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Medically Fit but Functionally Unable; Determinants of Disability Among COVID-19 Patients in Aseer Region, Saudi Arabia

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Abstract

Background: COVID-19 has had profound impacts on both physical and cognitive health, leading to functional impairments among hospitalized patients. This study aims to examine the changes in functional status during hospitalization and identify factors influencing recovery and disability among COVID-19 patients.

Methods: A cohort of COVID-19 patients hospitalized at Aseer Central Hospital was studied. Data on bio-demographic factors, clinical characteristics, and functional independence were collected using the Functional Independence Measure (FIM) at admission and discharge. Variables such as age, body mass index (BMI), and ICU admission were analyzed to assess their influence on functional outcomes. A cross-sectional design was used for data analysis.

Results: The study found a significant decline in functional independence during hospitalization. Most patients were independent at admission, but by discharge, a considerable number required varying degrees of assistance. The mean FIM score decreased significantly from admission to discharge ($P < 0.001$). Age, BMI, and ICU admission were significant factors influencing functional decline. Patients who required ICU care or mechanical ventilation experienced the most substantial losses in functional independence.

Conclusions: COVID-19 significantly impairs functional independence, with prolonged hospitalization and critical illness exacerbating physical and cognitive decline. The findings highlight the need for early rehabilitation and post-acute care interventions, particularly for older patients and those with severe illness.

Keywords: COVID-19, Functional independence, Disability, Prevalence, Determinants, Saudi Arabia

Introduction

It was a critical moment when the World Health Organization (WHO) declared the outbreak of the novel coronavirus disease (COVID-19), primarily caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a pandemic in early March

2020 [1]. By the end of 2022, over 600 million people recovered from COVID-19 globally, of whom over 800,000 COVID-19 survivors were reported in Saudi Arabia [2]. COVID-19 not only causes significant mortality but also leads to considerable respiratory, physical, and psychological dysfunction in patients and survivors [3, 4]. Activities of daily living were shown to be particularly hampered among COVID-19 survivors [5]. Up to 35% of COVID-19 patients suffer significant esophageal dysfunction that increases their mortality and morbidity risk [6]. A long-term functional disability that lasts for several years after respiratory infections have been reported following the outbreak of adult respiratory distress syndrome about ten years ago [7]. COVID-19 follow-up data so far suggests that functional disability continues to deteriorate even six months following recovery from respiratory symptoms [8].

The COVID-19 pandemic, beyond its direct impact on respiratory and physical functions, has significantly disrupted healthcare services, particularly rehabilitation services. Global studies have highlighted the negative effects of the pandemic on the rehabilitation outcomes of patients who were part of regular musculoskeletal rehabilitation programs before and during the pandemic [9]. The provision of effective rehabilitation services during the pandemic posed considerable challenges, especially for frontline healthcare providers [10]. Additionally, the pandemic led to a substantial increase in the demand for rehabilitation services in many regions worldwide [11]. There is a clear need for guidance on the effective components of rehabilitation for COVID-19 survivors. Evidence supports the positive impact of physical rehabilitation interventions following COVID-19 recovery [12]. Rehabilitation was also identified as a key recommendation in a consensus statement produced by an expert panel from various fields, including rehabilitation, sport and exercise medicine (SEM), rheumatology, psychiatry, general practice, psychology, and specialist pain. This panel, based at the Defense Medical Rehabilitation Centre Stanford Hall in the United Kingdom, emphasized the importance of rehabilitation in post-COVID recovery [13].

However, we are unaware of any research investigating the extent of disability among COVID-19 survivors in Saudi Arabia. Hence, little is known about incidence, prevalence and risk factors for such disability. Therefore, it is difficult to predict rehabilitation requirements for this cohort at the hospital and/or community settings.

We set out to fill this enormous local knowledge gap. Our primary objective, therefore, is to predict disability occurrence and to determine the need for rehabilitation after COVID-19 infection in the Aseer region.

Methods

This prospective cohort study was conducted among COVID-19 inpatients admitted to the Aseer Central Hospital (ACH) between August 20, 2020, and November 20, 2020. Aseer Central Hospital, located in Abha, Saudi Arabia, is a prominent healthcare facility providing a wide range of medical services to the region. As a main hospital in the Aseer Province, it offers advanced diagnostic, therapeutic, and emergency care, and plays a vital role in serving both the local population and those from surrounding areas. The hospital is known for its comprehensive medical services, including specialized care in various fields such as cardiology, neurology, surgery, and intensive care. It is also involved in research and medical education, contributing to the development of healthcare in the region. The study included all adult patients (aged 18 years or older) admitted with a COVID-19-related diagnosis, excluding only those who refused participation or were unable to participate. Data were collected through a combination of face-to-face interviews, thorough physical examinations, and reviews of medical

records. The data collection tool captured a range of demographic characteristics (age, sex, marital status, nationality, education level, living arrangements), clinical information (COVID-19 status, physical comorbidities), lifestyle factors (smoking and substance misuse), and functional outcomes. Key assessments included the Functional Independence Measure (FIM) scale and walking speed, measured using the six-minute walking test. Data were gathered at two-time points: on admission and at discharge, with information corroborated by the hospital's electronic medical records system.

Data analysis

The data were collected, reviewed, and then fed to Statistical Package for Social Sciences version 26 (Released 2019. Armonk, NY: IBM Corp). All statistical methods used were two-tailed with an alpha level of 0.05 considering significance if the P value was less than or equal to 0.05. An overall FIM score was computed by summing the different items of the scale. The total score on the Functional Independence Measure (FIM) ranges from 13 to 91, the cut-off points can be adjusted as follows: a score between 13 and 39 indicates complete dependence, where the individual requires maximal assistance. A score between 40 and 65 reflects modified dependence, indicating the need for some assistance, but the individual is capable of performing some activities independently. A score between 66 and 91 suggests independence, meaning the individual can perform most activities without assistance. These cutoffs are proportionally adjusted to fit the total score range from 13 to 91 [14]. Descriptive analysis for categorical data was done using frequencies and percentages, whereas numerical data were presented as mean with standard deviation. Also, patients' clinical data, hospital admission, and discharge with mortality rate were tabulated while the overall knowledge level was graphed. Cross tabulation for showing factors associated with functional disability among COVID-19 patient using Pearson Chi-Square test and exact probability test for small frequency distributions. Hierarchical linear regression was used to assess the adjusted predictors of FIM score on discharge adjusting for their on-admission FIM score as a covariate.

Results

The table shows the bio-demographic characteristics of 173 COVID-19 patients in the Aseer region, Saudi Arabia. The mean age of the patients was 59.1 ± 16.8 years old. The majority were male (65.3%), Saudi nationals (82.1%), and married (85.0%). Regarding education, 40% had an education below high school level, and more than half (53.8%) were obese based on BMI data. Most patients were non-smokers (93.1%) and with no alcohol intake (99.4%). Psychiatric disease and interpreter dependency were not frequent, reported in only 4.6% and 2.9% of patients, respectively.

Table 2 summarizes the vital signs and laboratory findings of 173 COVID-19 patients in the Aseer region of Saudi Arabia. The assessment of vital signs shows a mean temperature of 36.91 ± 0.68°C, a mean arterial pressure (MAP) of 90.37 ± 10.89 mmHg, and an average heart rate of 88.49 ± 14.52 beats per minute. The respiratory rate averaged 21.28 ± 4.91 cycles per minute. Oxygenation parameters, including FiO2 (71.61 ± 47.00) and PO2 (44.58 ± 17.50). Laboratory findings show a mean arterial pH of 7.72 ± 4.62, sodium levels of 134.61 ± 12.99 mmol/L, and creatinine levels of 1.13 ± 1.07 mg/dL. Also, elevated urea levels (49.51 ± 44.54 mg/dL) and blood sugar levels (181.56 ± 95.70 mg/dL) were reported.

Table 3 illustrates the clinical outcomes for COVID-19 patients in the study. Among the patients, 38 (22%) required mechanical ventilation, while the remaining 78% did not. Regarding ICU care, 52 (30.1%) patients were admitted to the ICU where 21 (40.4%) of them had a stay of less than a week, 13 (25%) stayed for 1-2 weeks, and 18 (34.6%) were in the ICU for more than two weeks. The length of stay in the ICU ranged from 4 to 75 days, with an average of 14.1 days. When considering overall hospital stays, 92 (53.2%) patients were discharged within a week, 50 (28.9%) stayed for 1-2

weeks, and 31 (17.9%) remained hospitalized for over two weeks. The average hospital stay was 9.4 days, with a median of 6 days. Regarding outcomes, 16 (9.2%) of patients died during hospitalization, while the vast majority (90.8%; 157) survived.

As for the functional disability among COVID-19 patients (Figure 1), it was clear that on admission, most of the patients (81.4%) were independent, 9.3% showed modified dependence and 9.3% were dependent. On discharge, 73.9% were independent, 12.7% showed modified dependence and 23.4% were dependent. FIM score significantly decreased from 80.7 ± 20.5 with a median score of 91 on admission to 71.4 ± 22.9 with a median score of 81 after discharge (P<0.001) (Figure 2).

As for the factors contributing to functional disability among COVID-19 patients (Table 4), 92.3% of patients under 50 were independent, whereas only 33.3% of those over 80 maintained their independence (p-value=0.001). As for gender, female cases showed higher rates of dependency, with 17.9% being completely dependent and 25.0% moderately dependent. In contrast, only 10.9% of men were completely dependent, and 5.9% were moderately dependent (p-value = 0.001). Body mass index (BMI) is another significant factor. Among obese patients, 17.2% were completely dependent, and another 17.2% were moderately dependent but patients with a normal or overweight BMI displayed lower rates of dependency (p-value= 0.048). Additionally, patients with less than a high school education had the highest levels of dependency, with 28.6% being completely dependent. Only 3.8% of patients with postgraduate degrees were completely dependent (p-value = 0.001). Smoking status, history of psychiatric conditions, and ICU admission did not show a significant impact on functional disability. However, the length of stay in the ICU was significantly associated with functional disability as patients who stayed more than two weeks in the ICU showed a high rate of complete dependence (71.4%; p-value =0.002). Likewise, the duration of hospital stay was significantly related to functional disability. Patients staying for more than two weeks had a higher rate of dependence (30%) compared to only 6.7% of those who stayed for less than a week, with a p-value of 0.022.

The hierarchical linear regression analysis in Table 5 highlights several key factors that predict the Functional Independence Measure (FIM) score at discharge for COVID-19 patients. One of the strongest predictors is the FIM score at admission, with a beta coefficient of 0.955 (p-value = 0.001), meaning that higher FIM scores upon admission are linked to higher scores at discharge. Age also plays a significant role, with a beta coefficient of -0.169 (p-value = 0.001), indicating that older patients tend to have lower FIM scores at discharge. Body mass index (BMI) is another important factor, with a beta coefficient of -0.220 (p-value = 0.018), suggesting that higher BMI is associated with lower FIM scores at discharge. Finally, ICU admission is a notable predictor, with a beta coefficient of -2.300 (p-value = 0.039), indicating that patients admitted to the ICU are likelier to have lower FIM scores upon discharge.

Table 1. Bio-demographic data of study COVID-19 patient, Aseer region, Saudi Arabia (n=173)

Bio-demographic data	No	%
Age in years		
< 50	54	31.2%
50-60	46	26.6%
61-80	52	30.1%
> 80	21	12.1%
Mean ± SD	59.1 ± 16.8	
Gender		
Male	113	65.3%
Female	60	34.7%
Nationality		
Saudi	142	82.1%
Non-Saudi	31	17.9%
Marital status		
Single	8	4.6%
Married	147	85.0%
Divorced / widow	18	10.4%
Educational level		
Below high school	66	40.0%
High school	43	26.1%
Bachelor degree	29	17.6%
Post-graduate degree	27	16.4%
Body mass index		
Normal weight	25	14.5%
Overweight	55	31.8%
Obese	93	53.8%
Interpreter		
Yes	5	2.9%
No	168	97.1%
History of psychiatric disease		
Yes	8	4.6%
No	165	95.4%
Smoking		
Current smoker	5	2.9%
Non-smoker	161	93.1%
Ex-smoker	7	4.0%
Alcohol intake		
Yes	1	.6%
No	172	99.4%

Table 2. Clinical assessment: Vital signs and laboratory findings among study COVID-19 patients, Aseer region, Saudi Arabia (n=173)

Clinical assessment	Range	Mean	SD
Vital signs			
Temperature	36.0-39.1	36.91	.68
MAP	60.0-122	90.37	10.89
Heart rate (beats/min)	57.0-143	88.49	14.52
Respiratory rate (cycles/min)	10-66	21.28	4.91
FI O2	7.3-617	71.61	47.00
PO2	15.0-98	44.58	17.50
PCO2	50-316	38.70	23.70
Laboratory findings			
Arterial PH	2.5-67	7.72	4.62
Na+	13.8-154	134.61	12.99
Creatinine	0.1-10.4	1.13	1.07
Urea	8.0-293	49.51	44.54
BSL	55.0-676	181.56	95.70

Table 3. Clinical Outcomes including ICU admission, hospitalization duration and mortality among study COVID-19 patients

Variable	No	%
Mechanical ventilation		
Yes	38	22.0%
No	135	78.0%
ICU admission		
Yes	52	30.1%
No	121	69.9%
ICU LOS (days) (n=52)		
< 1 week	21	40.4%
1-2 weeks	13	25.0%
> 2 weeks	18	34.6%
Range	4-75	
Mean ± SD	14.1 ± 13.9	
Median	14.0	
Hospital stay in days		
< 1 week	92	53.2%
1-2 weeks	50	28.9%
> 2 weeks	31	17.9%
Range	1-75	
Mean ± SD	9.4 ±10.1	
Median	6.0	
In-hospital mortality		
Died [#]	16	9.2%
Survived	157	90.8%

#: 12 died on admission and 4 died later

Table 4. Factors associated with functional disability among COVID-19 patients in Aseer region

Factors	Functional disability on discharge						p-value
	Complete Dependence		Modified Dependence		Independent		
	No	%	No	%	No	%	
Age in years							
< 50	0	0.0%	4	7.7%	48	92.3%	
50-60	3	7.1%	5	11.9%	34	81.0%	.001*
61-80	9	20.0%	8	17.8%	28	62.2%	
> 80	9	50.0%	3	16.7%	6	33.3%	
Gender							
Male	11	10.9%	6	5.9%	84	83.2%	.001*
Female	10	17.9%	14	25.0%	32	57.1%	
Body mass index							
Normal weight	3	13.0%	3	13.0%	17	73.9%	.048*^
Overweight	3	6.4%	2	4.3%	42	89.4%	
Obese	15	17.2%	15	17.2%	57	65.5%	
Educational level							
Below high school	16	28.6%	8	14.3%	32	57.1%	
High school	2	4.9%	5	12.2%	34	82.9%	.001*^
Bachelor degree	0	0.0%	2	7.4%	25	92.6%	
Post-graduate degree	1	3.8%	3	11.5%	22	84.6%	
Smoking							
Current smoker	0	0.0%	1	20.0%	4	80.0%	.468^
Non-smoker	21	14.5%	19	13.1%	105	72.4%	
Ex-smoker	0	0.0%	0	0.0%	7	100.0%	
History of psychiatric disease							.297^
Yes	0	0.0%	2	28.6%	5	71.4%	
No	21	14.0%	18	12.0%	111	74.0%	
ICU admission							
Yes	7	18.9%	5	13.5%	25	67.6%	.497
No	14	11.7%	15	12.5%	91	75.8%	
ICU LOS (days)							
< 1 week	1	5.3%	4	21.1%	14	73.7%	.002*^
1-2 weeks	1	9.1%	1	9.1%	9	81.8%	
> 2 weeks	5	71.4%	0	0.0%	2	28.6%	
Mechanical ventilation							
Yes	5	19.2%	4	15.4%	17	65.4%	.529
No	16	12.2%	16	12.2%	99	75.6%	
Hospital stay in days							
< 1 week	6	6.7%	11	12.2%	73	81.1%	.022*^
1-2 weeks	9	19.1%	8	17.0%	30	63.8%	
> 2 weeks	6	30.0%	1	5.0%	13	65.0%	

Table 5. Multiple hierarchical linear regression analysis for predictors of FIM score on discharge among COVID-19 patients

Factors	B	SE	Beta	p-value
FIM score while admission	.955	.041	.850	.001*
Age	-.169	.049	-.124	.001*
BMI	-.220	.092	-.074	.018*
ICU admission	-2.300	1.010	-.021	.039*

P: Pearson X^2 test *^: Exact probability test*
** P < 0.05 (significant)*

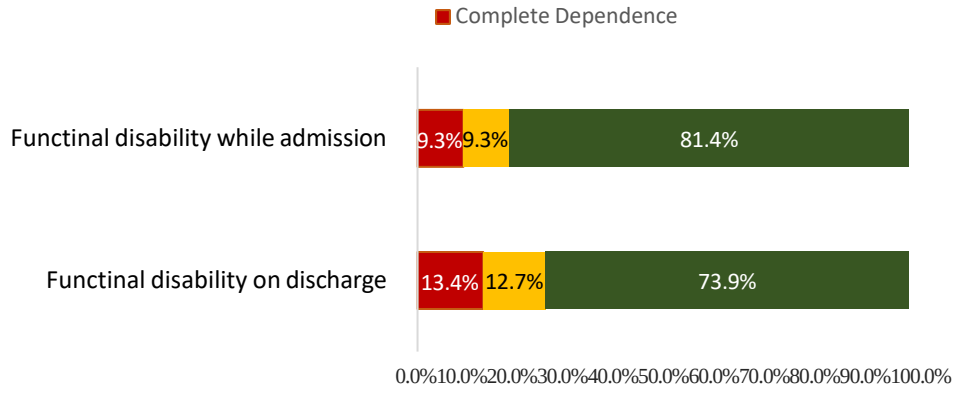

Figure 1. Functional disability on admission and after discharge among COVID-19 patients in Aseer region, Saudi Arabia

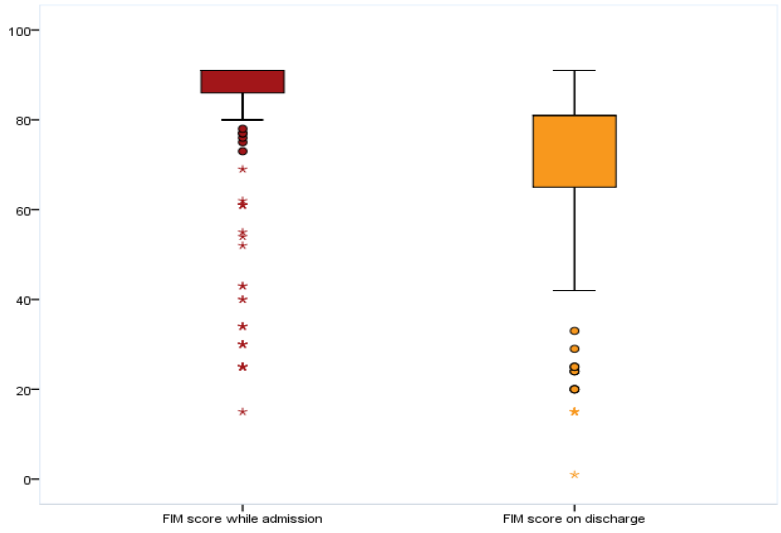

Figure 2. Box-plot for FIM score among COVID-19 patients on admission and after discharge

Discussion

The current study assessed the physical disability and its determinants among COVID-19 patients in the Aseer Region, Southern Saudi Arabia. The average age of the study participants was high, with the majority aged between 61-80 years, which is consistent with global observations that older adults are more vulnerable to severe COVID-19 outcomes [15]. In contrast, younger populations (under 50 years) accounted for one-third of the cases, indicating that although age is a major risk factor, younger adults are also at risk, especially in situations of chronic conditions [16, 17]. Considering gender, most cases were males which was consistent with findings from Saudi national studies indicating that males tend to have a higher incidence of severe disease [18, 19]. Also, among the current study cases, the prevalence of obesity was significant, with more than half of patients classified as obese. This observation aligns with global trends, as obesity has been consistently associated with an increased risk of severe COVID-19 and poor health outcomes [20-22].

Regarding clinical assessments, the mean temperature was 36.91°C, which was within normal limits, though a substantial number of patients had a fever (range 36.0-39.1°C). The mean heart rate (88.5 beats per minute) and respiratory rate (21.28 cycles per minute) were within typical ranges for hospitalized COVID-19 patients, suggesting moderate severity. Respiratory concession, indicated by oxygen levels (PO2), was observed with a mean of 44.58, showing that patients experienced significant pulmonary impairment, as expected in COVID-19 cases.

In terms of clinical outcomes, approximately one-third of patients required admission to the ICU, which aligns with international findings indicating that a significant proportion of COVID-19 patients needed intensive care [23]. The average length of stay in the ICU was around two weeks, reflecting a moderate to severe disease progression. Additionally, one-fifth of the patients needed mechanical ventilation, highlighting the severe respiratory involvement in this subgroup. Hospitalization durations varied widely, with over half of the patients being discharged within a week, suggesting that many were not critically ill. However, the in-hospital mortality rate raises concerns, as it has been associated with factors such as advanced age, comorbidities like obesity, and delays in hospital admission [24].

As for functional disability, the findings from this study reveal a significant decline in functional independence among COVID-19 patients during their hospital stay, as mirrored by changes in their Functional Independence Measure (FIM) scores. Upon admission, most patients were functionally independent, with a smaller proportion showing varying degrees of dependence. However, by discharge, there was a notable shift, with more patients becoming partially or fully dependent. This change highlights the substantial impact that COVID-19 has on physical and cognitive function, particularly among older patients or those with more severe illnesses [25, 26]. Many patients required intensive care unit (ICU) admission, and some even needed mechanical ventilation, which likely contributed to the decline in their functional abilities. The average FIM score dropped significantly from admission to discharge, with a marked reduction in the ability to perform daily activities independently. The decline in functional status is consistent with the effects of prolonged hospitalization, especially in older patients who are more susceptible to the negative consequences of extended bed rest, muscle deconditioning, and widespread inflammation caused by COVID-19 [27, 28]. Moreover, the stress associated with critical illness such as the necessity for ICU care and mechanical ventilation may worsen these issues, further impairing muscle strength and cognitive function [29]. Together, these factors highlight the lasting effects of COVID-19, particularly in individuals who experience severe illness or require intensive treatment. Such findings of functional disability following severe lung infection were long observed among survivors of acute respiratory distress

syndrome [30]. Also, in the USA, Gallagher MW et al. [31] highlight the significant psychological effects of COVID-19, particularly the increased risk of anxiety, depression, and functional impairment. COVID-19-related experiences were strongly associated with higher odds of anxiety and depression, with stress from the virus contributing significantly to functional impairment. Similarly, our study observed a marked decline in physical function during hospitalization, reflecting the broad, multifaceted toll the virus takes on both mental and physical health. Another study by Andrade-Junior MC et al. [32] assessed functional impairment among ICU-admitted COVID-19 patients and provided valuable insights into the physical impairments and recovery trajectories of COVID-19 patients, which can be compared to our study's focus on functional disability and independence during hospitalization. Both studies highlight that COVID-19 not only affects physical health during the acute phase but can also lead to long-term functional limitations. While some improvements, such as in mobility and respiratory function, may occur over time, our study's participants, like those in the Andrade-Junior MC study, did not return to their baseline levels of independence. This underscores the enduring impact of COVID-19 on both physical and functional health. Locally, our study's findings match more closely with Althomali OW et al.'s research [33], which highlighted the negative impact of COVID-19 on lung capacity and overall functional health, including both physical and cognitive impairments. This contrasts with the findings of Azzam NA et al. [34], who reported that COVID-19 had little effect on disability and health-related quality of life (HRQoL). The discrepancy may be due to differences in study populations or the severity of illness, as Azzam's cohort may have been less affected by the virus.

The study examined the factors influencing functional disability in patients with COVID-19. It found that patients with higher Functional Independence Measure (FIM) scores upon admission were more likely to maintain their functional independence, emphasizing the significance of baseline functional capability as a predictor of recovery. Older age was linked to poorer outcomes, likely due to decreased physiological resilience and a higher prevalence of chronic conditions, which can hinder recovery processes. Additionally, a higher body mass index (BMI) was found to negatively affect functional outcomes, as obesity often worsens immobility, inflammation, and complications during illness. Patients requiring admission to the intensive care unit (ICU) experienced greater functional decline, potentially due to muscle weakness induced by critical illness, immobility, and the physical effects of intensive care interventions. These findings underscore the necessity for early rehabilitation, targeted nutritional support, and strategies to prevent muscle deconditioning in at-risk groups to enhance functional recovery following severe COVID-19.

Strengths and limitations

This study has several strengths, including its thorough analysis of bio-demographic, clinical, and functional data from COVID-19 patients, offering valuable insights into the factors that influence recovery and disability within a specific regional context. By using standardized tools like the Functional Independence Measure (FIM) and incorporating a range of variables such as age, BMI, and ICU admission, the study enhances the reliability and relevance of its findings. Additionally, the focus on both pre-and post-discharge functional status provides a well-rounded view of patient outcomes. However, there are some limitations, including the relatively small sample size, which may limit the ability to generalize the results. The sample comes from a

single region, it may not reflect variations in care practices or disease severity found elsewhere. Moreover, potential confounding factors, such as pre-existing comorbidities or access to rehabilitation, could influence the results.

Conclusions and recommendations

This study highlights a significant decline in functional independence among COVID-19 patients during hospitalization, with many transitioning from being fully independent to varying levels of dependence by discharge. Factors such as older age, female gender, higher BMI, prolonged ICU stays, and extended hospitalizations were strongly associated with reduced functional independence. ICU admission stood out as a major predictor of poorer outcomes, reflecting the challenges faced by critically ill patients in regaining their functionality. Importantly, pre-admission functional status emerged as the strongest determinant of recovery, underscoring the critical role of baseline health in influencing post-hospital outcomes. The findings stress the lasting impact of COVID-19, not just on physical health but also on patients' quality of life and independence, especially for those with severe or prolonged illness. The observed decline in functional independence suggests that recovery may take considerable time, extending well beyond discharge. Healthcare systems should prioritize post-acute care and rehabilitation programs for COVID-19 patients, particularly for older individuals and those with severe disease. Early interventions such as physical therapy and cognitive support could play a crucial role in preventing further functional decline and accelerating recovery.

To improve our understanding, future studies should include larger and more diverse populations to explore the long-term effects of respiratory infections on functional health. Additionally, research should examine the role of pre-existing conditions and access to rehabilitation services in shaping recovery outcomes, enabling more targeted and effective support for survivors.

Abbreviations

FIM: Functional Independence Measure
COVID-19: Coronavirus Disease 2019
SPSS: Statistical Package for Social Science
CI: Confidence Interval
ICU: Intensive Care Unit

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Author contributions

Manuscript concept design: Z.R., Acquisition of the data: A.Z. and A.A., Interpretation of the data: Z.R., Preparation of the manuscript: Z.R., A.Z, Revised manuscript preparation: Z.R. All authors reviewed the results and approved the final version of the manuscript.

Data Collector

Wafa Khamis, Shahad Almutairi, Abdulhadi Alqahtani.

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Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate. This project was approved by the local Ethics Committee of Arak University (code.IR.ARAKU.REC.1401.010) and listed in the Iranian Registry of Clinical Trials (code no. IRCT20220409054456N1). Before

experimental procedures began, all the participants reviewed and voluntarily signed an informed written consent form.

Consent for publication

The written consent for publication has been obtained from the patient.

Competing interests

The authors declare no competing interests.

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