

Severity of liver disease and quality of life in liver transplantation

Gravidade da doença hepática e qualidade de vida no transplante de fígado

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Abstract

Objective: To analyze the influence of liver disease severity on the quality of life of patients before and after liver transplantation.

Methods: A descriptive study with 150 liver transplant recipients over 18 years of age. Severity was assessed using Child and MELD, and the Liver Disease Quality of Life was administered. The t-test or Mann-Whitney test was used to compare the mean values of the domains, and an ANOVA or Kruskal-Wallis test was used for between group comparison.

Results: Prior to transplantation, patients with Child class C had lower quality of life scores than those with Child class A. Patients with MELD lower than or equal to 15 had a significant increase of mean values in ten domains, whereas patients with MELD scores greater than 15 had increased mean values in 12 domains.

Conclusion: There was a negative influence of severity on quality of life prior to transplantation, according to Child-Turcotte-Pugh. The MELD did not interfere significantly in the post-transplantation outcomes, even though the mean values increased.

Resumo

Objetivo: Analisar a influência da gravidade da doença hepática na qualidade de vida dos pacientes antes e depois do transplante de fígado.

Métodos: Estudo descritivo com 150 receptores de transplante hepático, maiores de 18 anos. A gravidade foi avaliada pelo *Child* e MELD e aplicado o *Liver Disease Quality of Life*. Foi utilizado teste *t* ou *Mann-Whitney* para comparação das médias dos domínios e ANOVA ou Kruskal-Wallis para comparação entre grupos.

Resultados: Antes do transplante, os pacientes com *Child* C obtiveram menores escores de qualidade de vida do que os com *Child* A. Pacientes com MELD menor ou igual a 15 tiveram aumento significativo das médias em 10 domínios, enquanto os pacientes com MELD superior a 15 tiveram aumento nos 12 domínios.

Conclusão: Houve influência negativa da gravidade pelo CTP na qualidade de vida antes do transplante. O MELD não interferiu significativamente nos resultados pós-transplante, mesmo com elevação das médias.

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Conflicts of interest: none to declare.

Introduction

End-stage liver failure is a pathological condition that has great impact on people's lives, with liver transplant providing the only possibility for reversing the terminal situation, which impacts the biological, psychological and social levels.⁽¹⁾

In 2013, Brazil ranked second in absolute numbers for liver transplantation among 30 surveyed countries, second only to the United States. Between 2005 and 2015, 14,817 liver transplants were performed.⁽²⁾

General indicators of the severity of liver failure are used in the assessment of candidates for transplantation: Child-Turcotte-Pugh (CTP) and the Model for End-stage Liver Disease (MELD). These indicators are used to establish liver transplantation priority, disease prognosis, prediction of survival and mortality after transplantation, in addition to serving as a parameter for assessing health-related quality of life (HRQOL).⁽³⁾

The CTP Classification is based on latest results of liver function laboratory tests, including bilirubin, albumin, prothrombin time, and severity of patient symptoms regarding ascites and degree of hepatic encephalopathy. Results are scored on a scale ranging from 5 to 15 points; they are stratified into class A (5-6), B (7-9) or C (10-15), where greater values indicate greater disease severity, providing predictive values of one-to-two year patient survival.⁽³⁾

Since 2002, the MELD scale has been used by the Organ Procurement and Transplantation Network (OPTN) as a basis for allocation of deceased donor livers for transplantation among adults in the United States. In Brazil, the liver transplant allocation system has followed the criterion of severity of liver disease based on the MELD score since 2006, regardless of the amount of time on the waiting list. The score is based on a formula whose variables are: serum creatinine (Cr), total bilirubin (BT), prothrombin time (PT) and international normalized ratio (INR), ranging from 6 to 40 points; it

also considers the disease progression and therapeutic indication, and is able to predict the three-month mortality risk.⁽⁴⁾

During the literature review, relevant studies on the impact of using the MELD on patient survival on the waiting list for liver transplantation were identified. However, studies evaluating the relationship between severity criteria and quality of life of patients post-transplantation are still incipient, indicating the need for further studies to more deeply investigate the topic, also considering the risks and high costs related to the procedure.^(5,6)

The quality of life of these individuals can be assessed by generic and specific instruments. Among the generic instruments already validated for the Brazilian population, there are: the Medical Outcomes Study Short-Form 36 (SF-36), the World Health Organization Quality of Life Instrument (WHOQOL), and its abbreviated version WHOQOL-bref. Instruments for the assessment of patients with liver disease include the Hepatitis Quality of Life Questionnaire (HQOLQ), the Chronic Liver Disease Questionnaire (CLDQ), and the Liver Disease Quality of Life (LDQOL) stand out.⁽⁷⁾

The LDQOL was selected for this study, due to its ability to identify issues that are more specific than the impact of liver disease and the individual's response to liver transplant.

From this perspective, the study aimed to analyze the influence of the severity of liver disease on the quality of life of patients before and after liver transplantation.

Methods

A quantitative, descriptive study performed in the Liver Transplant Center of Ceará/University Hospital Walter Cantídio (HUWC), a national reference center for liver transplantation.

To determine population size, the number of patients remaining alive, who had transplants between 2002 and 2011, was considered, totaling 439 patients. The calculation for a finite sample was per-

formed, with a 95% confidence level and a sample error of 4%. The following inclusion criteria were used: patients undergoing liver transplantation at least six months prior to the study, eighteen years of age or older, and who were regularly monitored in the transplant service.

Transplant recipients transferred to other states, patients undergoing liver transplantation due to fulminant hepatitis or double liver-kidney hepatitis, patients with hearing loss and mental disability were excluded from the study. In total, 150 patients participated in the survey, which was considered a representative number.

Data were collected from July 2012 to January 2013, by administering an instrument developed by researchers, containing demographic (gender, age, race) and clinical (etiology, CTP and MELD) aspects and the LDQOL questionnaire. The questionnaire included 75 questions about signs and symptoms of the disease and the effect of treatment on daily living, distributed in 12 domains: symptoms related to liver disease, effects of liver disease on activities of daily living, concentration, memory, sexual function, sexual problems, sleep, loneliness, hopelessness, quality of social interaction, health distress, and self-perceived stigma of liver disease. The questions are answered by evaluating the frequency, intensity, or agreement with the statements on a Likert scale, with scores ranging from zero to six points.⁽⁸⁾ It is a specific tool for assessment of the quality of life in liver disease, translated and validated for the Brazilian population,⁽⁹⁾ in which the questions are answered by evaluating the frequency, intensity, or agreement with the statements on a Likert scale, with scores ranging from zero to six points.

The LDQOL was administered by the researchers through interviews, six months after transplantation, during the postoperative follow-up visits at the liver transplantation clinic. It was administered twice for each patient: the first, considering the pre-transplantation period experienced by the patient, and then considering the current quality of life (after transplantation).

The Statistical Package for the Social Sciences (SPSS) was used for data analysis. The comparison of means before and after transplantation was performed using the Student's t-test or Mann-Whitney when two means were assessed, and by ANOVA or Kruskal-Wallis when three or more means were assessed. A significance level of 0.05 was adopted.

Patients authorized their participation by signing the Terms of Free and Informed Consent Form. The study was approved according to the standards of the National Health Council - Resolution 196/96 - Protocol : 041.06.12 of the University Hospital Ethics Walter Cantídio Committee, Federal University of Ceará.

Results

Regarding demographics, among patients undergoing liver transplantation, there was a predominance of males (n=120; 80%); the prevalent age range was 40 to 59 years of age (n=71; 47.3%), followed by 60 to 76 years (n=51; 34%), and finally 18 to 39 years (n=28; 18.7%), with a mean of 52.4 years. The race with the highest proportion was mixed (n=90; 60%), followed by white (n=45; 30%), black (n=14; 9.3%), and indigenous (n=1; 0.7%).

Alcohol abuse was the most prevalent etiology of liver disease in the study group, with a total of 58 (38.7%) patients, followed by hepatitis C (n=42; 28%), and cryptogenic cirrhosis (n=22; 14.7%), in addition to other diseases such as hepatitis B, Wilson's disease and hepatocellular carcinoma (HCC).

Regarding the criterion of disease severity for allocation in the liver transplantation waiting list before surgery, most (n=116) patients had a MELD equal to or greater than 15, corresponding to 77.3% of the sample; 15 (10%) had a MELD less than 15; and, 19 patients (12.7%) had no MELD charted. Preoperatively, 56 patients (37.3%) were classified as CTP level C, 76 (50.7%) as level B, and only 9 (6%) as level A; 9 (6%) had no CTP documented (Table 1).

Table 1. Analysis of the influence of CTP on LDQOL quality of life domains before liver transplantation (n=141)

LDQOL Domains	Child A	Child B	Child C	p-value
	Mean ± SD			
Symptoms related to liver disease	80.7 ± 16.9	66.9 ± 18.5	56.9 ± 23.2	0.001
Effects of liver disease	73.7 ± 17.3	58.2 ± 21.9	51.7 ± 22.8	0.015
Concentration	77.7 ± 24.4	64.0 ± 30.3	47.6 ± 29.0	0.001
Memory	78.1 ± 33.3	64.2 ± 30.0	49.3 ± 28.5	0.003
Quality of social interaction	80.5 ± 10.7	70.9 ± 17.8	62.9 ± 20.0	0.007
Health distress	56.6 ± 27.1	57.1 ± 27.3	50.8 ± 30.5	0.459
Sleep	67.4 ± 20.5	55.5 ± 24.6	46.6 ± 20.6	0.014
Loneliness	93.4 ± 19.6	89.9 ± 19.1	89.5 ± 19.1	0.851
Hopelessness	82.5 ± 19.6	76.1 ± 23.6	68.6 ± 23.5	0.099
Stigma of liver disease	77.4 ± 31.3	62.5 ± 30.5	49.2 ± 34.6	0.013
Sexual function*	75.0 ± 36.8	58.3 ± 34.1	64.9 ± 29.0	0.511
Sexual problems*	75.9 ± 41.2	68.0 ± 32.8	76.6 ± 30.2	0.565

*The Sexual function domain had n = 47, and Sexual problems had n = 40

The analysis of the influence of the severity of liver disease according to the CTP classification on the quality of life before transplantation showed that patients with Child class C had lower mean values compared to patients with Child classes A and B, in ten of 12 domains, except for sexual function and sexual problems. There was a greater compromise ($p < 0.05$) symptoms related to liver disease, effects of liver disease on activities of daily living, concentration, memory, quality of social interaction, sleep and stigma of liver disease, indicating a significant difference based on multivariate comparison of the Child classes C and A groups in the domains: symptoms (56.9 vs. 80.7; $p = 0.004$), effects of liver disease (51.7 vs. 73.7; $p = 0.017$), concentration (47.6 vs. 77.7; $p = 0.014$), memory (49.3 vs. 78.1; $p = 0.021$), social interaction (62.9 vs. 80.5; $p = 0.023$), sleep (46.6 vs. 67.4; $p = 0.034$) and stigma (49.2 vs. 77.4; $p = 0.043$). The differences between Child classes B and C were significant in the domains: symptoms (56.9 vs. 66.9; $p = 0.016$), concentration (47.6 vs. 64.0; $p = 0.005$), memory (49.3 vs. 64.2; $p = 0.013$), social interaction (62.9 vs. 70.9; $p = 0.038$) and stigma (49.2 vs. 62.5; $p = 0.050$).

The comparison of CTP before and after transplantation was not performed because there was no documentation of the scale after transplantation.

The analysis of quality of life according to LDQOL in accordance with the MELD value is shown in tables 2 and 3.

Table 2. Analysis of the quality of life domains of the LDQOL scale before and after liver transplantation in patients with MELD scores lower than or equal to 15 (n=15)

LDQOL Domains	Pre-transplantation	Post-transplantation	p-value
	Mean ± SD		
Symptoms related to liver disease	68.0 ± 13.8	93.0 ± 6.6	<0.0001
Effects of liver disease	49.2 ± 21.9	87.2 ± 13.8	<0.0001
Concentration	65.7 ± 30.1	93.7 ± 12.0	0.007
Memory	65.1 ± 32.2	85.2 ± 19.2	0.070
Quality of social interaction	67.0 ± 19.7	83.8 ± 10.1	0.002
Health distress	53.3 ± 23.5	85.3 ± 15.4	<0.0001
Sleep	51.9 ± 24.6	77.3 ± 16.4	0.002
Loneliness	84.7 ± 26.0	99.4 ± 2.0	0.046
Hopelessness	74.3 ± 19.8	92.6 ± 13.7	0.012
Stigma of liver disease	51.1 ± 32.8	95.5 ± 6.5	<0.0001
Sexual function*	68.7 ± 27.6	64.5 ± 39.3	0.895
Sexual problems*	77.7 ± 25.6	63.8 ± 47.4	0.655

*The Sexual function and Sexual problems domains had n = 4

Table 3. Analysis of the quality of life domains of the LDQOL scale before and after liver transplantation in patients with MELD scores greater than 15 (n=15)

LDQOL Domains	Pre-transplantation	Post-transplantation	p-value
	Mean ± SD		
Symptoms related to liver disease	63.1 ± 21.4	93.5 ± 9.3	<0.0001
Effects of liver disease	57.5 ± 22.5	91.6 ± 11.2	<0.0001
Concentration	57.7 ± 30.7	91.9 ± 15.0	<0.0001
Memory	59.6 ± 30.7	82.3 ± 22.5	<0.0001
Quality of social interaction	69.1 ± 18.8	83.7 ± 11.0	<0.0001
Health distress	55.0 ± 28.7	88.4 ± 14.7	<0.0001
Sleep	53.6 ± 23.5	78.9 ± 16.4	<0.0001
Loneliness	91.4 ± 16.9	96.5 ± 12.0	<0.0001
Hopelessness	73.8 ± 24.4	91.7 ± 15.5	<0.0001
Stigma of liver disease	59.5 ± 33.1	93.4 ± 12.3	<0.0001
Sexual function*	56.6 ± 34.8	88.9 ± 18.2	<0.0001
Sexual problems*	65.4 ± 35.9	92.0 ± 21.3	0.001

*The Sexual function and Sexual problems domains had n = 28

The analysis of the comparison of the LDQOL quality of life domains before and after transplantation, according to the MELD criterion less than or equal to 15, showed a significant increase in the means in ten of 12 domains, with a higher statistical significance ($p < 0.0001$) in the domains: symptoms (68.0 vs 93.0), effects of liver disease (49.2 vs. 87.2), health distress (53.3 vs. 85.3) and stigma of liver disease (51.1 vs. 95.5), whereas patients with MELD scores greater than 15 showed significant results in all domains.

On the other hand, there were no significant differences in the evaluation of the influence of the severity of liver disease according to the MELD on post-transplant quality of life. The results were homogeneous.

Discussion

There was a prevalence of alcoholic liver disease (38.7%) and hepatitis C (28%) as indications for transplantation among the participants. The order of primary disease etiology prevalence differed from the data released by the Organ Procurement and Transplantation Network, including a total 5,805 liver transplants in adults in the United States, in which Hepatitis C was first with 23.5%, followed by alcoholic cirrhosis, with 17.6%.⁽¹⁰⁾

It should be noted that hepatitis C and alcohol abuse were among the most frequent causes in other international studies.^(11,12) According to data of a study performed at the University of Pittsburgh, including 668 adult patients from Minnesota, Nebraska and California (San Francisco) who received a liver transplant due to non-fulminant hepatic disease, among the patients who survived the first year, the most prevalent causes were primary sclerosing cholangitis (17.8%), hepatitis C (16.4%) and alcohol (11.8%).⁽¹¹⁾

The same study evaluated the sustainability of the quality of life benefits by monitoring 381 recipients for 12 years after transplantation according to the diagnosis, using the questionnaire from the National Institutes of Diabetes and Digestive and Kidney Diseases - Liver Transplantation (NIDDK-LTD), and found that patients with an autoimmune disease had a decline in HRQOL in the physical suffering, social role/function, personal function and general health perception domains. Patients with alcoholic liver disease and hepatitis C+ had a consistent reduction in all domains one year after the transplant, with physical functioning and personal functioning worsening significantly over time.

However, in a study that included 353 liver transplant patients with alcoholic cirrhosis in Finland, in which the HRQL 15D instrument was administered, patients with alcoholic cirrhosis, acute liver failure, primary biliary cirrhosis or primary sclerosing cholangitis had similar scores in the HRQL 15D, whereas patients with liver tumors had lower scores that were non-significant. The group of patients with various chronic liver diseases

had statistically significant higher HRQL levels than the other groups ($p=0.003$).⁽¹³⁾

Regarding the MELD assessment of study participants, most patients had a value that was equal to or greater than 15 (77.3%) at the time of the disease. The data showed that patients had more severe disease compared with those in a Brazilian study in which 59% of the transplanted patients had a MELD greater than 15, and 41% had MELD scores less than or equal to 15;⁽⁷⁾ another study in London, with 1,032 transplanted adult patients, which measured MELD in the immediate pre-transplant period, found that 45.1% of patients had MELD scores less than 15, 26.7% between 15-25, and 28.2% were higher than 25.⁽¹⁴⁾

The CTP criterion has previously been the most frequently used in the assessment of disease severity. In recent years, international research has highlighted the positive impact of the implementation of MELD criteria in allocating organs, with a reduction in mortality rates of patients on the transplantation waiting list.

Confirming these data, a study with 154 liver transplant patients in Germany showed an increase in the value of the median MELD score, comparing one year before and two years after its implementation in the service, ranging from 19.1 ± 8.1 to 22.1 ± 10.5 , with a statistically significant difference ($p=0.007$). The mean time on the waiting list decreased from 369 days, in the pre-MELD period, to 238 days one year after the implementation of the MELD ($p=0.1$), and 247 days two years after its implementation ($p=0.17$). There was also a significant reduction of mortality on the waiting list, from 18.4% in the period before the adoption of the MELD to 10.4% in the period after one year ($p=0.04$), and 9.4% after two years ($p=0.015$).⁽⁵⁾

In addition, another study showed that the MELD score was an independent risk factor for mortality after liver transplantation ($p<0.001$).⁽¹⁴⁾

However, when it comes to the assessment of the impact of the MELD on quality of life, studies are scarce and insufficient, and there is much controversy among the authors. In this study, significant differences were found between mean LD-QOL scores, compared before and after transplan-

tation, indicating a positive impact on quality of life of transplant recipients with different degrees of liver disease severity, assessed by the MELD at the time of transplantation. However, no association was observed between the MELD values on the quality of life areas, considering that there was a great difference in sample groups compared according to the MELD.

This fact can be explained by the considerable number of patients with hepatocellular carcinoma (HCC) participating in the study, a condition in which the calculated MELD is disregarded, and the minimum MELD is 20 points, contributing to the high MELD values found in this study and the difficulty of comparing the findings.

Another study with 126 adults, 65 of whom were awaiting liver transplantation and 61 who had already received a transplant, regularly monitored by the reference transplantation service at Hospital das Clínicas in São Paulo (SP), Brazil, showed better quality of life scores in seven of the 12 areas assessed by the LDQOL in patients eligible for transplantation with a MELD less than or equal to 15, with statistically significant results: memory ($p=0.001$), social interaction ($p=0.008$), health distress ($p=0.042$), loneliness ($p<0.001$), stigma of liver disease ($p = 0.004$), sexual function ($p = 0.01$) and sexual problems ($p=0.012$). By using the Medical Outcome Study 36-Item Short-Form Study Health Survey (SF-36) scale, differences were observed in eight domains: social aspects ($p<0.001$), bodily pain ($p=0.002$), limitations due to physical health ($p= 0.001$), and general health perception ($p=0.043$). In the group of transplanted patients, the pre-transplant MELD value did not affect quality of life after transplantation,⁽⁸⁾ which agrees with the findings of the present study.

In contrast, a similar study performed in the United States with 104 patients on the waiting list and the post-transplant, based on the SF-36 scale, MELD value > 18 had a significant positive effect on the limitations due to physical health domain ($p=0.052$), and a superficial effect on pain ($p=0.072$).⁽¹⁵⁾

In a study of 347 liver transplant recipients, 265 from the University of Florida and 95 from a medical center in Massachusetts, also in the United States, patients with MELD scores greater than 25 reported better significant parameters after one year of transplant in functional capacity ($p=0.02$), limitations due to physical health ($p=0.04$), general health ($p=0.03$), vitality ($p=0.02$) and summarized physical component ($p=0.01$) when compared to patients with MELD scores of 16-25, indicating that patients with more severe pre-transplantation clinical status achieved higher quality of life scores after the procedure.⁽¹⁶⁾

However, it should be emphasized that although the MELD has already been recognized for its ability to predict mortality, functioning as a current measure for allocating livers for transplantation, there are not enough studies to support the association of MELD values with quality of life, considering that the MELD does not take into account other aspects that directly impact the perception of the patient's quality of life, such as ascites and encephalopathy.

On the other hand, when analyzing the results of this study before transplant, considering the CTP classification, patients categorized as Child C had worse scores in ten of the 12 domains measured by LDQOL, suggesting a negative influence of the severity of liver disease on patients' quality of life, with a significant difference ($p<0.05$) among the three groups in the following domains: symptoms, disease-related effects, concentration, memory, quality of social interaction, sleep, and stigma of the disease.

Similar results were obtained in another study that evaluated the influence of CTP on patients' quality of life, and decreased levels of HRQOL were found among Class C liver transplantation candidates, compared with class A, with significant differences in eight of 12 domains: symptoms related to liver disease ($p=0.08$), effects of liver disease ($p=0.002$), memory ($p=0.042$), preoccupation ($p=0.004$), loneliness ($p<0.003$), hopelessness ($p=0.005$), sexual function ($p=0.010$) and sexual problems ($p=0.041$).⁽⁸⁾

These data were further confirmed in a publication about the reliability and validity of the

Spanish version of the LDQOL, with 200 liver transplantation candidates, in which class A patients had better means than those of classes B and C, in nearly all dimensions except for loneliness, with major differences among patients in the following dimensions: symptoms (77.8, 67.1 and 63.9, respectively, $p < 0.001$ between Child classes A and C), liver disease-related effects (65.9, 49.9 and 55.9, respectively, $p < 0.05$ between Child classes A and B), and sexual functioning (75.4, 63.7 and 57.0, respectively, $p < 0.005$ between Child classes A and C).⁽¹⁷⁾

Another previous study with 150 patients waiting for a transplant at the University of California, Los Angeles center, found a moderate negative correlation between the total value on the SF-36 instrument and CTP classification ($r = -0.40$), with major differences in the physical dimension, including functional capacity ($r = -0.44$), limitations due to physical health ($r = -0.46$) and pain ($r = -0.30$); and general health ($r = -0.20$), and a moderate correlation between CTP classes and emotional aspects ($r = -0.38$) and mental health ($r = -0.43$). When the Chronic Liver Disease Questionnaire (CLDQ) was administered, a moderate negative correlation was also found between the total score ($r = -0.39$, $p < 0.001$), with a moderate correlation between the CTP and the abdominal symptoms ($r = -0.38$), fatigue ($r = -0.43$), systemic symptoms ($r = -0.31$), activity ($r = -0.35$) and emotional functioning domains ($r = -0.37$); and a weak correlation with the preoccupation domain ($r = -0.27$).⁽¹⁸⁾

In the study of development and validation of the Spanish version of the CLDQ, performed with 149 patients with chronic liver disease, the overall CLDQ scores for Child classes A, B, and C, were 5.2, 5.0, and 4.5, respectively ($p < 0.012$) and 5.5 in patients without cirrhosis.⁽¹⁹⁾

Conclusion

The analysis of the influence of the severity of liver disease showed a significant increase in quality of life scores in ten of 12 domains, comparing the

stages before and after transplantation among patients with a MELD score less than or equal to 15; and improvement in all domains in patients with MELD scores higher than 15. However, the MELD value did not interfere significantly on the results of the scale after transplant. In contrast, there were significant differences in HRQOL values among the CTP classes before transplantation, indicating a greater impairment of quality of life for patients with more severe disease.

Collaborations

Aguiar MIF and Braga VAB state that they contributed to the study design, analysis, data interpretation, article writing, relevant critical review of the intellectual content, and final approval of the version to be published. Almeida PC, Garcia JHP and Lima CA collaborated in writing the article, data analysis, relevant critical review of the intellectual content, and final approval of the version to be published.

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