

Impact of covid-19 pandemic on quality of life and psychosocial difficulties among liver transplant recipients

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ABSTRACT

Background: The first wave of the COVID-19 pandemic affected health in all domains i.e., physical, mental, and social aspects. Liver transplant (LT) recipients faced a multitude of challenges during the first wave of lockdown. The aim was to identify the psychosocial difficulties and quality of life during the first year of the pandemic. **Methods:** A cross-sectional survey was conducted on LT recipients with a predefined structured questionnaire that included clinical, COVID-19 anxiety scale, and Post-Transplant Quality of life questionnaire (pLTQ). **Results:** A total of 109 patients were studied; with a mean age of 50.5 ± 11.1 years, with a median post-transplant follow-up of 52.4 months and a live donor transplant in the majority (79.8%). Almost all (99.1%) could come to the hospital for regular follow-up, prior to the pandemic. But during the first wave only 57% could maintain planned hospital visits and about 88% could not pursue their regular activities, and 39% missed their routine exercise because of imposed restrictions. Similarly, financial implications were responsible for 4% defaulting from treatment; while 7.3% managed by curtailing supportive drugs (on their own) leading to deranged liver tests in 4.6%; requiring immediate attention. The psychosocial difficulties raised the stress of pandemic (median score 18), and impacted quality of life (mean total pLTQ score 4.7 ± 0.9) **Conclusions:** For LT recipients, the first wave of COVID-19 pandemic affected their physical, mental, financial, and social wellbeing; in addition to the disease itself. Awareness, psychosocial support, and comprehensive care are some unmet needs for this special group; especially when it is expected that subsequent waves may continue to occur.

Keywords: Liver transplant recipients and COVID-19, post transplant quality of life, psychosocial difficulty, psychological issues in transplant recipients

Introduction

The corona virus disease 2019 (COVID-19) pandemic caused by severe acute respiratory syndrome corona virus 2 (SARS-CoV-2) has affected globally including India.^[1] The

morbidity and mortality from COVID-19 are worse in patients with the pre-existing co-morbid illness.^[2,3] Liver transplant (LT) recipients, by virtue of being on immuno-suppressants, represent a vulnerable patient cohort with an increased risk of infection and/or possible severe course of the illness.^[4] The presence of metabolic-related co-morbidities, known to increase with time since transplant might be associated with an increased risk of severe COVID-19 disease and need to be studied which have important public health implications.^[5-7] Moreover, these patients could not meet primary care physicians

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as well during the lockdown leading to further adverse consequences.

Overall the clinical features, optimal therapeutic approach, and outcomes of COVID-19 among solid organ transplant (SOT) recipients are still scarcely studied.^[8,9] Although a recent systematic review among SOT recipients alerted clinicians on increased mortality risk in patients older than 60 years^[10], the same has not been studied exclusively on LT patients. There have been single center reports from Hong Kong, Italy, and Spain indicating conflicting findings of the effect of COVID-19 on post-transplant patients.^[5,11–13] Moreover, for this group of patients, European Association for the Study of the Liver (EASL) in a position paper recommended against reducing immunosuppressive therapy except under special circumstances. It was recommended to reduce direct exposure to hospitals as much as possible. However, in a country like India, all patients did not have equal access to good quality internet and devices to be in regular touch with their clinicians.^[14] This could cause a significant burden on their quality of life and ongoing compliance to treatment advice.

In this subgroup of patients, problems could be not only from the direct effects of the virus and associated increased morbidity and mortality, but also the added impact of COVID-19 related lockdown and associated psychosocial difficulties.^[15,16] The restrictions on daily activities, sports, recreations, and outdoor visits for jobs or income were also affected. The constant fear of getting an infection leading to anxiety and the emotional issues due to lockdown could compound the perceived stress. The difficulty faced in a routine hospital visit, getting the essential medicine, and attending a hospital upon medical need were the indirect consequences of COVID-19 but had a bearing on the comprehensive care of post-transplant recipients. As general population surveys from the country indicated a significant psychosocial burden, there was a need to study the magnitude of the same in post-transplant patients. This can help to understand the quality of life, difficulties faced, and the anxiety as well as psychosocial stress among the LT recipients. A total of 3000 annual LT is done in India (with live donor liver as the predominant method), including the Institute of Liver and Biliary Sciences (ILBS) where the current study was designed is a university hospital with nearly 100 transplants per year. The present study was conducted with the aim to study these psychosocial difficulties and their impact on the post-transplant quality of life in post-LT patients from our center.

Methodology

This was a cross-sectional online survey conducted on LT recipients from the ILBS. All patients above 18 years of age who had a regular follow-up after LT were included in the study. Those having irregular follow-up (defined as last visit more than 6 months to transplant clinic), incomplete questionnaires, and not willing for informed consent were excluded. The protocol was approved by the Institute Ethics committee vide letter

no IEC/2020/78/MA09 dated 10.06.2020 before initiating the online survey and the first page of the survey included an informed consent form which could be signed electronically. Those who provided informed consent and completed the questionnaire were included in the analysis after removing any identifying information.

Study procedure

Before beginning the study, a questionnaire was developed to capture psychosocial difficulties (daily life difficulties, service accessibility issues, status of exercise and nutrition) during the COVID-19 pandemic through two focused group discussion sessions. The first session consisted of four clinicians (including one psychiatrist and co-author MV) who have been dealing with post-transplant patients and the second session was with two patients and their caregivers. Based on these, a thematic analysis was performed and items identified for making the “Psychosocial difficulty” scale (Annexure I). The questions in this part were made on a 0–4 scale and the final score was obtained by adding all the responses (Range: 0 – 32).

After developing the scale, the online questionnaire was created and a list of all patients that visited between January and June 2020 was compiled. These participants were then sent the questionnaire using the “Google form” platform. Only the principal investigator had access to the data sheet and no modification was allowed after rolling the survey on 30th June 2020. A period of 3 weeks (21 days) was decided to collect the responses. Once the data collection was completed, the data was imported through MS-Excel and all identifying information was removed before the file was circulated for coding and analysis.

Other study questionnaires

The questionnaire consisted of three parts. The first part had clinical and demographic variables (age, gender, marital status, type of transplant, etc.) The second part is the “Psychosocial difficulty” scale (Annexure I) and finally, COVID-19 related anxiety (COVID-19 anxiety scale) and post-transplant quality of life questionnaire (pLTQ- 32 item for last 4 weeks) was in the third part.

COVID-19 Anxiety scale (CAS) is a 5-item screening instrument designed to identify anxiety associated with the COVID-19 crisis.^[17] Each item evaluates distinct physiologically-based fear or anxiety reaction to Corona virus-related thoughts and information. The scale has good diagnostic properties and cut off score of ≥ 9 (optimized; [AUC = 0.94, $P < .001$]). pLTQ is used to assess specific factors affecting the lives of LT recipients. The domains included are related to symptoms, mood, and limitation of the activities of daily living, energy level, and transplant-related care. It is a 32 item scale which is grouped into eight domains: Worry (seven items), Emotional (four items), Physical Function (six items), Medications (four items), Healthcare (four items), Graft Rejection Concern (two items),

Financial (two items), and Pain (three items). The scoring is on 7-point Likert scale, where 1 corresponds to “always” and 7 to “never”. It provides individual scores for each domain as well as a total score, which is multidimensional.^[18]

Statistical analysis

Socio-demographic variables and clinical parameters were analyzed through descriptive statistics. Shapiro-Wilk test was utilized to assess data normality. The scores of the psychosocial difficulty scale, pLTQ, and COVID anxiety scale were expressed as mean and standard deviation. A significance level of $P < 0.05$ (two-tailed) was used in the analysis. SPSS Statistic 22.0 (IBM SPSS Statistics, New York, United States) was used for statistical analysis.

Results

The survey form was sent to a total of 156 participants that were on regular follow-up at ILBS, New Delhi in the preceding 6 months leading to the beginning of the first wave of pandemic and related restriction. Out of them, a total of 110 patients filled the study questionnaire (one was incomplete and hence it was excluded from the final analysis). Participants' mean age was 50.5 (± 11.1) years with 88% being males; and a median duration of 52.4 (range: 4.1 – 118.8) months post-transplant. Almost all participants were married (99.1%). The majority had a live donor LT (79.8%) from a family member. The commonest donors were children and spouses of the recipient (35.6% each) followed by other first degree relatives (25.8%).

Clinical conditions and follow up prior to the pandemic

At the time of transplant, one-third (35.1%) had documented dependence on alcohol or tobacco. But almost all reported not using them following the transplant during the pandemic period. More than half (52.7%) had no form of complications in the post-operative period. During the initial 3 months around 20.2% had some form of minor complication (did not require any surgical intervention). Additionally, approximately 23.9% had some form of complication between 3 months and 1-year period and less than 10% (8.2%) had some issues after 1 year of transplant. Almost all (99.1%) were on regular follow-up and treatment prior to the pandemic [Table 1].

Impact of pandemic

Approximately 90% of post-transplant patients (88%) were not able to pursue regular activities during the pandemic [Table 2]. This included approximately one-fourth (23%) of patients who had problems accessing any form of treatment for their liver disease. Out of these, the common issues were the inability to reach the hospital (7.3%) and the inability to afford the cost of treatment (3.7%). A small proportion of patients also reported to be taking only essential medications due to lack of funds (7.3%), and about 5% were taking medications without a formal consultation (4.6%). Most patients did

Table 1: Baseline Clinico-demographic parameters Scaled variables

	Minimum	Maximum	Mean	Median	SD
Age	19	76	50.49	51	11.08
Duration from transplant (months)	4.10	118.88	54.32	52.37	25.76
Total COVID anxiety scale	0	15	1.11	0	2.43
Total Psychosocial difficulty	5	24	16.28	18	4.78
Categorical variables [N = 109]					
Variable	Categories		Frequency [n (%)]		
Gender	Male		96 (88.1)		
	Female		13 (11.9)		
Marital status	Single		1 (0.9)		
	Married		108 (99.1)		
Type of liver transplant	Deceased Donor		22 (20.2)		
	Live donor		87 (79.8)		
Relationship with donor (in Live donor transplant)	Spouse		31 (35.6)		
	Other first degree relative		25 (28.8)		
	Kid		31 (35.6)		
Regular treatment before COVID-19	Yes		108 (99.1)		
	No		52 (47.7)		
Immediate post-transplant complications	Yes, during the initial 3 months		22 (20.2)		
	Between 3 months and 1 year		26 (23.9)		
	Yes, after 1 year of transplant		9 (8.2)		
Comorbid conditions	DM/HTN/Cholesterol		15 (13.8)		
	No comorbidity		49 (44.5)		

not suffer any medical complications during the lockdown period (87.2%).

Approximately 39% could not continue their usual pre-lockdown exercise and physiotherapy routine. The continuity of clinical care affected the majority of patients while 41% could not attend their routine clinical consult (fearing hospital visit). The reasons suggested by participants were lockdown restriction (6.4%), lack of self-interest (10.1%), and fear of infection outdoor (27.5%). About 17% reported no consultation with their transplant physicians for follow-up. However, more than half (56.9%) still preferred coming to the hospital for routine follow-up as well as for other issues. About one-fourth (26.6%) preferred tele-consultation to discuss their treatment needs. About 13% of the respondents had medical complications requiring a hospital visit, but could not attend the clinic and took over teleconsultations. Most patients (87%) did not suffer any medical complications during the lockdown period. Despite the lockdown, more than 90% (93%) could maintain the prescribed nutritional status [Figure 1].

The median psychosocial difficulty score was 18 (Mean = 16.28; SD = 4.78) with a range of 5 to 24 [Figure 1]. The results of the pLTQ in the study population [Table 3]. The mean total score was 4.67 ± 0.9 points. The lowest mean score was observed in the rejection domain (4.7 ± 1.9), and in the financial domain (3.5 ± 0.9); indicating poor quality of life in these domains. The highest mean scores were in medication (6.3 ± 0.8) and health (5.9 ± 0.7) related

Variable	Categories	Frequency (%)
Are you actively pursuing activities as before	No	96 (88.1)
	Yes	13 (11.9)
Effect of COVID-19 pandemic	My treatment is continuing as previously planned	84 (77.1)
	I have to forgo my treatment due to inability to reach hospital	8 (7.3)
	I have to forgo my treatment due to inability to afford the cost of treatment	4 (3.7)
	I am taking only essential medications due to lack of funds	8 (7.3)
	I am taking medications on my own without a formal consultation	5 (4.6)
	None	95 (87.2)
Medical Problems due to COVID pandemic	Deranged liver test, Increase in sgpt&sgot	5 (4.6)
	COVID 19 disease	1 (0.9)
	Biliary complication	6 (5.6)
	Others	2 (1.7)
Status of exercise/ physiotherapy	Continued as before	61 (56.0)
	Severely reduced due to restriction	7 (6.4)
	Reduced due to lack of self interest	11 (10.1)
	Reduced due to fear of infection outdoor	30 (27.5)
Nutritional status during COVID-19	No Change	102 (93.6)
	Decrease due to availability and affordability	3 (2.7)
	Decreased due to poor motivation as hospital visit reduced	4 (3.7)
Obtaining healthcare	Routine follow up as planned	62 (56.9)
	Preferred tele-consultation	29 (26.6)
	Fearing hospital visit	18 (16.5)

Variables	Total	Emotional	Worry	Medications	Physical Function	Health	Rejection	Financial	Pain
Items, n	32	4	7	4	6	4	2	2	3
Mean	4.67	4.3	5.1	6.3	5.4	5.9	4.7	3.5	5.3
SD (±)	0.9	0.7	1.4	0.8	1.2	0.7	1.9	0.9	1.1

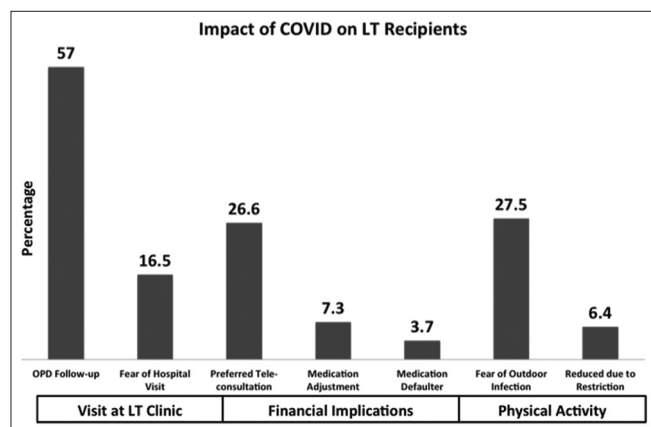


Figure 1: Implication of lockdown on continued care of LT recipients

domains. Based on the COVID-19 anxiety scale, there was no significant COVID-19 anxiety in the participants (Range: 0-15) with mean score of 1.11 (SD = 2.43). Figure 2 indicated the response rates on various psychosocial aspects and showed that more than 52% of patients reported restriction in activities most or all of the time. Moreover, about 11% reported a new onset of sleep difficulties and 16% had irritability most or all of the time. A significant proportion also reported excessive worries (27%) and fears (19%) during the pandemic period.

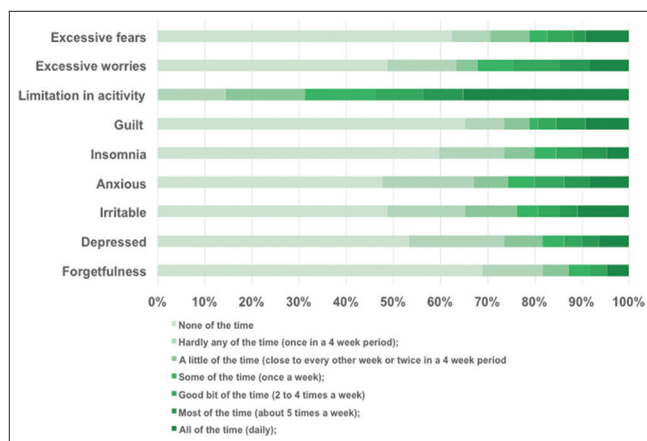


Figure 2: Psycho-social difficulties among LT recipients during COVID-19 related lockdown

Discussion

Despite the common understanding about difficulties in treatment accessibility during the COVID-19 pandemic, the data on LT patients is scarce.^[5] Thus, we tried to assess the psychosocial difficulties and quality of life in patients who were otherwise maintaining well post their transplant from our center. While there have been Indian studies on general population

difficulties and psychological issues^[19,20] during the pandemic. The present study is the first of its kind on LT recipients with data on more than 100 patients on the direct and indirect consequences of COVID-19 in this special population i.e., LT recipients. We found that not only the infection, but the fear of getting COVID-19 might have altered the life of transplant recipients in a significant way due to financial, social, physical, and mental problems. This was a double jeopardy situation for them as not following up for treatment (due to COVID-19 related fear and anxiety) will impact them as badly as getting the infection if they moved out for treatment-related aspects.^[21]

In our study, we found that almost all transplant recipients (approx. 90%) were not able to pursue their treatment-related activities during the pandemic. This can potentially impact post-transplant outcomes in LT recipients, which has been fairly good from the center until this time.^[22,23] The median duration of the patient's post-transplant was approximately four and a half years. Thus, most of these patients were maintained well before the pandemic. We also found that a proportion of our patients were not able to buy or procure medications during this period thus potentially affecting their overall health. This is similar to literature for chronic diseases where maintaining medication adherence had been a major issue during the pandemic and associated lockdown.^[24] The quality of life was also found to be low across domains as compared to other post-transplant recipients before the pandemic.^[25,26] Another important aspect was the psychosocial difficulty score based on a self-devised scale (Appendix I). This indicated that most patients (more than 2/3rd participants) experienced significant (more than median score of 18) amount of psychosocial difficulties during the COVID-19 pandemic. There has been scant literature on this aspect in transplant patients^[27] and hence we decided to use a self-devised scale based on the expertise of senior authors of the study. This scale can be validated further in this group of patients.

An unexpected finding was the absence of COVID-19 related anxiety in the study participants. This was contrary to the current understanding about increased fear and anxiety in transplant patients.^[28,29] There could be multiple reasons for the same. Firstly, it has been known that chronic disease patients tend to underreport depression and anxiety symptoms^[30,31] with their physicians. Secondly, patients suffering from medical illnesses feel stigmatized about having psychiatric disease and hence underreport anxiety-related questions.^[32,33] Moreover, transplant recipients can be a little different from the general population. They are likely to be more conscientious and have problem-solving approaches for coping with problems, which makes them seek transplants, be selected for one, and be on regular follow up. These qualities can play a role in dealing with problems and protecting from anxiety. Lastly, this scale has only recently been developed for understanding COVID-19 related anxiety and was not validated for the Indian population. Larger multicenter studies with validated tools may provide a better estimate of this important aspect in the life of post-transplant patients.

Our study also demonstrated that while these findings sound expected, but their systematic documentation is important to inform policymakers; in order to customize targeted interventions in the coming time. The study has several implications in real-life practice, but can still be a guide to many transplant centers to amend their protocol for follow up in LT clinics. Comprehensive health is a need at this time i.e., physical, financial, mental, and social wellbeing. Adoption of teleconsultation is an unmet need for assuring a good outcome. Philanthropic support is needed at this moment to support the post-transplant patients to ensure continued care and compliance to life saving medications like immune-suppressants.

Our study had some limitations, some of which were due to the inherent nature of online surveys.^[34] These include recall bias; being representative of the English-speaking population only and social desirability bias. The generalizability of findings needs to be further studied as the survey was conducted among ILBS patients only. The sample size calculation was not done prior to the study. Moreover, the study was conducted during the initial stages of the pandemic when the additional effects of lockdown could have impacted the study results. Additionally, the findings of the psychosocial difficulty scale and COVID-19 anxiety scale should be understood with caution as this scale has not been validated in the past.

Despite the limitations, this study is an important step in the direction of understanding difficulties faced by LT recipients during the pandemic. One possible solution can be using family physicians as a bridge for patients who live far away from tertiary care centers. They can liaise with LT specialists to maintain the overall health of recipients. For better understanding, there should be large scale systematic studies done globally on LT recipients to understand their psychological issues and explore potential solutions. This can provide useful insights into the life of LT recipients and can help clinicians tailor their treatments accordingly in the future; especially when this pandemic is here to stay.^[35]

A significant proportion of LT recipients faced significant psychosocial difficulties during the initial phase of the pandemic. Since the pandemic seems to be continuing, addressing these difficulties will require a combined effort of specialists, primary care physicians, and policy makers.

Highlights:

- LT recipients faced significant psychosocial difficulties which impacted their quality of life in multiple domains during the COVID-19 pandemic
- A continuous and interactive liaison of specialists, primary care physicians, and policy makers are required to tackle the growing issues of LT recipients during the pandemic

Conclusions

Post LT recipients had a multitude of challenges due to the ongoing COVID-19 pandemic. The poor quality of life and

psychosocial stress need to be addressed by holistic LT follow-up protocols. The need for addressing the non-COVID implications like physical activity, continued medication and regular follow-up, adoption of telemedicine support, and financial support to these patients. Restructured LT clinics and comprehensive interventions should be planned to improve the psychological well-being of these patients in the current difficult times.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Author contribution

AC conceptualized, collected the data and revised the draft. MV prepared the questionnaire; prepared and revised the manuscript. BS did tabulation, analysis and figures. VP, PS, NSP, NM helped in collecting the data and revision of draft. VS did follow up of the patient and data acquisition. RK helped in final proof reading and provided logistic support.

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Conflicts of interest

There are no conflicts of interest.

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