



Long-term physical and mental Health-Related Quality of Life in Italian patients post COVID-19 hospitalisation

Marco Viola^{1,2,3} · Carlotta Sacerdote⁴ · Giovannino Ciccone⁴ · Edoardo Donarelli¹ · Manolis Kogevinas³ · Assunta Rasulo⁴ · Anna Toscano¹ · Eva Pagano⁴ · Rosalba Rosato¹

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Abstract

Purpose Prior evidence suggests that patients' Health Related Quality of Life (HRQoL) worsens after COVID-19. This study aimed to investigate HRQoL in Italian patients post-hospitalization for COVID-19, focusing on changes in physical and mental HRQoL over time since COVID-19 diagnosis.

Methods A cohort of patients hospitalized for COVID-19 at Molinette Hospital in Turin, Italy, was contacted post-discharge to assess HRQoL using the SF-36 questionnaire. Patients completed the questionnaire only once at a different time since diagnosis. This design allowed for the analysis of responses up to three years after diagnosis. Measured scores were compared with normative data from the Italian population using z-scores. HRQoL differences by gender, comorbidities, and self-perception of health status before and after COVID-19 were tested. The effect of time since diagnosis on physical (PCS) and mental (MCS) SF-36 scores was analysed using multiple linear models and stratified analyses.

Results A total of 601 patients completed the questionnaire. HRQoL was significantly lower compared to the normative Italian population. Men and individuals without comorbidities had better HRQoL, and self-perceptions of health status before and after COVID-19 influenced HRQoL. Time since diagnosis was associated with improved PCS, but MCS remained unaffected. Mental health declined in patients using anxiolytics post-COVID-19, and increasing age negatively affected physical health.

Conclusion Our findings highlight the impact of time since diagnosis on HRQoL post-COVID-19 in an Italian population and suggest the need for further investigation into the pandemic's effects on HRQoL. Physicians should implement measures to improve mental HRQoL post-COVID-19.

Plain English Summary

The relationship between COVID-19 and both physical and mental health is a highly debated topic. COVID-19 impairs mental health and reduces the ability to engage in normal physical activities. However, the long-term consequences (12–36 months) of COVID-19 remain relatively unexplored, particularly in the Italian population. In this study, we examined a sample of Italian patients after hospitalisation for COVID-19 to assess changes in their physical and mental Quality of Life over time since their diagnosis. Our findings indicate that COVID-19 significantly worsened Quality of Life scores for these patients after hospitalisation compared to current normative scores for the Italian population. Over time, physical Quality of Life tends to improve in these patients, but mental Quality of Life does not show a similar trend. These results suggest the need to re-evaluate the impact of the COVID-19 pandemic on Quality of Life in Italy and emphasize the importance of addressing mental health to enhance the Quality of Life for those affected by COVID-19.

Keywords Quality of life · Post COVID-19 hospitalisation · Long-term · SF-36 · Physical and mental consequences · Time since diagnosis

✉ Marco Viola
m.viola@unito.it

¹ Department of Psychology, University of Turin (UniTO), Turin, Italy

² Universitat Pompeu Fabra (UPF), Barcelona, Spain

³ Barcelona Institute for Global Health (ISGlobal), Barcelona, Spain

⁴ Unit of Cancer Epidemiology, Città della Salute e della Scienza, University-Hospital, Torino, Italy

Introduction

The coronavirus disease (COVID-19) can lead to various impairments of physical and mental health after the acute phase, which prevent a complete return to the previous state of health [1, 2].

Health-related Quality of Life (HRQoL), a multidimensional construct that encompasses a broad concept influenced in complex and interrelated ways by mental health, physical health, personal beliefs and social relationships, has been widely studied in the context of COVID-19. A reduction in HRQoL, psychological distress, anxiety and depression, worry and stress as well as changes in the routine and lifestyle of those affected have already been observed [3–7]. In patients with the most severe illnesses requiring hospitalisation, the effects of COVID-19 on HRQoL have been documented mainly in the short period after discharge [8–11].

Some recent studies have shown that more than half of elderly patients reported a negative change in HRQoL 6 months after hospitalisation due to COVID-19, with consequences on the physical and mental aspect 6 months and 1 year after discharge [12–14]. HRQoL is also an issue long after infection, even if there is little evidence in the literature about the impact of COVID-19 on HRQoL in the period after one year post-infection. There are some previous studies that have examined the association between HRQoL and time since COVID-19, including patients admitted to the intensive care unit (ICU) [15, 16]. Several studies have reported on the effects of COVID-19 on HRQoL in the short term and up to one year after hospitalisation and one study showed that HRQoL was impaired regardless of time since discharge or recovery [17, 18].

In addition, the long-term consequences (12–36 months) of COVID-19 on HRQoL are still relatively unexplored, and there was limited evidence beyond one year post-infection. There is consistent evidence in the literature on changes in HRQoL over time in various clinical conditions. The change in health status triggered by a catalytic event (illness, trauma, accident, etc.) may subsequently lead to a change in the individual's internal standards, reprioritization or reconceptualization of the construct of HRQoL itself. Such changes in health status may trigger an altered response via mechanisms to adapt to this change. The mechanisms relate to cognitive, affective and behavioural strategies for coping with the catalyst and usually lead to an improvement in psychological HRQoL. This response-shift have been extensively documented in various clinical conditions such as patients with multiple sclerosis and cancer [19–21]. Understanding the impact on HRQoL due to long-term effects of COVID-19 may help to develop prevention strategies and support rehabilitation and targeted interventions [17, 22–24].

The study had two aims: firstly, to investigate the HRQoL of a population of patients hospitalised with a diagnosis of COVID-19 and to compare their HRQoL scores as measured by the Short Form Health Survey 36 (SF-36 scale) with Italian normative data overall and by gender [25]. Second, to investigate whether time since diagnosis had an impact on physical and mental HRQoL up to 3 years after hospital discharge, adjusted for clinical and demographic characteristics. The hypothesis was that long-term HRQoL would change after discharge from COVID-19 and that mental and physical outlook would improve over time.

Methods

Study population

The study population consisted of 1162 patients who participated in the study 'Monitoring of hospitalised patients with COVID-19' at the Molinette Hospital in Turin (Italy) from March 2020 to June 2022 [26]. Between June 2022 and June 2023, a cross-sectional study was conducted on discharged patients, focusing on their HRQoL. Each patient completed the questionnaire only once at a different time since diagnosis. Patients between the ages of 18 and 80 were eligible for the study. 601 individuals provided informed consent for participating in the study and completed the questionnaire.

Age, gender, educational level and marital status were used to describe the participants. Clinical information collected during hospital admission were used to compute severity of illness and comorbidity indices. In particular, the latest version of the National Early Warning Score (NEWS), was used as an indicator of disease severity [27, 28]. The NEWS2 provides a standardized score based on the weighted assessment of different physiological measures (respiratory rate, oxygen saturation, systolic blood pressure, pulse rate, level of consciousness or new-onset of confusion, temperature). Due to the sparse distribution of data, the NEWS2 score was used as dichotomized indicator in the analyses ($NEWS2 \leq 4$ as low risk, $NEWS2 > 4$ as medium/high risk). Comorbidities were assessed using the Charlson Comorbidity Index (CCI), which predicts one-year mortality risk accounting for a range of clinical chronic conditions [29, 30]. The cumulative CCI score is a weighted sum of individual clinical condition (heart disease, diabetes and cancer, among others), with more severe conditions assigned a higher score. CCI score was categorized into two different levels of severity (0 vs. 1 or more). Admission to the ICU and the use of anxiolytics before and after COVID-19 were also recorded.

The study design adheres to STROBE guidelines by explicitly outlining the cross-sectional observational nature

of the research. The study was approved by the Ethics Committee of the Molinette - Città della Scienza e della Salute Hospital (Turin, Italy). Informed consent was obtained from all participants and data were pseudonymized to avoid possible identification of patients.

Questionnaire data

HRQoL has been evaluated using the Italian version of the SF-36 questionnaire, a self-administered questionnaire containing 36 items and one of the most widely employed generic measures of HRQoL that may be used to people in all the different states of health [25, 31]. The Italian version of the SF-36 has been validated in the general population and has demonstrated a high degree of reliability.

The SF-36 questionnaire measures mental and physical health using eight dimensions with multiple items covering functional status, well-being and overall health assessment: physical functioning (PF, 10 items), role limitations due to physical problems (RP, 4 items), bodily pain (BP, 2 items), general health perceptions (GH, 5 items), vitality (VT, 4 items), social functioning (SF, 2 items), role limitations due to personal or emotional problems (RE, 3 items), general mental health (MH, 5 items), and two composite scores: the physical and mental component scores (PCS and MCS, respectively). The PCS and MCS scores were calculated as weighted linear combinations of the eight scale scores of the SF-36 and have a mean of 50 and a standard deviation of 10 [31]. Item scores in each dimension were summed and transformed on to a scale from 0 (worst health) to 100 (best health). Composite scores range from 0 to 100, representing respectively the lowest and highest HRQoL scores, respectively. Multivariate Imputation by Chained Equations (MICE) was used to impute individual SF-36 items with missing values, adjusting for age, gender, educational level, presence of comorbidity and severity [32, 33]. The SF-36 has been validated in the general population and it is not intended for a specific disease. Therefore, it is possible to use normative data from the Italian population to compare the scores obtained from our sample and the general population (overall and by gender).

To assess self-perception of health changes before and after the COVID-19 infection, patients were asked to think about how they felt before COVID-19 infection and to rate their state of health at the time of the survey compared to then. Five different dimensions of health were considered: general health, memory, attention, concentration and emotional state. For each dimension we asked the following question: “How would you rate your general health now compared to before you were hospitalised with COVID?” with a rating from 1 to 5 for the following alternatives: “Definitely better now than before COVID-19”, “Slightly better

now...”, “About the same...”, “Slightly worse now...” and “Definitely worse now...”. According to their scores,

patients were grouped into three categories based on their overall self-assessment: those who perceived the quality of life after COVID-19 as “better or equal”, “worse”, or “definitely worse” compared to before COVID-19 (for details see Table S1 in the supplementary material).

Statistical analyses

Descriptive analyses were performed in the form of mean values, standard deviations, or frequencies and percentage according to the type of variable for all the patient characteristics. A preliminary analysis comparing patients characteristics (age, gender, CCI score, and NEWS2) among adherents and non-adherents has been conducted.

To compare the values of the SF-36 with those of the Italian normative ones, z-scores were calculated overall and by gender, as follow: $Z = \frac{\text{sample mean} - \text{normative mean group}}{\text{standard deviation of normative group}}$ [25].

Therefore, negative z-scores indicate that the average value of the sample is lower than that of the population, while positive z-scores indicate the opposite. Z-scores were also calculated according with the perception of influence of COVID-19 on health status.

Differences in SF-36 scales and composite scores, by gender, self-perception and presence of comorbidities were analysed using t-tests or one-way ANOVA depending on the number of groups compared. The SF-36 questionnaire’s reliability was evaluated using Cronbach’s Alpha.

To assess the impact of time since diagnosis on HRQoL, we divided patients into 3 groups according to the year in which they completed the questionnaire after discharge from hospital (first, second and third year after hospitalisation) and calculated the mean HRQoL scores in the three groups.

The effect of time since diagnosis on PCS and MCS scores was analysed using a multiple linear model in which age at entry (divided into four age categories: 18–54, 55–64, 65–74, 75–80 years), gender, education level (with or without high school diploma), CCI score (without comorbidities, and with at least one comorbidity), admission to the intensive care unit, the NEWS2 score and the use of anxiolytics after COVID-19 were used as covariates. Since this was not a longitudinal study, baseline variables such as the CCI score, ICU admission, and the NEWS2 score were used as proxy of the severity clinical conditions at the time of hospital admission; the variable concerning the use of anxiolytics was instead used to compare the primary situation with that after hospitalization and discharge.

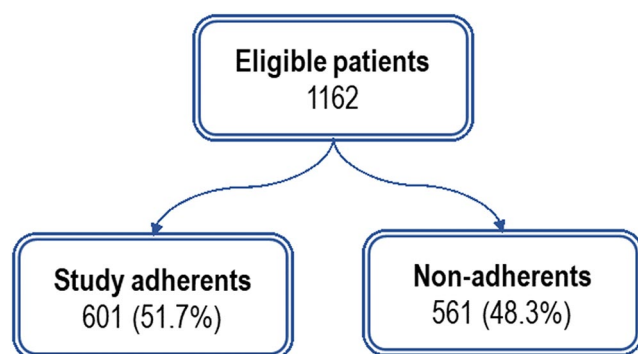


Fig. 1 Patients flow chart

A stratified analysis was performed according to the change in self-perception.

All analyses were performed with the statistical software RStudio (2023.06.01 + 524 “Mountain Hydrangea” release).

Results

Of the 1162 patients who were eligible for the study, 601 patients gave their consent to the study and filled out the questionnaire (51.7%) (see Fig. 1).

The demographic and clinical data of the patients are reported in Table 1. The average age was 61.0 years (SD 12.4, range 18–80) and almost two out of three participants were men ($n=375$, 62.4%). Almost half of the sample had at least one comorbidity at hospital admission, and 18.8% of them were admitted to the ICU.

In order to assess if there was selection bias among those who chose to participate in the survey and those who did

not, a preliminary analysis has been conducted. As shown in Table S2 (supplementary material), there was no difference in age and gender between study participants and non-participants. However, non-participants had worse comorbid conditions (for $CCI \geq 1$, 46.9% participants, 51.5% non-participants, p -value=0.13) and lower severity (for NEWS2 medium/high, 22.6% participants, 16.8% non-participants, p -value < 0.05).

A total of 65 (10.8%) questionnaires showed at least one missing item on the SF-36 and were imputed before the SF-36 scales were calculated. The SF-36 showed good internal consistency, Cronbach’s Alpha of 0.96. The mean scores of the SF-36 scales ranged from 50.94 for the GH scale to 67.70 for the SF scale. The PCS and MCS scores were 42.41 and 45.55, respectively, below the mean of 50. Significant gender differences were observed in all the scales (Table 2). When comparing our sample with normative data using the z-score, we found negative z-scores, indicating that the scores for each SF-36 scale were lower than the normative data. The largest difference was observed for the PCS, with a z-score for women of -0.99, meaning that the surveyed women had a physical score that was almost one standard deviation (11.2 points for normative female score) lower than the normative population. The same pattern was observed for men. The gender difference in MCS was smaller (Table 3).

The mean SF-36 scores were also compared between the patients’ groups according to self-perception and presence of comorbidities ($CCI \geq 1$). These analyses yielded results that were in line with expectations, i.e. significantly lower scores in almost all subscales for those who perceived worse or significantly worse health status after COVID-19 (Fig. S1

Table 1 Descriptive characteristics of the patients included into the study

Characteristics ($n=601$)		<i>n</i>	%
age (years), mean = 61.0, SD = 12.4	18–54	167	27.8
	55–64	163	27.1
	65–74	202	33.6
	75–80	69	11.5
gender	female	226	37.6
	male	375	62.4
married status	yes	394	65.5
	no	207	34.5
educational level	without high school diploma	239	39.8
	at least high school diploma	362	60.2
Intensive Care Unit	no	488	81.2
	yes	113	18.8
CCI score, median = 0 (IQR: 0–2)	CCI = 0	319	53.1
	CCI ≥ 1	282	46.9
NEWS2 score clinical risk	low	465	77.4
	medium/high	136	22.6
perception of health status	Definitely worse Post COVID-19	71	11.8
	Worse Post COVID-19	268	44.6
	Better or Equal Post COVID-19	262	43.6

Table 2 SF-36 values for the whole sample and by gender, t-test and 95%CI mean difference

SF-36 scales	Total	Female	Male	95% CI Mean difference
	Mean (sd)	Mean (sd)	Mean (sd)	
PF	67.55 (29.57)	56.19 (30.99)	74.39 (26.46)	(-23.05,-13.33)
RP	58.11 (42.03)	46.35 (42.24)	65.20 (40.33)	(-25.72,-11.98)
BP	65.13 (28.69)	52.31 (27.96)	72.85 (26.29)	(-25.06,-16.01)
GH	50.94 (22.98)	43.97 (22.46)	55.14 (22.29)	(-14.87,-7.46)
VT	51.34 (21.52)	43.61 (21.59)	56.00 (20.11)	(-15.88,-8.91)
SF	67.70 (25.54)	59.85 (25.79)	72.43 (24.21)	(-16.76,-8.42)
RE	66.17 (41.16)	58.55 (42.26)	70.76 (39.84)	(-19.05,-5.36)
MH	65.20 (20.59)	59.12 (21.79)	68.87 (18.93)	(-13.20,-6.32)
PCS	42.41 (11.63)	37.60 (11.53)	45.30 (10.70)	(-9.56,-5.84)
MCS	45.55 (11.28)	43.24 (11.92)	46.94 (10.66)	(-5.59,-1.80)

PF: physical functioning, RP: role limitations due to physical problems, BP: bodily pain, GH: general health perceptions, VT: vitality, SF: social functioning, RE: role limitations due to personal or emotional problems, MH: general mental health, PCS: physical component score, MCS: mental component score

Table 3 HRQoL scores and calculated z-scores related to the normative Italian population scores overall and by gender

SF-36 scales	Female – z scores	Male – z scores	Total – z scores
PF	-0.95	-0.66	-0.73
RP	-0.72	-0.52	-0.56
BP	-0.57	-0.24	-0.31
GH	-0.83	-0.66	-0.64
VT	-0.67	-0.52	-0.51
SF	-0.58	-0.37	-0.42
RE	-0.33	-0.27	-0.27
MH	-0.15	-0.13	-0.07
PCS	-0.99	-0.69	-0.74
MCS	-0.14	-0.17	-0.10

PF: physical functioning, RP: role limitations due to physical problems, BP: bodily pain, GH: general health perceptions, VT: vitality, SF: social functioning, RE: role limitations due to personal or emotional problems, MH: general mental health, PCS: physical component score, MCS: mental component score

and Table S3 in the supplementary material) and in the presence of comorbidities (Fig. S2 and Table S4 in the supplementary material).

The analyses of the SF-36 HRQoL as a function of time since diagnosis showed that patients who completed the questionnaire in the second year after discharge from hospital had a higher score than the group of patients in the first year. From the second to the third year, however, there was a decrease in almost all scores (mainly in VT, RE and MH), with only the PF and SF scores showing an almost consistent trend (Fig. S3 in the supplementary material).

For the PCS, time since diagnosis showed a positive impact after adjusting for age, gender, scholasticity, presence of comorbidities, use of anxiolytics, severity of NEWS2 and ICU admission, with significantly higher scores for the second and third year with respect to the first one, indicating a recovery of physical HRQoL at increasing time since infection. The PCS score was higher in men, without comorbidities, and with a higher level of education, while it decreased

with increasing age and with the use of anxiolytics post COVID-19. For the MCS, only a small positive effect from the first to the second year was evidenced. The MCS score was higher in men and decreased significantly in people using anxiolytics post COVID-19 (Table 4).

In the analysis stratified according to the three groups of self-perception, for patients who perceived a constant physical HRQoL after COVID-19 the effect of time had the same trend but less strong. No time effect was found in the group with a definitely worse HRQoL after COVID-19. Regarding the MCS, in all groups there is an improvement in scores during time, although the coefficients are almost never statistically significant. Time since diagnosis was significantly associated with the PCS only in the group that perceived a worsening of their condition after COVID-19 (Table S5 in the supplementary material). The Figs. 2 and 3 show the predicted PCS and MCS scores for the three groups with different self-perception by time in year between diagnosis and the compilation of the questionnaire.

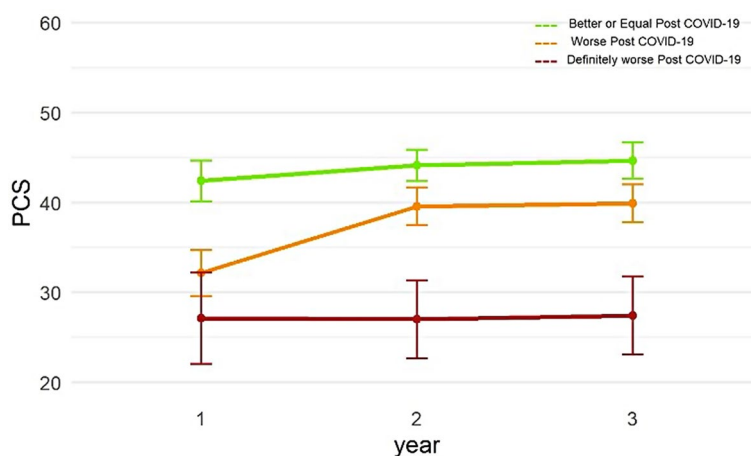
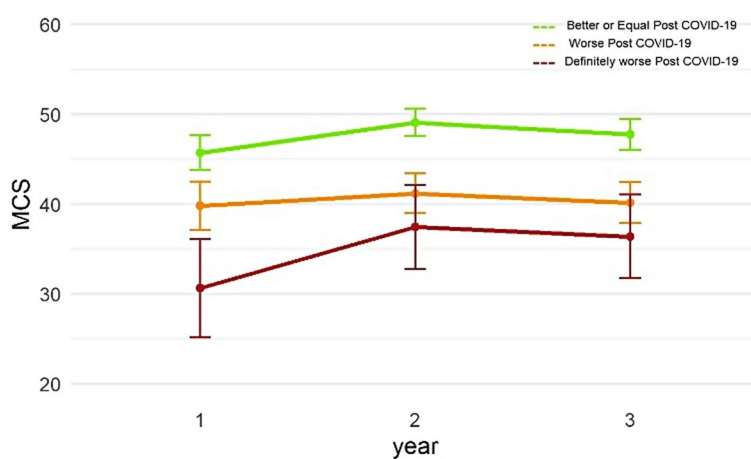
Discussion

The findings of this cross-sectional study confirm the negative impact of COVID-19 infection on HRQoL after the disease. Patients reported lower HRQoL scores after hospitalisation for COVID-19 compared to normative data from the Italian general population. Over time, from one to three years after hospitalisation with COVID-19, a steady increase in HRQoL scores was observed in almost domains, especially in physical QoL, while changes in mental HRQoL appear to be less pronounced. The most significant increase in the physical dimension occurs from the first to the second year post-hospitalisation, while the change from the second to the third year is less marked. Nevertheless, the overall values remain lower than those of the general Italian

Table 4 Multiple linear regression analysis for PCS and MCS scores as dependent variables and time, age, gender, CCI, ICU, NEWS2, education background and use of anxiolytics as independent variables

	PCS		MCS	
	Estim. Coeff.; SE	<i>p</i> -value	Estim. Coeff.; SE	<i>p</i> -value
(Intercept)	37.07; 1.64	<0.001	43.50; 1.73	<0.001
time – 2 year	3.26; 1.34	<0.05	2.25; 1.40	0.109
time – 3 year	3.29; 1.42	<0.05	0.35; 1.49	0.813
age - group 55–64	-1.40; 1.15	0.225	0.86; 1.21	0.474
age - group 65–74	-1.34; 1.14	0.243	1.06; 1.20	0.380
age - group 75–80	-4.24; 1.54	<0.01	1.34; 1.62	0.407
gender (M)	7.07; 0.89	<0.001	2.34; 0.94	<0.05
CCI (≥ 1)	-5.10; 0.88	<0.001	0.04; 0.93	0.969
Intensive care (yes)	-1.30; 1.10	0.238	-0.76; 1.15	0.513
NEWS2 (medium/high)	-1.06; 1.03	0.302	-1.62; 1.08	0.133
educational level (at least a high school diploma)	4.61; 0.89	<0.001	1.73; 0.93	0.065
use of anxiolytics (yes)	-1.74; 0.93	0.062	-6.73; 0.98	<0.001

For PCS: $R^2=0.25$, for MCS: $R^2=0.12$

Fig. 2 Predicted response means for PCS score and standard errors on time between diagnosis and compilation of the questionnaire, by self-perception. The lines refer to a subject with age between 18 and 54 years, female, without comorbidities, without intensive care, with a low level of NEWS2, with an educational level lower than high school diploma and without use of anxiolytics post COVID-19**Fig. 3** Predicted response means for MCS score and standard errors on time between diagnosis and compilation of the questionnaire, by self-perception. The lines refer to a subject with age between 18 and 54 years, female, without comorbidities, without intensive care, with a low level of NEWS2, with an educational level before high school diploma and without use of anxiolytics post COVID-19

population. Mental health and emotional role, in the third year post-COVID-19 hospitalisation, exhibited values similar to those observed one year after hospitalisation, indicating that the emotional sphere is the most challenging aspect to recover after the infection.

Our findings are consistent with those in the literature, although several studies have reported the effects of COVID-19 on HRQoL in the short term and up to one year after infection, while there is little evidence for the period after one year post-infection. A recent systematic review stated that approximately one-third of patients with

severe COVID-19 reported persistent impairments in functional status and lower HRQoL scores one year after discharge [34]. Among the studies assessing HRQoL through the SF-36, Banno et al. reported lower scores in almost all domains and in PCS and MCS, with 56% of participants reporting PCS score lower than 50 one year after ICU discharge [35]. The same results were found in our sample. Mental health, role-emotional, and role-physical were the most impaired domains, with no improvement at 1 year and remaining severely impaired over time [36].

In the study by Mastrorosa et al., which analysed a population of both hospitalised and non-hospitalised patients one year after infection, it was observed that both PCS and MCS scores of the SF-36 scale were lower than the average scores of the Italian population [2]. Moreover, mental state did not seem to improve at one-year and even tended to be worse than at the time closer to the onset of COVID-19 symptoms. These findings highlight that the impact of COVID-19 on QoL extends beyond the initial months following the acute infection and remains a significant concern over the long term [2]. A systematic review by Paterson et al. stated that the long-term sequelae of COVID-19 are just beginning to emerge in these years, making it difficult to estimate the effects over the next years [37]. COVID-19 has not only worsened the living conditions of the population, but it has also increased the risk of consequences on QoL or health in general, which also leads to a lack of recovery of mental conditions over time.

In the sample studied, the use of anxiolytics increased from 17.6% before COVID-19 to 30.8% after COVID-19. People who took anxiolytics after COVID-19 had lower MCS scores, indicating a deterioration in mental health after COVID-19, with the typical effect of increased use of medication (especially benzodiazepines) as an aid in more complex situations [38].

Impact of COVID-19 on QoL was higher among women, and patients with comorbidities; these results were in line with those previously reported in the literature [18, 30, 39, 40].

Regarding the self-perception of health before and after COVID-19, the three groups showed different SF-36 QoL profiles, and only the scores of the patients reporting similar health status before/after hospitalisation aligned with the normative Italian data, whereas the other two groups reported notably poorer scores compared to the normative Italian data. An interesting result is the presence of an interaction between the pattern of change overtime and the self-perception, with a higher recovery for the intermediate group on the PCS and for lower level for the MCS. Such interaction should be further studied.

Strengths and limitations

The study is based on a large sample of patients hospitalised for COVID-19, with availability of many clinical data at the disease onset, encompassing various levels of disease severity. This allowed for adjustments to account for time-dependent effects and relevant confounders.

The single questionnaire, completed by individuals at different time points, provided insights into patterns of recovery up to three years post-discharge.

However, the study is cross-sectional, lacking both longitudinal data and baseline HRQoL measurements at the individual patient level, which limits the ability to evaluate the impact of COVID-19 at patient level.

Furthermore, the normative data used to assess the population-level impact of COVID-19 were derived from periods preceding the pandemic. It may be valuable to re-evaluate these normative data or examine their stability and validity over time, particularly in the post-COVID-19 period.

Conclusions

For our knowledge, this is one of the first studies regarding the relationship between QoL and time up to three years since COVID-19 diagnosis in hospitalised patients.

Our main findings suggest that time since COVID-19 diagnosis improves QoL physically, while it can be perceived a very slight upgrading mentally; in general, the QoL scores are lower compared to the Italian normative values, and only the group of patients that feels similar pre and post COVID-19 has QoL scores similar to normative Italian values. These data suggest the need for further investigation into the overall impact of the COVID-19 pandemic on HRQoL in the post-COVID-19 period.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s11136-024-03882-y>.

Author contributions All authors contributed to the study conception and design. Material preparation was performed by Marco Viola, Carlotta Sacerdote, Anna Toscano, Assunta Rasulo and Rosalba Rosato. Data collection was performed by Marco Viola, Edoardo Donarelli, Anna Toscano and Assunta Rasulo. Analysis was performed by Marco Viola. The first draft of the manuscript was written by Marco Viola and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Declarations

Ethical approval This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of the Molinette Hospital - Città della Scienza e della Salute (Turin, Italy) (code 157/2022).

Consent to participate Informed consent was obtained from all individual participants included in the study.

Consent to publish Patients signed informed consent regarding publishing their data.

Competing interests The authors have no relevant financial or non-financial interests to disclose.

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