

Patient-reported Outcome Measures After Hospitalization During the COVID-19 Pandemic, a Survey Among COVID-19 and Non-COVID-19 Patients.

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Abstract

Background: Many people recovering from COVID-19 suffer from long-term sequelae. The objective of this study was to assess health-related quality of life (HRQoL) in COVID-19 patients a few months after discharge.

Methods: We conducted a retrospective cross-sectional case-control study on COVID-19 and non-COVID-19 pneumonia patients admitted to Shamir Medical Center, Israel (03-07/2020). In the months following discharge, patients were invited to participate in a survey and fill the RAND-36 questionnaire. Patient's characteristics and comorbidities were extracted from electronic charts.

Results: Among 66 COVID-19 participants, the median age was 58.5 (IQR 49.8-68.3), 56.1% were female, and more than a third were obese (36.4%). The median length of stay was 7 days (IQR 4-10). Patient-reported outcome measures were reported at a median follow-up of 9-months (IQR 6-9). Pain, general health, vitality, and health change had the lowest scores (67.5, 60, 57.5, and 25 respectively). Matching to patients hospitalized with pneumonia due to other pathogens was performed on 42 of the COVID-19 patients. Non-COVID-19 patients were more frequently current or past smokers (50% vs 11.9%, $p<0.01$) and suffered more often from chronic lung disease (38.1% vs 9.5%, $p=0.01$). The score for health change was significantly lower in the COVID-19 group (25 vs 50, $p<0.01$).

Conclusions: Post COVID-19 patients continue to suffer from an assortment of symptoms and perceive a deterioration in their health many months after hospitalization. This emphasizes the importance of prolonged medical follow-up in this population, and the need for additional research to better understand this novel's disease long-term effects.

Introduction

Over the last year, the global and scientific community have been striving to better understand the different aspects of COVID-19, a novel infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).(1) During this time, much knowledge has been acquired and many aspects of this disease have been described, including long-term effects and complications.(2, 3) It appears that many patients continue to suffer from long-term effects weeks and even months after discharge from hospitalization. Both physical and mental health-related symptoms were mentioned in recent studies, including breathlessness, fatigue, muscle weakness, anxiety, and depression.(4–8) Accordingly, pulmonary diffusion capacities may be impaired and abnormal chest imaging manifestations may be evident.(5, 9–11) As data accumulates regarding the long-term burden from COVID-19, it is important to better understand patient's perception of their health and quality of life, typically known as Patient-reported outcome measures (PROM). In previous studies, HRQoL decreased up to six months after recovery from acute infection.(4–6, 10, 12–14) Other pathogens causing pneumonia and hospitalization can adversely affect PROMs and cause a decrease in HRQoL during the months following discharge.(15–17) Therefore, we wished to examine whether COVID-19 is similar or unique in its impact on HRQoL.

Methods

Patients:

A retrospective cross-sectional case-control study was performed regarding patients 18 years or older, discharged from hospitalization between March 1 and 31 July 2020 from Shamir (Assaf Harofeh) Medical Center (Zerifin, Israel). All patients were admitted to a designated department after SARS-CoV-2 infection was confirmed by RT-PCR nasopharyngeal swab. We excluded patients who could not complete the questionnaire (via phone or internet form) due to physical or cognitive impairment. After recruitment, a subset of participants was matched for sex and age to patients hospitalized during the same period due to pneumonia or respiratory infection to an internal medicine department. All patients were tested negative to SARS-CoV-2 during or on admission. In the matched group patients were excluded if self-reported as being tested positive to SARS-CoV-2 in the follow-up period after hospital discharge. The study was approved by the Shamir Medical Center Helsinki Committee for Human Experiments, approval number: 0366-20-ASF.

Data collection and definitions:

Data was extracted from electronic medical records including patient demographic information, tobacco smoke addiction, underlying comorbidities, and need for oxygen supplementation. Disease severity was characterized by the highest of a four-category scale, according to guidelines published by the Israeli ministry of health. The scale consisted of the following categories: mild disease severity- described as an O₂ saturation of 94% or above on room air, a respiratory rate less than 30 breaths per minute (BPM), and no radiological abnormalities on chest X-ray. Moderate disease severity- signs of COVID-19 pneumonia on chest X-ray and severe disease - O₂ saturation of 93% or lower on room air or a respiratory rate of 30 BPM or more. Critical disease- need for High flow nasal cannula (HFNC) oxygen supplementation, Non-invasive or invasive ventilation.

Patient-reported outcomes:

Five to nine months following discharge, patients were sent a text message offering them to participate in the research study and fill out an online version of the RAND-36 questionnaire, patients willing to participate but which had difficulty filling out the online questionnaire, were contacted and the survey was filled by telephone. All data was collected anonymously.

The RAND 36-Item Health Survey (RAND-36) is a validated, easily administered, and widely used HRQoL survey instrument, comprised of 36 items that assess eight health concepts: physical functioning, role limitations caused by physical health problems, role limitations caused by emotional problems, social functioning, emotional well-being, energy/fatigue, pain, and general health perceptions. Scores for each domain can range from 0 (worst) to 100 (best), higher scores indicate better HRQoL. (18–20) Rand-36, and the similar license-based SF-36, have been used to evaluate the quality of life in various respiratory

and infectious conditions including Middle East Respiratory Syndrome (MERS) and SARS-CoV-1.(21, 22) In addition to the RAND-36 patients were requested to report persistence of symptoms since discharge.

Statistical analysis

All analyses were performed by using SPSS V23.0 (IBM Corp. Armonk, NY, USA). Continuous data are expressed as mean \pm standard deviation (SD) or as median and interquartile range (IQR) if they were not normally distributed, and categorical data is expressed as frequencies and percentages. Normal distribution was evaluated by histogram and Q-Q plot.

The correlation between continuous and ordinal variables and the outcomes of questionnaires was estimated by using Spearman's correlation coefficient. Mann-Whitney test and the Kruskal-Wallis test were used to compare questionnaires' tails between categories.

McNemar's test was used to compare categorical variables between the two matched groups. Paired sample t-test and Wilcoxon signed-rank test was applied to compare continuous variables between the two matched groups. P-value was significant if $\alpha < 0.05$. All statistical tests were 2 sided.

Results

From 1, March to 31, July 2020, 309 patients were discharged from hospitalization due to Covid-19. 66 patients participated in our research (21.36%). Demographic characteristics and comorbidities are shown in Table 1. Age on admission was 58.5 years (49.8–68.3), 56.1% of patients being female. More than a third of the patients were obese (36.4%) with a high mean BMI of 29.1. After obesity, hypertension was the most frequent comorbidity (31.8%), followed by diabetes (24.2%), ischemic heart disease (13.6%), and chronic lung disease (12.1%).

Hospitalization characteristics, length of follow-up, and PROMs are also reported in Table 1. The median length of stay for patients hospitalized for COVID-19 was 7 days (IQR 4–10). Most patients had a mild (40.9%) or moderate disease (30.3%) not requiring oxygen supplementation in 75.7% of cases. Still, 28.8% of the patients had severe disease with almost a quarter requiring either oxygen supplementation via a nasal prone, mask (19.7%), HFNC, or noninvasive ventilation (4.5%).

PROMs were obtained after a median follow-up of 9-month (IQR 6–9). In the results from the Rand-36 questionnaire emotional role, physical role, social and physical function had the highest scores (100, 87.5, 87.5, and 80 respectively), while emotional well-being, pain, general health, and vitality had lower scores (74, 67.5, 60, and 57.5 respectively) and health change had the lowest score with a median of 25.

There was no significant association between age or gender and the different HRQoL scores. Overall, patients with comorbidities had lower scores on many of the different categories, some significantly so. In this regard, especially notable is the pain score in which significant differences were found in patients with or without ischemic heart disease (22.5 vs 77.5 $p = 0.01$), diabetes (33.7 vs 80 $p < 0.01$), lung disease (22.5 vs 72.5 $p = 0.04$), and obesity (33.7 vs 85 $p = 0.02$). Considering hospitalization characteristics, no

association was found between length of stay and the different scores, although all the different scores were lower by disease severity and need for any oxygen supplementation. However, these differences were not statistically significant. Finally, the length of follow-up was weakly but significantly correlated to physical function and emotional well-being ($r_s=0.255$, $p = 0.04$ and $r_s=0.283$, $p = 0.02$ respectively). In-group association between patient demographics, patient comorbidities, hospitalization characteristics, and questionnaire scores are shown in Table S1 and S2.

Many patients complained about the sequela of COVID-19 infection; 57% of patients still suffered from at least one symptom and 34% suffered from 2 symptoms or more. Most frequently reported was fatigue (50%), followed by myalgia (23.7%), weakness and shortness of breath (18.4% each) (Fig. 1). Eighty-nine percent of patients with severe disease suffered at least one symptom compared to 65% and 44% of patients with moderate and mild disease severity, respectively.

We matched for age and/or gender a subgroup of 42 COVID-19 patients to patients hospitalized with pneumonia due to other pathogens. A comparison of the groups is shown in Table 2. Non-COVID-19 patients were more frequently current or past smokers (50% vs 11.9%, $p < 0.01$) and suffered more often from chronic lung disease (38.1% vs 9.5%, $p = 0.01$). COVID-19 patients had longer hospitalizations than patients in the non-COVID-19 group (8 vs 4 days, $p < 0.01$), and were also followed up after a shorter period (7.5 vs 9-month, $p < 0.01$). Comparing the different RAND-36 scores, non-COVID-19 patients had lower scores in most categories with a trend towards significance in physical function and role (55 vs 80, $p = 0.07$ and 25 vs 75, $p = 0.07$ respectively). On the other hand, health change was significantly lower in the COVID-19 group (25 vs 50, $p < 0.01$).

Discussion

PROMs capture a patient's perception of their health through standardized validated questionnaires. These questionnaires can address various aspects of health such as quality of life, physical, mental, and social well-being. These measures increase our understanding of disease burden as well as promoting advanced person-centered clinical care and research.(23)

Acute hospitalization from any cause may influence a person's quality of life, especially in older adults. In recent months it has become increasingly apparent that COVID-19 can have a prolonged impact after acute illness, termed by some "long COVID"(24) or "post-acute COVID-19 syndrome"(2), thus it is paramount to expand our knowledge on PROMs in this population.(25) Previous studies assessing post-COVID PROMs are mostly short-termed, revealing a decrease in most domains of HRQoL scores.(4–7, 10, 12–14)

In this study, we focused on COVID-19 patients who were hospitalized during the first 6 months of the pandemic. We followed up on patients to better understand the impact of hospitalization on their quality of life. At the time of follow-up, five to nine months after discharge, PROMs were assessed. Overall,

patients with severe COVID-19 had lower scores in all HRQoL domains, but these findings were not statistically significant, most likely due to the small sample size, especially in the severe COVID group.

Recent findings have shown that COVID-19 survivors continue to report new-onset symptoms up to six months after recovery from acute illness, mainly fatigue, muscle weakness and dyspnea.(4–8) In our study with a longer median follow-up of 9 months, 56% still suffered from at least 1 symptom. Most commonly, patients reported constitutional symptoms such as fatigue or myalgia, in addition to respiratory and neurological symptoms. As might be expected, with increased severity of disease, a larger proportion of patients reported continued symptoms, only 44% and 65% of patients after mild and moderate disease, compared to 89% after severe disease.

A recent study has shown that six months after acute illness more than 50% of patients had residual chest imaging abnormalities and lung diffusion impairment which was independently associated with disease severity during acute illness.(5) These findings suggest that SARS-CoV-2 can cause long-term pulmonary damage, which might explain persistent symptoms.

To further understand the long-term effect of COVID-19 disease as compared to similar respiratory illness, we matched a subgroup of our study patients to patients that were hospitalized with non-COVID-19 pneumonia during the same period. Though patients with COVID-19 had significantly longer hospitalizations (8 vs 4 days), non-COVID patients had more often chronic lung disease (possibly due to a larger percent of past and current smokers).

This correlates well with our results, as patients with non-COVID-19 related disease had lower scores in most domains, but with a trend to significance only in physical function and role ($p = 0.07$). Yet, the score on health change was significantly lower in the group of COVID-19 patients (25 vs 50, $p < 0.01$). This score is constructed by the patient's perception of their change in health relative to a year before, where a score of 50 is equal to no health change and a score of 25 is equal to their health being somewhat worse. This finding is consistent with our data showing many patients continuing to be symptomatic at follow-up, suggesting prolonged morbidity after acute illness. Accordingly, the non-COVID-19 group had lower scores in many HRQoL domains, but there was no overall change in their perceived health.

A limit on this finding might be the slightly lower, but significant, median follow-up time in the COVID-19 group (7.5 vs 9 months). Under the assumption that symptoms after hospitalization may decline over time, at a shorter period of follow-up, patients may be more symptomatic. In contrast to this assumption in data from all 66 COVID-19 patients included in this study, the median follow-up was nine-month but still, the median health change score was 25, indicating this limitation might not be relevant to our current findings. Our findings are also limited by a small study group from a single center.

Conclusions

Our study suggests that patients continue to suffer from an assortment of symptoms and perceive a deterioration in their health many months after hospitalization due to COVID-19. This emphasizes the

importance of pronged medical follow-up in this population, and the need for additional research to better understand this novel disease's long-term effects.

List Of Abbreviations

PROM- Patient-reported outcome measures

HRQoL- health related quality of life

SARS-CoV-2- severe acute respiratory syndrome coronavirus 2

BPM- breaths per minute

HFNC- High flow nasal cannula

MERS- including Middle East Respiratory Syndrome

SD- standard deviation

IQR- interquartile range

BMI- body mass index

NIV- noninvasive ventilation

Declarations

Ethics approval: the study was approved by the Shamir Medical Center Helsinki Committee for Human Experiments, prior to its initiation. Approval number: 0366-20-ASF.

Consent to participate: signed informed consent was waived by the local ethics (Helsinki) committee, the nature of the study was explained the participants before filling the questionnaire.

Consent for publication: all authors give their consent for publication.

Availability of data and material: available upon request from the author (matanelkan@gmail.com).

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Authors' contributions: ME, AD, RZ and RK conceived the presented idea and designed the study. ME, MK, DK, CH, and RK conducted the survey and gathered the data. ME and RK analyzed and interpreted the data. ME wrote the manuscript. All authors read and approved the final manuscript.

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Tables

Table 1

Demographic characteristics, hospitalization and follow-up characteristics, and patient reported outcomes of patients hospitalized due to COVID-19.

Demographics	(n = 66)
Age (years), median (IQR)	58.5 (49.8–68.3)
Female gender (%)	37 (56.1)
Comorbidities	
Smoking	
Current (%)	3 (4.5)
Past (%)	5 (7.6)
Hypertension (%)	21 (31.8)
Ischemic heart disease (%)	9 (13.6)
Heart failure (%)	6 (9.1%)
Diabetes Mellitus (%)	16 (24.2)
Chronic Lung disease (%)	8 (12.1)
Chronic renal failure (%)	1 (1.5)
Obesity (%)	24 (36.4)
BMI (n = 59), mean \pm SD	29.1 \pm 6.5
Hospitalization and follow-up	
Length of stay (days), median (IQR)	7 (4–10)
Disease severity	
Mild (%)	27 (40.9)
Moderate (%)	20 (30.3)
Severe and critical ^a (%)	19 (28.8)
Oxygen status	
None (%)	50 (75.7)
NP or mask (%)	13 (19.7)
HFNC or NIV (%)	3 (4.6)
Follow-up (month), median (IQR)	9 (6–9)

Demographics	(n = 66)
Additional hospitalization during follow-up	
None (%)	58 (87.9)
1 (%)	5 (7.6)
2 or more (%)	3 (4.5)
Health related quality of life	
Physical functioning, median (IQR)	80 (40-96.2)
Physical role, median (IQR)	87.5 (25–100)
Emotional role, median (IQR)	100 (0-100)
Vitality, median (IQR)	57.5 (30-76.2)
Emotional well-being, median (IQR)	74 (52–88)
Social functioning, median (IQR)	87.5 (50–100)
Pain, median (IQR)	67.5 (24.4–100)
General health, median (IQR)	60 (35–80)
Health change, median (IQR)	25 (25–50)
BMI- body mass index, HFNC- high flow nasal canula, NIV- noninvasive ventilation, SD- standard deviation, IQR- interquartile range. a- Critical n=1.	

Table 2

Comparing Demographic characteristics, hospitalization and follow-up characteristics, and PROMs between COVID-19 and non-COVID-19 patients.

Demographics	COVID-19 (N = 42)	Non-COVID (n = 42)	p
Age (years), median (IQR)	60 (51-69.2)	61 (49.7–69)	0.34
Female gender (%)	24 (57.1)	25 (59.5)	> 0.99
Comorbidities			
Smoking, ever (%)	5 (11.9)	21 (50)	< 0.01
Hypertension (%)	14 (33.3)	20 (47.6)	0.21
Ischemic heart disease (%)	7 (16.7)	4 (9.5)	0.55
Heart failure (%)	4 (9.5)	5 (11.9)	> 0.99
Diabetes mellitus (%)	9 (21.4)	9 (21.4)	> 0.99
Chronic lung disease (%)	4 (9.5)	16 (38.1)	0.01
Obesity (%)	13 (31)	12 (29.3)	> 0.99
BMI, mean \pm SD	28.2 \pm 5.4	28.4 \pm 4.8	0.84
Hospitalization and follow-up			
Length of stay (days), median (IQR)	8 (5-10.2)	4 (3–5)	< 0.01
Follow-up (month), median (IQR)	7.5 (6–9)	9 (7–10)	< 0.01
Additional hospitalization during follow-up (%)	6 (14.3)	5 (11.9)	> 0.99
Health related quality of life			
Physical functioning, median (IQR)	80 (43.7–100)	55 (8.7–95)	0.07
Physical role, median (IQR)	75 (18.7–100)	25(0–75)	0.07
Emotional role, median (IQR)	83.3 (0-100)	100 (0-100)	0.73
Vitality, median (IQR)	60 (28.7–71.2)	50 (23.7–80)	0.61
Emotional well-being, median (IQR)	76 (52–88)	68 (47–85)	0.52
Social functioning, median (IQR)	87.5 (46.9–100)	75 (37.5–100)	0.35
Pain, median (IQR)	67.5 (24.4–100)	45 (11.9–90)	0.20
General health, median (IQR)	65 (38.7–80)	55 (37.5–75)	0.25
Health change, median (IQR)	25 (25–50)	50 (43.7–75)	< 0.01

Demographics	COVID-19 (N = 42)	Non-COVID (n = 42)	p
BMI- body mass index, SD- standard deviation, IQR- interquartile range.			

Figures

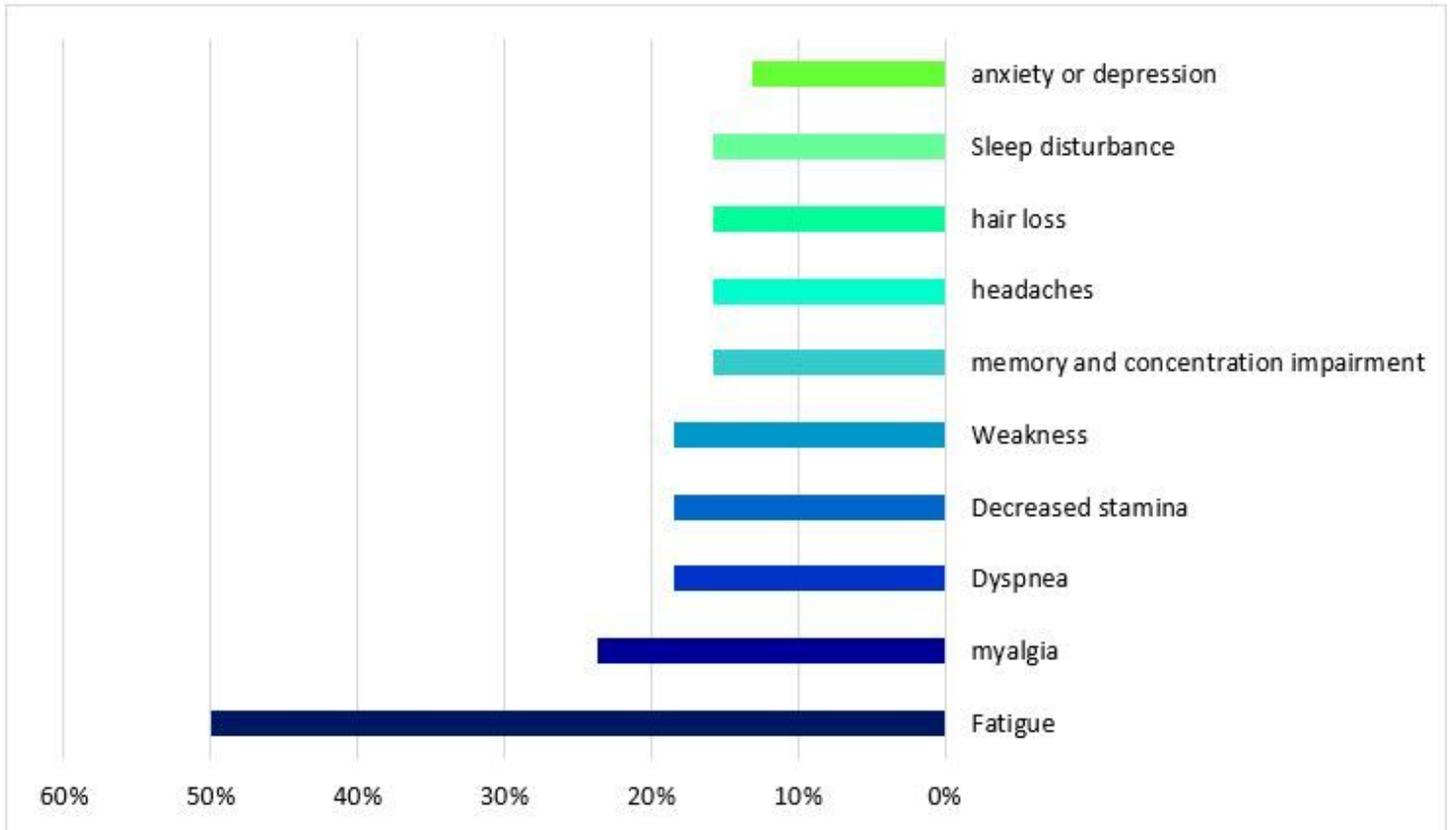


Figure 1

Frequency of persistent symptoms at follow-up in patients hospitalized due to COVID-19

Supplementary Files

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