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**OR 8173**

**Impact of the COVID-19 lockdown on liver transplant recipients. A single center observational study**

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**AUTHOR CONTRIBUTIONS**

All authors contributed to and have approved the final manuscript.

All authors had access to the study data and critically reviewed, revised and approved the final manuscript. All the authors fulfil the four ICMJE authorship criteria (substantial contributions to conception or design of the work, or the acquisition, analysis, or interpretation of data for the work; drafting of the work or revising it).

A.C., R.O., L.M.G., S.H., J.A.A., J.C. and E.F. participated in research design; A.C., A.O., L.M.G., S.H., R.O., J.I.F., L.A., E.J.A., J.A.A., J.C. and E.F. participated in the performance of the research; A.C., A.O., L.M.G., S.H., R.O., J.I.F., L.A., E.J.A., J.A.A., J.C. and E.F. participated in the writing of the paper; A.C., A.O., L.M.G., S.H., J.I.F., J.A.A., J.C. and E.F. participated in data analysis

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## **ABSTRACT**

**Background:** the impact of the COVID-19 outbreak and lockdown on liver transplant (LT) patients remains unknown. The aim of this cross-sectional study was to assess the consequences of the COVID-19 pandemic on the physical and mental health of LT patients during the lockdown period.

**Methods:** a web-based questionnaire was emailed to 238 LT patients undergoing regular follow-up at our unit between August and October 2020. This pseudonymized survey explored demographic and lifestyle variables (i.e., eating and physical habits), disruptions in routine medical care, different dimensions of mental health, COVID-19-related mood and coping (worries/anxiety, depression, insomnia, fear of COVID, resilience, etc.) and health perception using different validated instruments.

**Results:** altogether, 48.7 % (116 of 238) LT recipients accepted to participate in the study, 104 of whom gave their consent to publish the data. The median age was 63 years. Up to 39.4 % presented worrying scores indicating moderate/severe generalized anxiety disorder (GAD), whereas 25.5 % exhibited moderate/severe insomnia and only 10.5 % moderate/severe depression. Forty patients (38.5 %) gained weight, 24 % experienced a worsening in their eating habits and 63.4 % referred to practicing less or

much less exercise during the lockdown. Only 25 % perceived a worsening in the control of their chronic comorbidities. Missed medical appointments (0.9 %) or poor adherence to therapy (1.9 %) were exceptional.

**Conclusions:** COVID-19 lockdown has negatively impacted the mental and physical health of LT patients. Long-term consequences remain unclear.

**Keywords:** COVID-19. SARS-CoV-2. Liver transplant. Mental health. Anxiety. Quality of life.

## INTRODUCTION

On January 30<sup>th</sup>, 2020, the World Health Organization (WHO) declared the global 2019 coronavirus disease outbreak (COVID-19) a public health emergency (1). The Spanish Government declared a lockdown on March 14<sup>th</sup> as a result of the pandemic that lasted almost two months (2). As a result, the Spanish population was placed in social isolation with permission to leave the house limited to buying food or medicine. These measures greatly disrupted people's lives and had implications on health and wellbeing in the general population (3).

Previous studies on subjects who had been quarantined for acute infectious diseases, like severe acute respiratory syndrome (SARS) or Middle East respiratory syndrome (MERS), reported a high prevalence of symptoms of psychological distress (4,5). These included anxiety, depression, insomnia and fear of getting sick or dying. Fear is an adaptive defense mechanism that is fundamental for survival and involves several biological processes of preparation for a response to potentially threatening events. However, when it is disproportionate, as in a pandemic, it becomes harmful. Thus, it has been associated with increasing degrees of anxiety, stress and insomnia in healthy individuals and with more intense symptoms in those with pre-existing psychiatric disorders (6).

There are indications of increased levels of post-traumatic stress disorder and depression following SARS-CoV-2 infection (7). Quarantine and the isolation associated with the pandemic are additional risk factors for psychological impact. Other reported consequences of quarantine stress are the onset and continuation of tobacco

consumption and alcohol abuse (8) and a change in lifestyle and eating habits leading to an unhealthy diet (6,7). All of them carry an increased risk of obesity, diabetes and cardiovascular disease (CVD).

However, little is known about the long-term impact of the COVID-19 lockdown on the global health (physical and mental) of liver transplant (LT) patients. The disruption of routine medical care is especially problematic for patients with chronic conditions that require regular follow-up such as LT recipients. They require continuous medical surveillance due to polypharmacy, comorbidities and the risk of allograft rejection. Therefore, the aim of the present study was to evaluate the impact of the COVID-19 lockdown in Spain on the overall health of LT recipients.

## **MATERIAL AND METHODS**

### **Study design and participants**

A web-based cross-sectional pseudonymized survey was performed based on Survey-Monkey™. This study was approved on July 19<sup>th</sup>, 2020 by the Ethics Committee of Cantabria (act 19/2020).

The on-line survey was developed by members of the LT Unit and Psychiatric Department of the University Hospital Marqués de Valdecilla (Spain). It covered five sections about health habits and physical and mental repercussions during the period of home confinement established by the Spanish authorities from March 15<sup>th</sup> to May 4<sup>th</sup>, 2020 (Fig. 1). The on-line survey was piloted with the research team prior to being sent to all LT patients undergoing regular follow-up at the LT unit of our hospital. Exclusion criteria were the patient's refusal to participate, active cancer, an estimated life expectancy of less than one year, severe psychiatric disease and inability to participate due to either technological barriers or impossibility to attend to the outpatient clinic to complete the survey. All participants were requested to sign the informed consent either online or at the hospital. The data were collected electronically between August and October 2020.

### **Survey sections**

The first section included sociodemographic data (Table 1) and medical comorbidities. The second section comprised items related to lifestyle, sources of information about COVID-19 and self-care during the lockdown. Participants were also required to answer different questions about weight gain and eating and exercise habits.

In the third section, participants were invited to fill out different validated questionnaires on reactions and coping strategies to the COVID-19 pandemic and other general questionnaires to evaluate mental health. The Fear of COVID-19 Scale was used to measure the fear of suffering COVID-19. This scale ranges from 7 to 35 points, the latter indicating a maximum level of fear (9). Pathological worry was addressed using the Spanish abbreviated version of the Penn State Worry Questionnaire (PSWQ-11), the gold standard measure of unspecific worry that characterizes generalized anxiety disorder (GAD) (10,11). On this scale, the highest possible score indicating a state of maximal concern is 55 and the cutoff points to identify a moderate and severe GAD are 33 and 38 points, respectively. The ability to recover from stress was evaluated using the Spanish version of the brief resilience scale (BRS-6) (12,13). The BRS-6 was coded as low (1.00-2.99), normal (3.00-4.30) and high (4.31-5.00). Insomnia severity was evaluated using the Spanish version of the seven-item insomnia severity index (ISI), the cutoffs for moderate and severe insomnia were 15 and 22 points, respectively (14). The Spanish version of the List of Threatening Experiences (LTE) was used to assess recent stressful events, which is a subset of 12 life event categories with considerable long-term contextual threat (LTE-12) (15,16). Finally, depression was evaluated using the patient health questionnaire 9 (PHQ-9) (17). The PHQ-9 classed the level of depression severity as minimal (0-4), mild (5-9), moderate (10-14) and severe ( $\geq 15$ ).

The fourth section was designed to identify self-reported changes in LT treatment and adherence to treatment, and to evaluate the perception of health surveillance during the lockdown. Participants were also asked if they had experienced a SARS-CoV-2 infection. In the fifth section, the patients were asked about their health-related quality of life using the EuroQol-5D-3L. A descriptive evaluation of five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) was performed. Each dimension has three possible levels scored from 1 (no problems) to 3



(extreme problems); a score of 1 in all the five items was considered as full health. In a second part, patients had to complete the EQ-5D visual analogue scale (VAS), a 0-100 scale where they were asked to indicate overall health perception, 0 being the worst and 100 the best imaginable health condition, respectively (18).

### **Statistical analyses**

Quantitative variables were expressed as the mean (standard deviation) or median (range or interquartile range [IQR]), and qualitative variables as absolute values and proportions. Statistical analysis was performed with IBM SPSS Statistics v22.0 for Mac (IBM Corp., Armonk, NY).

## **RESULTS**

Of 315 LT patients undergoing regular follow-up at our LT unit, 238 were eligible to participate in the study. One hundred and sixteen (48.8 %) accepted and completed the survey (Fig. 2). Finally, 104 LT participants gave their consent to publish the data. None of the participants reported current or past COVID-19 disease.

### **Socio-demographic and medical characteristics of the participants**

The median age of the participants was 63 years (range 30-83) with a median time since LT of 99 months (6-320) (Table 1). Overall, 75 % of the patients were males, and most were of Spanish nationality (97 %). More than half of the participants (53.8 %) had basic studies and most participants (86.5 %) were confined at home and unemployed. Participant characteristics and comorbidities are shown in table 1.

### **Lifestyle, information seeking on COVID-19 and self-care**

Most patients (75 %) acknowledged living with someone during the confinement and one quarter did not have a garden, terrace or outside access. The most frequent causes for going out during the COVID-19 lockdown were shopping (supermarket, pharmacy) and waste disposal (80 %). The majority of patients felt sufficiently informed about the coronavirus pandemic.

The vast majority of patients (90 %) reported washing hands and wearing masks more frequently than before the COVID-19 lockdown. Only 7.7 % required medical assistance or testing for SARS-CoV-2 infection, with no positive cases. Moreover, less than 1 % of the patients started or increased their alcohol or tobacco consumption, and none started using other substances such as cannabis, cocaine or other drugs.

### **Mental health, mood and coping during COVID-19 lockdown**

Participants showed intermediate levels of fear on the Fear of COVID-19 Scale (median 18; IQR: 7-28). When COVID-19-related worries were addressed using the Spanish version of the PSWQ-11, the median score was 30 (11-47). According to the PSWQ-11, 60.6 % of the patients did not present GAD (95 % CI: 50.5-69.9), whereas 18.1 % (11.6-27.1) and 21.3 % (14.2-30.6) had moderate and severe GAD, respectively. Most participants had no insomnia or only subclinical insomnia (74.5 %; 64.8-82.2) on the ISI scale. However, up to 23.4 % (16.0-32.9) had moderate clinical insomnia and 2.1 % (0.6-7.4) severe insomnia. Eleven participants (10.5 %; 6.0-17.9) reported at least a moderate degree of depression defined as a PHQ9  $\geq$  10, whereas only four patients (3.8 %; 1.5-9.5) had major depression (PHQ9  $\geq$  15). Finally, most participants suffered no additional stressful events (60.6 %; 50.9-69.4) in the LTE scale, and showed normal or high levels of resilience (79.6 %; 70.3-86.5).

### **Physical health, well-being and medical care**

Forty participants (38.5 %) experienced weight gain. Twenty-five patients (24 %) reported worsening eating habits (eating extra, more often, unhealthily or erratically) and 63.4 % practiced less or much less physical activity than before.

A minority of patients (1 %) missed medical consultations because of fear of SARS-CoV-2 infection, and most participants had their face-to-face consultations changed to telephone consultations (75 %). Missed medication doses or drug schedule changes were exceptional (1.9 %). Moreover, no patient reported problems in collecting their medication during the confinement. No patient experienced rejection or other liver-related complications. Twenty-six patients (25 %) perceived the control of their chronic medical comorbidities as worse or much worse, while the remaining patients



perceived the same control as before lockdown. Participants who perceived a poorer control attributed it to worse eating and exercise habits (42.3 %), higher levels of anxiety, fear or stress (37.5 %) and/or to greater difficulties in obtaining adequate medical assistance (20.2 %) during the COVID-19 lockdown.

### **Health-related quality of life**

The proportion of patients in full health was 48.07 % (50/104). Figure 3 shows the level of reported problems in each of the five dimensions of the EQ-5D-3L questionnaire. Although most of the patients did not present problems in the different dimensions evaluated, up to 30 % of the patients presented moderate/high levels of pain/discomfort and anxiety/depression. The median EQ-5D-3L VAS score was 78 points (IQR: 21).

### **DISCUSSION**

The COVID-19 confinement period resulted in poorer diet and physical exercise habits leading to poor weight control, and a perception of worse control of their medical conditions in up to 25 % of the LT patients surveyed. Remarkably, up to 40 % exhibited moderate or severe levels of anxiety and up to one quarter referred moderate or severe insomnia. However, high rates of resilience were detected.

Our LT population felt well informed about the development of the pandemic and also had intermediate levels of concern and fear of COVID-19 infection, as recently reported (19). There were no cases of infection in the study period. Health authorities during this period reported a mean and maximum incidence of 110 and 263 cases per 100,000 inhabitants, respectively. In contrast with previous studies (8,19,20), most participants showed a high adherence to immunosuppressive and other prescribed drugs, with no changes in their tobacco or alcohol habits, likely related to the short period of confinement. Given the potential risk of infection in hospitals, most participants had their face-to-face consultations changed to telephone consultations soon after lockdown. As shown by other studies (21-23), this change seemed to have no impact on the medical surveillance of our LT recipients.

Up to 39 % of participants showed moderate or severe GAD, which had an impact on their perception of quality of life. Previous reports about COVID-19 and psycho-emotional distress have also reported moderate and severe depressive or anxious symptoms in about one third of patients (24-29). The lower percentage of moderate-severe depression (10.5 %) in our study appears to correlate with the high degree of resilience shown by our patients. Indeed, only a few respondents reported a loss of confidence and interest in things or poorer decision making, all of which represent coping mechanisms to overcome a crisis. In line with previous reports, the most common symptoms of our patients were related to sleeping disorders (30,31). Up to 72.3 % of the patients showed some degree of insomnia during the lockdown, with 25 % reporting moderate-severe insomnia. These changes are probably related to changes in sense of time, sedentary lifestyle, prolonged television viewing time and increased use of electronic devices.

Since the start of the lockdown, almost 40 % of the patients reported weight gain mainly related to changes in eating habits and a reduction in physical activity. These changes in short periods of time can become permanent and lead to substantial weight gain (32). In fact, up to 40 % of the patients who perceived poorer control of their chronic comorbidities attributed it to diet and exercise. Regardless of this, given their well-known association with deleterious health outcomes (33-35), our study highlights the need to implement strategies to further increase home-based physical activity and to encourage adherence to a healthy diet during periods of confinement.

Some of the limitations of our study are related to the cross-sectional design that evaluated a short period of time. The absence of baseline records for some of the instruments used, the single-center nature of the study and a possible selection bias related to low participation may also constitute certain limitations. However, the extraordinary nature of the situation makes the findings relevant to foresee and face similar situations in the future.

In conclusion, there is a negative impact of confinement on both physical and mental health of LT patients. It is likely that longer periods of confinement and observation may show a greater impact. Therefore, it is necessary to develop psychological and nutritional support measures and enhance physical exercise to minimize these

negative effects.

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**Table 1. General characteristics of the study population**

<i>Variable</i>	<i>(n = 104)</i>	<i>Variable</i>	<i>(n = 104)</i>
<i>Socio-demographic</i>		<i>Medical history</i>	
Age (years)	63 (30-83)	<i>LT-related</i>	
Gender (men)	78 (75)	Etiology of liver disease	
Spanish nationality	101 (97.1)	Alcohol	45 (43.3)
Educational level		Hepatitis C	28 (26.9)
Primary Education	31 (29.8)	Others	31 (29.8)
Secondary Education	25 (24)	LT indication	
Advanced Vocational Training	18 (17.4)	Decomp. cirrhosis	47 (45.2)
University degree	30 (28.8)	HCC	42 (40.4)
Marital status		Others	15 (14.4)
Married/living with a partner	78 (75)	Months from LT	99 (6-320)
Single	9 (8.7)	<i>Comorbidities</i>	
Separated or divorced	7 (6.8)	Diabetes	56 (53.8)
Widowed	10 (9.5)	Hypertension	62 (59.6)
Occupation		CVD	34 (32.7)
Employed	14 (13.5)	Bronchopulmonary	34 (32.7)
Working at home	8 (7.7)	Obesity	43 (41.3)
Working out	6 (5.8)	CKD	41 (39.4)
Unemployed/looking for a job	18 (17.3)		
Retired	72 (69.2)		
Studying	0 (0)		
Place of residence			
Rural	67 (64.4)		
Urban	37 (35.6)		

Qualitative variables are expressed as number and percentage (n; %); quantitative variables are expressed as median and range (median; range). LT: liver transplant; HCC: hepatocellular carcinoma; CVD: cardiovascular disease; CKD: chronic kidney disease.

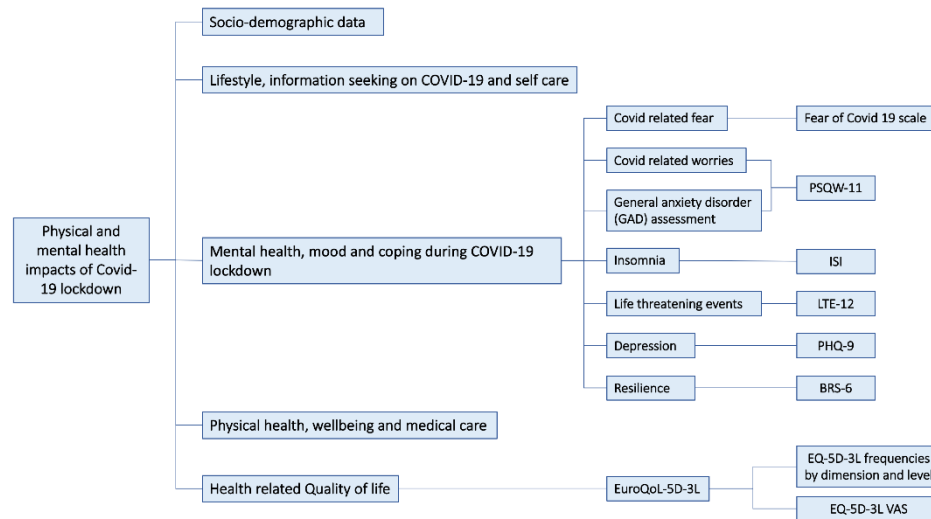


Fig. 1. Impact of COVID-19 lockdown on physical and mental health. Study diagram.

PSWQ-11: Spanish abbreviated version of the Penn State Worry Questionnaire (PSWQ); ISI: insomnia severity index; LTE-12: list of threatening experiences (12 categories); PHQ-9: patient health questionnaire 9; BRS-6: brief resilience scale; EQ.5D-3L VAS: EuroQol-5D-3L visual analogue scale.

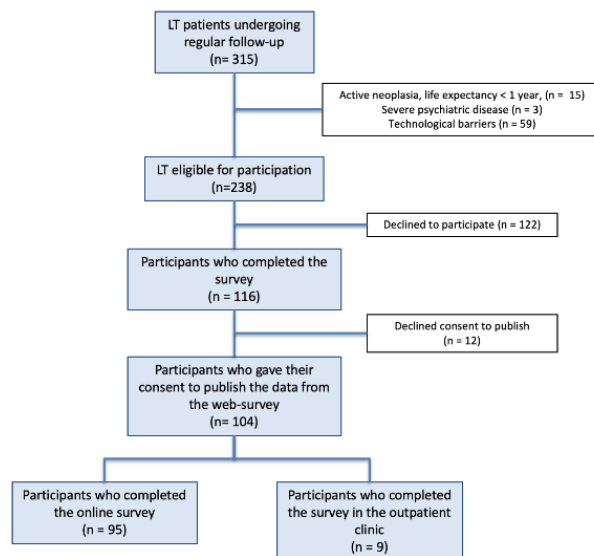


Fig. 2. Flow-chart of the study.

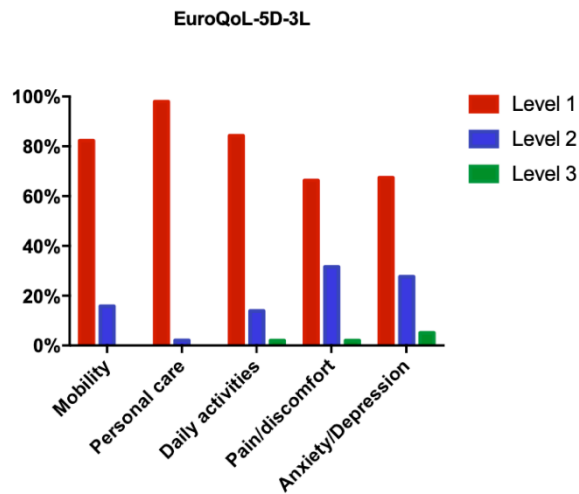


Fig. 3. Health-related quality of life (EuroQoL-5D-3L). Descriptive evaluation of each of the five dimensions of the EuroQoL-5D-3L in levels. Level 1: absence of problems; Level 2: some degree of problems or moderate feeling; Level 3: impossibility of doing different actions or severe discomfort.