVID-19. Therefore, we designed a remote monitoring device, called RESPINOS. Our study aimed to assess the validity of RESPINOS to measure the vital signs of quarantine COVID-19 patients and compared to the standard device.

METHODS

Design and participants

We performed a cross - sectional study in Dr. Soetomo Hospital, Surabaya, Indonesia. We needed a minimal of 138 participants as the minimal sample size based on the estimated prevalence of COVID-19 was 10-15% with 5% margin error and 95% confidence interval. The inclusion criteria were all mild – moderate COVID-19 patients treated in our hospital. The exclusion criteria were patients with unable to cooperate in operating the tool. The protocols the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)(14) checklist and the principles outlined in the declaration of Helsinki were applied in the study.(15) Our present study had been registered and approved by the local ethical committee of Dr. Soetomo Hospital (No: 0239/KEPK/VIII/2021). Prior to recruit in the study, we had explained to the participants on the aims, benefits, and risks of the study. We also informed that the participants could quite any time from our study. All the participants were voluntary, and we did not provide the incentive.

Study covariates

The predictor covariate in our present study was the implementation of RESPINOS tool (Figure 1). The steps for using RESPINOS were as follows: (1) attached the sensors of airflow, oxygen saturation, heart rate, and temperature to the devices; (2) turned on the device by pressing the power button; (3) connected the device to the smartphone; (4) attached the sensor of oxygen saturation to the patients finger and instructed the patients to hold the sensor of temperature; (5) the patient were instructed to breathe through the airflow sensor; (6) performed the "start" command via the smartphone; (7) after the measurements had been taken, performed the "stop" command. The outcome measures in our study were respiratory rate, heart rate, temperature, and oxygen saturation. The data were compared to the measurements of standard tools, such as: respiratory and heart rate monitor (Sinoheart, Changsha Sinocare Inc, Hunan, China), oxygen saturation monitor (ELITechGroup, Puteaux, France), and thermometer (Onemed, Surabaya, Indonesia).

Figure 1. A). RESPINOS remote monitoring device. B). The implementation of RESPINOS to measure the vital signs of COVID-19 patients.

Statistical analysis

We presented our data in mean ± SD or n (%). The comparison of respiratory rate, heart rate, temperature, and oxygen saturation between RESPINOS and standard tool was conducted using paired t test. The p value of more than 0.05 was considered having similarity effect. The agreement between the measurements by using RESPINOS and standard tool was performed by using kappa agreement. The agreement was achieved if the value of coefficient was more than the p value of kappa agreement. The software of Statistical Package for The Social Sciences (SPSS) version 17 (IBM SPSS, Chicago, IL) was used to analyze the data.

RESULTS

Patient selection

During the study period, a total of 186 mild – moderate COVID-19 patients was employed to our study. Among those, we excluded 6 patients due to unable to operate the device. Finally, a total of 180 sample size were included in our study. Table 1 outlines the baseline characteristics of the participants. The raw data of patients in our study is outlined in the Supplementary files.

The comparison of vital signs parameters between RESPINOS and standard tool

Our study indicated that the measurements of respiratory rate (p: 0.065), heart rate (p: 0.297), and oxygen saturation (p: 0.703) by using RESPINOS were similar to the measurements by using standard tool. Contrary, we failed to confirm the similarity of temperature measurement between using RESPINOS and standard tool ($p<0.001$). Moreover, in the agreement, we found that the value of kappa coefficient in respiratory rate (coef: 0.137; $p<0.001$), heart rate (coef: 0.384; $p<0.001$), and oxygen saturation (coef: 0.268; $p<0.001$) were higher the p value, and therefore, the agreement of the measurements of respiratory rate, heart rate, and oxygen saturation by using RESPINOS achieved the agreement to the standard tool. On the other hand, the agreement of temperature measurement between using RESPINOS and standard tool was not found (coef: 0.007; p: 0.141). The summary of the comparison of vital signs measurements between RESPINOS and standard tool is presented in the Table 2.

Table 1. Baseline characteristics of patients included in the study

Baseline characteristics	n (%) or mean ± SD
Age	55.58 ± 15.52
Gender	
Male	135 (75.0%)
Female	45 (25.0%)
Racial	
Madura	30 (16.7%)
Jawa	135 (75.0%)
Others	15 (8.3%)
Educational levels	
Elementary school	60 (33.3%)
Junior high school	15 (8.3%)
Senior high school	60 (33.3%)
University	15 (18.3%)
Others	30 (16.7%)
Body height (cm)	162.75 ± 8.024
Body weight (kg)	58.75 ± 12.53
BMI (kg/m2)	22.45 ± 6.24
Comorbidity	
Malignancy	30 (16.7%)
Immunocompromised state	15 (8.3%)
Heart failure, renal failure, obesity	15 (8.3%)

Note, data were presented in mean ± SD or n (%); BMI, body mass index; SD, standard deviation.

Table 2. The comparison of vital sign measurements between standard tool and RESPINOS

Parameters	Standard tool	RESPINOS	p	Kappa agreement	
				p	coefficient
Respiratory rate	21.00 (0.00 – 55.0)	20.00 (5.00 – 50.0)	0.065	0.000	0.137
Temperature	36.06 (0.00 – 37.1)	36.40 (35.1 – 97.4)	0.000	0.141	0.007
Heart rate	97.00 (68.0 – 147.0)	97.00 (67.0 – 147.0)	0.297	0.000	0.384
SpO2	96.00 (0.0 – 99.0)	96.00 (63.0 – 100.0)	0.703	0.000	0.268

Note, data were presented in median (min – max); SpO2, oxygen saturation.

DISCUSSION

Our study found that the implementation of RESPINOS to measure respiratory rate, heart rate, and oxygen saturation in mild – moderate COVID-19 patients had similar results to the measurements by using standard tool. Our study was the first report on the role of RESPINOS to measure the vital signs of COVID-19 patients. Therefore, the specific comparison was unable to carry out. However, the similar studies related to this topic had revealed the potential benefits of the use of portable vital signs monitoring in patients with COVID-19. A study found that the application of Internet of Things (IoT) technologies to follow up the vital signs of COVID-19 patients provided the usefulness and flexibility for health care profession.(16,17) Additionally, another study also found that the implementation of biometric monitoring technologies (BioMeTs) offered the beneficial for collecting the data vital signs in patients with COVID-19.(18) On other hand, study also revealed the benefits of ambulatory monitoring system (AMS) in patients with COVID-19.(19) Therefore, the implementation of technology based tool for the remote monitoring in patients with COVID-19 might provide superior benefits.

To the best of our knowledge, our present study used a new device to remote monitoring patients with mild – moderate COVID-19. Since the COVID-19 pandemic, the management with isolation and quarantine approach had been applied. However, in the living guideline of COVID-19 management, no recommendation was existed for the monitoring the vital signs of patients with COVID-19. In our study, we reported that the implementation of RESPINOS, a remote monitoring device, might provide the benefits for patients care with COVID-19. We expected that, the use of remote monitoring device should be recommended for the management of patients with COVID-19. However, further studies by improving the device and by performing the better study design might be required.

In our present study, we had several limitations. First, in this study, we used a new medical device. Therefore, we needed a long time to prepare the design and implementation. This point might have the impact on the delayed of clinical trials because we were waiting for the tool to be really feasible to be tested on patients. Second, during the study, we found several errors, including an error in measuring the temperature, an error in measuring the respiratory rate, and a server error. Therefore, this point had an impact on the delay in measurement. We also found that the device turned off when it was not connected to the charger.

CONCLUSION

Our study reveals that the implementation of RESPINOS as a remote monitoring device provides the similar findings to the standard device. Our current findings may be implemented for the vital signs monitoring of quarantine COVID-19 patients.

Conflict of interest
No conflict of interest was declared by the authors.

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