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The effect and implementation of the COVID Box, a remote patient monitoring system for patients with a COVID-19 infection in primary care: a matched cohort study

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Abstract

At the onset of the COVID-19 pandemic, the pressure on hospitals increased tremendously. To alleviate this pressure, a remote patient monitoring system called the COVID Box was developed and implemented in primary care. The aim was to assess whether the COVID Box in primary care could reduce emergency department (ED) referrals due to a COVID-19 infection. A matched cohort study was performed between December 2020 and June 2021. Patients with a COVID-19 infection in need of intensive monitoring based on the clinical judgement of their own general practitioner received the COVID Box in primary care combining home monitoring of vital parameters with daily video consultations. The control group was retrospectively matched by propensity score matching. We conducted a subgroup analysis in higher-risk patients with oxygen saturation measurements, considering oxygen saturation as a critical parameter for assessing the risk of a complicated infection. We included 205 patients, of whom 41 patients were monitored with the COVID Box (mean age 70 and 53.7% male) and 164 in the control group (mean age 71.5 and 53% male). No difference was found in ED referrals between the intervention and control groups in our primary analysis. In the subgroup analysis, we found a nonsignificant trend that remote monitoring could reduce the ED referrals. While the overall study found comparable ED referrals between groups, the subgroup analysis suggested a promising prospect in reducing ED referrals due to remote monitoring of higher-risk patients with acute respiratory disease in primary care.

Key words: infectious diseases; respiratory tract diseases; telemedicine; primary care; practice management; COVID-19

Introduction

At the onset of the COVID-19 pandemic, hospitals faced tremendous pressure due to a shortage of beds in both the wards and intensive care units [1]. Emergency departments in the Netherlands frequently lacked the capacity to accommodate all patients, occasionally leading to temporary closures [2]. Consequently, patients in need of urgent care were often redirected to other hospitals within the region or beyond, resulting in the inability of healthcare professionals to deliver normal care [1]. This stimulated the use of remote patient monitoring (RPM) systems to relieve hospitals from some of their workload. One of these RPM systems was the COVID Box, resulting in a 3-fold reduction in the number of hospital admissions of patients with a (suspected) COVID-19 infection after being assessed at the emergency department (ED) [3].

As the pandemic progressed, the workload of general practitioners (GPs) substantially increased [4]. The promising results of the COVID Box project in secondary and tertiary care, combined with the increased use of eHealth applications in primary care, resulted in the development of a new

variant of the COVID Box for a primary care setting. In this setup, the COVID Box, including a digital thermometer, pulse oximeter and blood pressure monitor, was deployed in conjunction with a daily video visit from a home care nurse. Current studies focusing on RPM systems in patients with a COVID-19 infection after an ED visit or hospital admission are showing promising results in safely reducing and shortening hospital admissions [3, 5, 6]. However, less is known about the effect and implementation of RPM systems in patients with a COVID-19 infection in primary care prior to an ED visit. Redirecting patients who could be treated outside the ED could help allocate more resources to patients requiring immediate and intensive care. Therefore, the aim of this study was to assess whether the COVID Box could reduce the number of COVID-19-related referrals to the ED for patients with a COVID-19 infection in primary care. Additionally, the study aimed to determine if the COVID Box could extend the time between the onset of COVID-19 infection and referral to the ED, the hospitalization rate of patients monitored with the COVID Box, and to investigate end-user satisfaction among patients and GPs.

Key Points

- GPs found telemonitoring with the COVID Box an acceptable, appropriate, and feasible intervention.
- Patients were satisfied with the COVID Box.
- No significant difference in ED referrals between COVID Box and regular care.
- A nonsignificant trend suggests the COVID Box may delay and reduce ED visits.

Materials and methods

A matched cohort study was performed. Patients received the COVID Box if: (i) they had a positive PCR test for a COVID-19 infection and were clinically ill based on oxygenation < 94%, temperature > 38.5°C for 5 days, a respiratory rate of >24 breaths/minute at rest, or signs of exhaustion; or (ii) had a high risk for hospital admission (age ≥ 75 years or other risk factors: diabetes, chronic obstructive pulmonary disease (COPD), chronic kidney disease, or immunodeficiency). Other inclusion criteria were: the ability to communicate in Dutch (both in writing and verbally) and an age ≥ 18. Patients were excluded if informed consent was not obtained after the home monitoring period had ended before inclusion.

We excluded all severely ill patients who were in obvious need of hospital care and who were immediately referred to the ED without being offered the COVID Box.

Participants within the intervention group were recruited from the end of December 2020 until June 2021 by 21 general practices located in the greater Leiden region (The Netherlands). Patients received information about the study upon the delivery of the COVID Box at home, and written informed consent was obtained when the home monitoring period had ended. Patients were not replaced if they decided to withdraw from the study.

Patients in the control group were selected from a primary care research database of the Extramural LUMC Academic Network (ELAN). This selection was based on the International Classification of Primary Care (ICPC) for proven COVID-19 ICPC R.83, starting between the 1st of October until the 10th of December 2020 and based on either a registered GP consultation or a home visit [7]. The ICPC R83 was assigned by the GP after receiving a positive PCR test result from the Municipal Health Services, the organization responsible for nationally conducting these tests. Additionally, codes for suspected COVID (R74) and fear of COVID (A27) were used, enhancing the reliability of the ICPC R.83 code [8, 9]. Since, this period fell before the implementation of the COVID Box and no similar initiatives were conducted in the region, these patients received standard care. This included an initial physical consultation and based on the clinical presentation, patients were either referred to the hospital or monitored by phone and instructed to contact the GP if symptoms worsened. Control patients were matched to intervention group patients based on propensity score matching in a 4:1 ratio. A propensity score was estimated using logistic regression on the following covariates: Charlson Comorbidity Index, age, gender, COPD, chronic kidney disease, immunodeficiency [10], and if there was a consultation or visitation with the GP coded under the ICPC R.83. Subsequently, this propensity score was used for nearest neighbor propensity score matching without replacement.

This study was approved by the Medical Research Ethics Committee Leiden Den Haag Delft. The study was conducted in accordance with the declaration of Helsinki.

Overview of COVID-19 during the study period

In December 2020, at the beginning of the study, a full lockdown was implemented in the Netherlands to ensure the delivery of acute and critical elective care. To optimize hospital bed usage and improve patient flow in the emergency departments regional management strategies were employed. This followed a period of rising infections and a partial lockdown beginning in October 2020. The lockdown remained in effect until June 2021, with restrictions gradually easing from April onwards [11].

In January 2021, vaccination efforts began with healthcare workers, followed by the vaccination of patients in risk groups and older age groups over the following months. By the end of the study, ~45% of the population had been vaccinated [12].

COVID Box in primary care

Patients with a COVID-19 infection in need of intensive monitoring, based on the clinical judgment of their own GP, received the COVID Box in primary care. This Box contained a digital thermometer (Meditem digital thermometer), a validated pulse oximeter (PO-80 Beurer), and a blood pressure monitor (Microlife BP B2 Basic). Furthermore, patients were provided with an iPad by the home care organization for video consultations with the nurse. This iPad, connected to the 4G network, automatically powers on at the scheduled time and the patient only needs to be seated in front of it.

Patients measured these vital parameters three times per day and had a daily video consultation with a trained nurse from a home care organization to discuss their measurements and complaints. If their measurement dropped below their personal target values, patients were instructed to contact the trained nurse between 8 a.m. and 11 p.m. During the night, they could contact the GP out-of-hours service. The patient's own GP was consulted in case of clinical deterioration including increased dyspnea, decrease in oxygen saturation and blood pressure below the patient's personal targeted value or concerns based on the gut feeling of the nurse about the condition of the patient. When the patient was recovered, the treatment was ended in consultation with their own GP.

Data collection

The medical history and clinical data including vital parameters, prescribed antibiotics, hospital admissions and number of consultations of the intervention group concerning the COVID-19 episode, categorized under ICPC code R.83, were collected up to 3 months following the initiation of the ICPC code R83. Since the decision to refer was based on clinical parameters, to the best of our knowledge, laboratory data were neither taken nor collected. Box data, including referral information, was retrieved from the home-monitoring care facility Marente in Leiden, The Netherlands. Patients were provided with questionnaires regarding their experience of

fear related to COVID-19 [13] and patient experience. For patients in the control group medical history, vital parameters, prescribed antibiotics, and number of referrals regarding the COVID-19 infection starting from the ICPC R83 registration date until 3 months after was extracted from the ELAN database. Furthermore, GP's received a questionnaire concerning the acceptability, appropriateness, and feasibility of the COVID Box in primary care [14]. Box data, including referral information, was collected from the home monitoring care facility Marente, located in Leiden, The Netherlands. Patients received questionnaires about their experienced fear of COVID-19.

Subgroup analysis

Oxygen saturation is considered a critical parameter for assessing the risk of a COVID-19 complicated infection since silent hypoxia could occur in both patients with or without a risk of a complicated COVID-19 infection [15, 16]. Therefore, a prespecified subgroup analysis was performed in higher-risk patients with oxygen saturation measurements present in their GP electronic medical records. Matched pairs of intervention and control group patients were identified and were included in the subgroup analysis if the oxygenation was known for the patients who received a COVID Box as well as for the matched control patients.

Study endpoints

The primary endpoint of this study was the reduction in the number of patients who were referred to the ED due to COVID-19 within 14 days after their first contact with the GP.

Secondary endpoints included (1) determining whether the COVID Box could extend the time between the onset of the COVID-19 infection and referral to the ED, and (2) evaluating end-user satisfaction of the COVID Box among patients and GPs.

Statistical analysis

Based on previous research on RPM systems in patients with a (suspected) COVID-19 infection, a sample size of $n = 50$ was considered sufficient [3]. Continuous variables were presented as mean $\pm$ standard deviation (SD) if they followed a normal distribution. For continuous variables not following a normal distribution, median and interquartile range (IQR) were used for summarization. To evaluate differences in referral to the ED between the intervention and control groups, a Kaplan–Meier analysis and stratified log-rank test were conducted. Hazard ratios were estimated via a Cox proportional hazards model with a robust variance estimator, accounting for clustering within matched sets [17]. Statistical significance was denoted by a two-tailed P value of < 0.05 . R statistical software version 4.0.3 was employed for conducting analyses using the R package MatchIt.

Results

Between 11 December 2020 and June 2021, 56 patients received the COVID Box in primary care. No data were registered for two patients, and informed consent was not obtained in 13 patients. As a result, the total analyzed intervention group consisted of 41 patients. The control group comprised 164 matched patients who received standard care. After

excluding intervention and control group patients without an oxygen saturation measurement, the subgroup consisted of 28 intervention patients and 53 controls.

Patients characteristics

Patient characteristics are described in Table 1. Patients who received the COVID Box and patients in the control group had a mean age of respectively 67.3 (15) and 66.9 (20.6) years and respectively 54% and 53% were male. Furthermore, respectively 11 patients (26.8%) versus 4 (2.4%) received antibiotics.

Among 85% of the COVID Box patients, a physical examination was conducted, compared to 38% in the control group. We identified no differences in physical examination results between the intervention and control groups.

Referrals to the emergency department

All 14 patients who received a COVID Box and were referred to the ED were subsequently admitted to the hospital. Additionally, 44 patients from the control group were referred to the ED. Among the referred patients, there were no patients with COPD in the group receiving the COVID Box, while there were five patients with COPD in the control group. As demonstrated in the Kaplan–Meier curve in Fig. 1, there was no difference in the risk of patients being referred to the ED between those who were provided with the COVID Box and those who received standard care (log rank test $P = 0.47$, HR 1.2 (95% CI 0.66–2.2)).

The subgroup analysis, as depicted in Fig. 2 and including solely patients with recorded oxygen saturation, showed a nonsignificant trend towards a lower risk of ED referral with the intervention ($P = 0.14$, HR 0.51 (95% CI 0.55–1.14)). Patients from the COVID Box group were referred to the ED after a median of 3.3 days, while this was 1.5 days for patients in the control group ($P = 0.08$).

Workload-GP

Patients were monitored with the COVID Box for an average of 7 days. During this time, 15 patients had contact with their own GP, including 11 through a home visit (median of 0 [0–1]) and 6 through a telephone consultation (median of 0 [0–1]). Additionally, there were 2 [1–3] contacts between the GP and the nurse from Marente.

Questionnaires

Out of the 41 patients, 26 (63.4%) completed the questionnaires after their recovery from COVID-19 infection. Patients concurred that the COVID Box intervention was satisfactory, and they disagreed about experiencing psychological or physical symptoms of fear during their COVID-19 infection (Fig. 3).

In total, 17 out of the 21 (81.0%) of the referring GPs agreed on the COVID Box being an acceptable, appropriate and feasible intervention (Fig. 4).

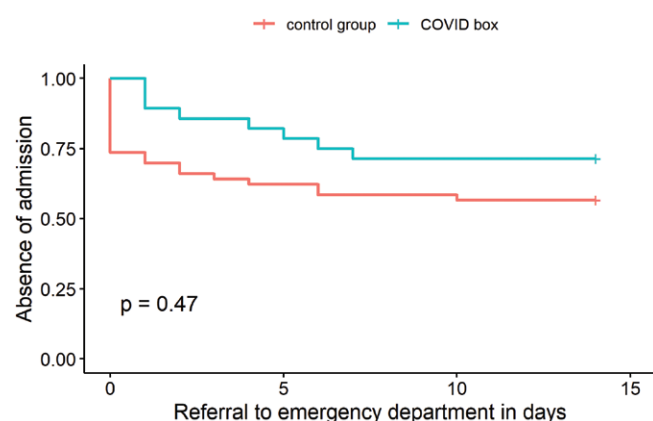
Discussion

Based on the investigated primary outcome measure between patients who were monitored with the COVID Box and patients receiving regular care, we found no difference in the number of referrals to the ED. However, we found a nonsignificant trend implying that remote monitoring could

Table 1. Demographic and clinical characteristics of 205 patients with COVID-19 (2020–2021).

	Intervention N = 41 Standard deviation (SD), median [IQR] or N (%)	Control N = 164 Median (IQR) or N (%)
Age years	67.3 (15)	66.9 (20.4)
Male	22(53.7%)	87 (53%)
Medical history		
CCI	3[2–6.5]	4[2–6]
Hypertension	18 (43.9%)	73 (44.5%)
Diabetes mellitus	12 (29.3%)	60 (36.6%)
Coronary heart disease	6 (14.6%)	22 (13.4%)
COPD	4 (9.8%)	17 (10.4%)
Malignancy	9 (22%)	56 (34.1%)
Chronic kidney disease	7 (17.1%)	6 (3.7%)
Immunocompromised	1 (2.4%)	2 (1.2%)
Physical examination performed, (% yes)		
SpO2	35 (85%)	63 (38%)
Temperature	27 (65%)	41 (25%)
Heart rate	15 (36%)	59 (36%)
Systolic blood pressure	23 (56%)	59 (36%)
Diastolic blood pressure	23 (56%)	59 (36%)
Physical examination measurements		
SpO2 (%)	95 (93–97)	96 (92–98)
Temperature (°C)	38 (37.1–38.5)	37.4 (37.0–38.2)
Heart rate (bpm)	90 (70–92)	80(70–90)
Systolic blood pressure (mmHg)	140 (120–150)	135 (121–150)
Diastolic blood pressure (mmHg)	78(70–80)	80 (75–88.5)
Referrals to the ED	14 (34.1%)	44 (26.8 %)
Started with antibiotics	11(26.8%)	4 (2.6%)
Contacts during COVID Box usage		
Contacts between GP and nurse	2 [1–3]	
GP home visits	0 [0–1]	
Telephone consultations	0 [0–1]	

Abbreviation: CCI = Charlson comorbidity index.

**Figure 1.** Kaplan–Meier survival curve for ED referrals of 205 patients with COVID-19 (2020–2021).

delay and potentially reduce the number of unnecessary ED visits in the subgroup of higher-risk patients with measured oxygen saturation. Since oxygen saturation is considered a critical parameter for assessing the risk of a complicated

COVID-19 infection due to silent hypoxemia that could occur in both patients with or without a risk of a complicated COVID-19 infection. The COVID Box could extend the time between the onset of COVID-19 infection and referral to the ED from 1.5 days to 3.3 days and all referred patients were admitted to the hospital. Furthermore, patients were satisfied with the COVID Box and GPs found it an acceptable, appropriate and feasible intervention. Therefore the COVID Box could be a promising RPM system for use in primary care to relieve pressure on hospitals during future seasonal infectious disease peaks.

During the COVID pandemic, the burden on the healthcare system increased, resulting in increased use of RPM systems [18]. These systems were mainly designed for patients with a proven COVID-19 infection who were discharged from the ED or hospital to relieve the burden on the hospitals [19]. RPM systems made it possible to safely monitor patients at home since they could identify the risk of deterioration and the need for advanced care or re-admission [19]. Although our study focuses on a more severe high-risk population in a primary care setting than most studies, our findings further support that RPM of patients with a COVID-19 infection is

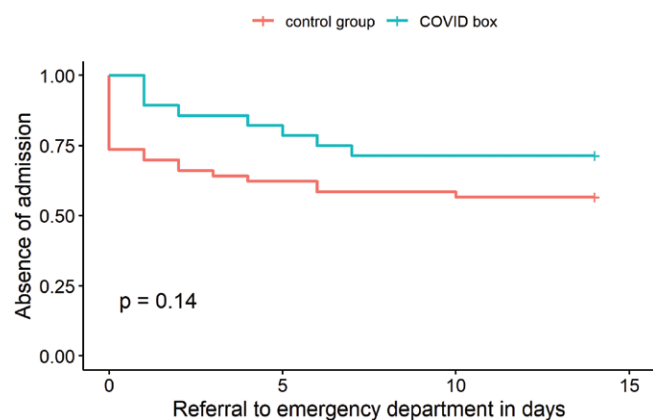


Figure 2. Kaplan–Meier survival curve for ED referrals in a subgroup of 81 patients with COVID-19 (2020–2021).

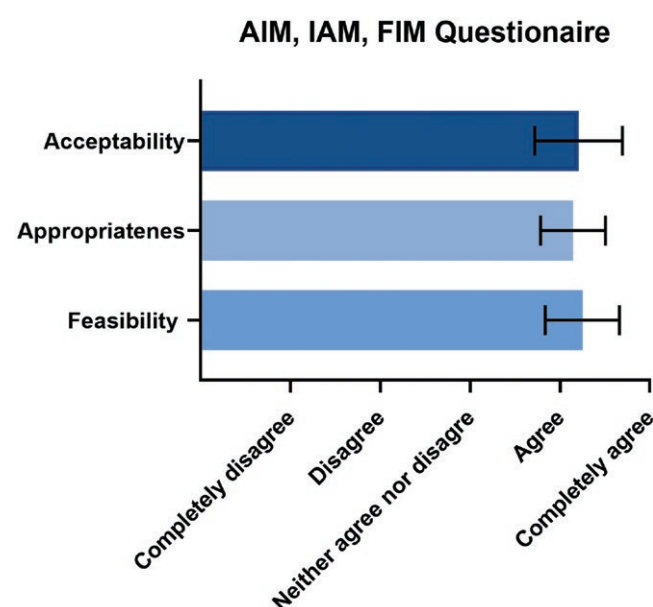


Figure 3. Results of patient satisfaction questionnaire and COVID-19 fear scale completed by 26 patients monitored with the COVID Box (2021).

feasible and could identify patients in need of hospital care, which is in line with previous findings in secondary care patients [19].

In a previous study where patients with COVID-19 were monitored in a primary care setting, 28% of the intervention patients were referred to the ED versus 34% in our study. Although both studies have a comparable percentage of referrals to the ED conclusions should be drawn with caution since both studies had a relatively small sample size. Furthermore, similarly, their study found no difference in the number of referrals between the intervention and control group [20]. Our primary analysis supports these findings.

However, in our intervention group, we found higher measurement rates of peripheral oxygen oxygenation (SpO₂), temperature and blood pressure suggesting that this group is comprised of high-risk patients that have a higher a priori chance of hospital submission. Furthermore, oxygen saturation measurements in COVID-19-infected patients were common practice in primary care to determine the risk of a complicated infection due to the positive predictive value of

oxygen saturation for a complicated infection [15]. In contrast, our secondary analysis demonstrated a trend in the high-risk patients monitored with the COVID Box towards a lower ED referral rate. Our subgroup sample size however was too small to make statistically reliable conclusions therefore these findings are purely exploratory.

Previous studies evaluating the patient and healthcare end-user satisfaction of RPM systems during the COVID pandemic demonstrated that patients felt secure and healthcare professionals were satisfied [21, 22]. This is in line with our findings since patients were satisfied and healthcare professionals found the COVID Box to be an acceptable, appropriate and feasible intervention.

Strengths and limitations

Due to the design of the trial, this matched cohort study comes with five notable limitations: (i) Our initial matching led to a selection bias resulting in a higher risk more high-risk patients in the intervention group compared to the control group. Resulting in an underestimated effect of the COVID-Box since patients with a more severe infection are referred to the ED more often. Therefore a sub analysis was conducted including only patients where oxygen saturation values were measured at their initial contact although the exclusion of patients without oxygen saturation values led to an even smaller sample size resulting in reduced power. (ii) Since the control group data was retrieved retrospectively from the ELAN database, this resulted in missing data leading to a possible under-rapportation of the number of ED referrals resulting in a possible underestimation of the effect of the COVID Box. Furthermore, not all information could be retrieved in the control group, e.g. mortality, number (count) of hospital admissions, number of non-respiratory presentations, and number of admission days not allowing to draw conclusions about mortality and admissions. Additionally, we cannot definitively determine whether the COVID Box intervention increased GP workload, as comparing the number of consultations between the control and intervention groups is challenging due to the unknown duration of the COVID-19 infection in the control group. However, we believe the missing laboratory data would not have influenced the referral decisions since these decisions are primarily based on clinical parameters according to the guidelines [23]. (iii) The study design introduces some degree of misclassification of the ICPC code R83. However, since the ICPC code was assigned based on PCR tests and there were alternative codes for fear of COVID-19 and suspected cases, this enhances the reliability of the data [8, 9]. The code was applied consistently across both control and intervention groups, suggesting minimal impact on the study's findings. (iv) The questionnaires were not sent to the healthcare providers and patients in the control group. Furthermore, the questionnaires were sent to the patients after they were recovered from their COVID infection leading to possible recall bias. (v) During the COVID pandemic, the situation continually evolved with numerous developments, including the introduction of vaccines. Despite these changes, the demand for boxes remained stable, peaking in April 2021 when infections were declining and the lockdown was easing, indicating that these factors did not impact the need for the COVID Box.

Our study also has strengths. We opted for a design with high external validity. This is in line with current studies



Figure 4. Results of acceptability, appropriateness, and feasibility questionnaires completed by 17 GP who offered the COVID Box (2021).

focusing on evaluating RPM due to the complexity of the interventions [24, 25]. This study design also allowed for a quick evaluation without randomization and extensive informed consent procedures for patients.

Clinical implications

Our study further supports previous evidence indicating that RPM is a promising tool for monitoring acutely ill patients in primary care. Although our study focuses on patients with a COVID-19 infection, this RPM system can also be suitable for other conditions, such as pneumonia or worsening heart failure symptoms in which a patient needs intensive monitoring but does not need hospital care yet. The combination of RPM and a home care organization enables to provide additional care to a patient if needed, making it possible for older and frail patients to recover in the comfort of their own home and reduce the risk of adverse outcomes such as delirium. Furthermore, this monitoring system could help more adequately identify patients in need of hospital care and assist in determining the optimal timing for referrals leading to more efficient use of healthcare resources. Efficient resource allocation, including minimizing unnecessary ED visits, was crucial during the COVID pandemic to ensure that care was delivered where and when it was most needed. Lastly, patients and healthcare professional using the box were satisfied. Further research should be conducted to evaluate the effect of the RPM concept of The Box on patients to recover at home prior to or after hospital admission.

Conclusion

While the overall study found comparable ED referrals between groups, the subgroup analysis suggested a promising prospect in reducing ED referrals due to remote monitoring of higher-risk patients with acute respiratory disease in primary care. Patients were satisfied and healthcare professionals found the COVID Box to be an acceptable, appropriate, and feasible intervention. Therefore, the COVID Box could be a promising RPM system for use in primary care to relieve

pressure on hospitals during future seasonal infectious disease peaks.

Conflict of interest

There are no conflict of interest.

Funding

The study was funded by departmental resources.

Ethical approval

This study was approved by the Medical Research Ethics Committee Leiden Den Haag Delft and the study was conducted in accordance with the declaration of Helsinki.

Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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