

# Liver transplantation in acute alcoholic hepatitis: should we say no?

## *Trasplante hepático en hepatitis alcohólica aguda: ¿debemos decir que no?*

Erika F. Rodríguez-Aguilar<sup>1</sup>, Mario García-Alanís<sup>2</sup>, Juanita Pérez-Escobar<sup>3</sup>, Diana Sánchez-Herrera<sup>4</sup>, Liz Toapanta-Yanchapaxi<sup>2</sup>, Esmeralda Ávila-Rojó<sup>2</sup>, Víctor Visag-Castillo<sup>5</sup>, and Ignacio García-Juárez<sup>2\*</sup>

<sup>1</sup>Liver Transplantation Unit, Hepatology Service, Hospital Clínic de Barcelona, IDIBAPS, Center for Biomedical Research Network on Liver and Digestive Diseases (CIBERHED, Centro de Investigación Biomédica en Red de Enfermedades Hepáticas y Digestivas), Barcelona, Spain;

<sup>2</sup>Department of Gastroenterology, Salvador Zubirán National Institute of Medical Sciences and Nutrition, Mexico City, Mexico; <sup>3</sup>Hepatology Service, Punto Clínico Especialistas, Mexico City, Mexico; <sup>4</sup>Department of Internal Medicine, Ángeles Pedregal Hospital, Mexico City, Mexico; <sup>5</sup>Department of Organ Transplant, Dr. Eduardo Liceaga Mexican General Hospital, Mexico City, Mexico

### Abstract

Alcohol liver disease is one of the main indications for liver transplantation (LT). Currently, an abstinence period < 6 months is required to include a patient with alcohol liver disease on the waiting list, a period that has not been shown to reduce the risk of relapse. Alcoholic hepatitis is characterized by hepatic decompensation secondary to recent, excessive consumption of alcohol, and LT may be the option in a well-selected group of patients who do not respond to medical treatment, but due to established sobriety intervals are excluded, this requires a change in the criteria established by the committees. We propose an evaluation algorithm to consider alcoholic hepatitis unresponsive to medical treatment for LT.

**Keywords:** Alcohol liver disease. Abstinence. Liver transplantation. Alcoholic hepatitis.

### Resumen

La enfermedad hepática por alcohol es una de las principales indicaciones de trasplante hepático (TH). Actualmente se requiere un período de abstinencia > 6 meses para incluir a un paciente con enfermedad hepática por alcohol en lista de espera de TH, periodo que no ha demostrado disminuir el riesgo de recaída. La hepatitis aguda por alcohol se caracteriza por una descompensación hepática secundaria a un consumo de alcohol excesivo reciente, y el TH puede ser la única opción en un grupo bien seleccionado de pacientes que no responden al tratamiento médico, pero debido a los intervalos de sobriedad establecidos son excluidos, y esto requiere un cambio en los criterios establecidos por los comités. Proponemos un algoritmo de evaluación para considerar para TH la hepatitis aguda por alcohol no respondedora a tratamiento médico.

**Palabras clave:** Enfermedad hepática por alcohol. Abstinencia. Trasplante hepático. Hepatitis aguda por alcohol.

### Basic concepts

Alcohol-related liver disease is one of the most important causes of cirrhosis in the world. Up to four out of five deaths in patients with liver disease are attributed

to alcohol consumption<sup>1</sup>. In Mexico, by 2016 the average per capita alcohol consumption was estimated at 6.5 liters, with 2.3% of the population with alcohol use disorder<sup>2</sup>. This generates a public health problem in our country that has a direct impact on high mortality and, as a

#### \*Correspondence:

Ignacio García-Juárez  
E-mail: drinter77@gmail.com

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consequence, high costs for the health system<sup>3</sup>. Currently, alcohol-related liver disease is one of the main indications for liver transplantation (LT) in the world. Currently, alcohol-related liver disease is one of the main indications for liver transplantation (LT) in the world. In the United States, the number of LT for acute alcoholic hepatitis in 2014 vs. 2019 was 28 patients vs. 139 patients (0.5% and 2% of all transplants in that country, respectively)<sup>4,5</sup>. This increase has been associated with a change in the etiology of cirrhosis, mainly with a decrease in cases of hepatitis C virus<sup>4-6</sup>.

## Acute alcoholic hepatitis

Alcohol-related liver disease has an acute form of presentation, called acute alcoholic hepatitis. Although the prevalence in the general population is not well known, it is known to account for 17% of patients hospitalized for decompensated chronic liver disease. Acute alcoholic hepatitis is characterized by a clinical syndrome secondary to heavy alcohol consumption within the last 6 months, jaundice within 60 days of the last drink, severe liver failure, and complications from portal hypertension<sup>7,8</sup>. A study in a Mexican population showed that short-term mortality in patients with acute alcoholic hepatitis was higher in those with acute kidney injury (relative risk: 6.7;  $p = 0.02$ ), and increased considerably if upper gastrointestinal bleeding and hepatic encephalopathy were added ( $p = 0.001$ )<sup>9</sup>.

In terms of treatment options, the long-term cornerstone is abstinence from alcohol. In acute cases, treatment with steroids is warranted when they are severe, and N-acetylcysteine combined with steroids was shown to increase short-term survival. As adjuvant therapy there are antioxidants, such as metadoxine; there are two studies in the Mexican population that evaluated its effectiveness in patients with acute alcoholic hepatitis and it was observed that, at a dose of 1500 mg, it improved survival rates from 3 to 6 months<sup>10,11</sup>.

The presentation may be refractory to medical treatment in up to 40% of patients, with a 30-day mortality of 70%, so LT may be the only curative treatment option in selected cases of severe alcoholic hepatitis<sup>7,8</sup>.

In the Mexican Consensus on Alcoholic Hepatitis published in 2020, it was determined that LT may be considered for patients with severe disease (Maddrey > 32), for those who do not respond to treatment (Lille > 0.45) or those ineligible for steroids, in their first event of hepatic decompensation and with a favorable psychosocial profile and social support<sup>3</sup>. In our country, at present, the decision to take this group of patients

to LT is determined by the committee of each center, and abstinence of more than 6 months continues to be a strict rule.

## The 6-month rule

Although controversial, most transplant centers require a period of abstinence  $\geq 6$  months before placing a patient with alcohol-related liver disease on the transplantation waiting list<sup>12,13</sup>, which is known as the “6-month rule.” The main arguments are based on the possibility of stabilization or improvement of liver function, the development and strengthening of the family support network, as well as the possibility of further intervention by a multidisciplinary team in order to achieve a change in lifestyle that strengthens long-term abstinence. It is important to mention that the United Network for Organ Sharing did not establish it as an absolute criterion and recommended its analysis in the regional boards<sup>14</sup>. Because of the increase in the number of candidates for LT due to acute alcoholic hepatitis, and the scarce information on the evolution of these patients on the waiting list, the study by Kitajima et al.<sup>15</sup> analyzed waiting list outcomes comparing them with other etiologies, such as alcohol-related cirrhosis, cholestatic liver disease, hepatitis C, and nonalcoholic steatohepatitis, and it found that 30-day mortality in patients with acute alcoholic hepatitis was 76.2%, higher than for the other indications, but between days 31 and 365 after admission to the waiting list, patients with acute alcoholic hepatitis had a lower risk of death and a higher probability of recovery, compared with other indications. These results confirm the importance of close follow-up and proper screening.

However, despite meeting the abstinence period prior to LT, it is associated with a risk of relapse. So far, 6 months has not been shown to be the “magic number” that decreases the risk of relapse after LT, and therefore has ceased to be an absolute rule<sup>16</sup>. Incidentally, the American Association for the Study of Liver Diseases recommends an abstinence period of at least 6 months, although it clarifies that this period should not be a definitive factor for a patient to be accepted as a candidate for LT<sup>17</sup>.

## Liver transplantation in acute alcoholic hepatitis

Today, LT is the curative treatment for liver cirrhosis in general, although in certain etiologies, such as acute alcoholic hepatitis, the long-term impact is still unclear.

In a retrospective study by Ursic-Bedoya et al.<sup>18</sup> on cases and controls of patients with biochemically proven alcohol consumption hours before LT, there was no difference at follow-up in overall survival compared to controls, with a higher rate of relapse (59.5% vs. 38.1%) and no difference in alcohol intake between the groups (33.3% vs. 29.8%). Despite the methodological design of the study, it supports trying LT in patients with acute alcoholic hepatitis without having devastating consequences, and reinforcing close follow-up with the aim of decreasing relapses.

In the study by Cotter et al.<sup>5</sup> 39,455 liver transplants were performed from January 2014 to December 2018, of which 1.1% (435 cases) were due to acute alcoholic hepatitis. These patients were younger (mean 39.4 years), with a higher MELD (Model for End-stage Liver Disease) score, longer intensive care stay, and dialysis requirement compared to other indications ( $p < 0.01$ ). Survival at 1 and 5 years was 91.7% and 81.9%, respectively, which was higher than in patients who underwent transplantation for other etiologies, such as alcohol-related liver cirrhosis, non-alcoholic steatohepatitis, autoimmune diseases, viral and cryptogenic hepatitis.

One of the risks following LT is relapse of alcohol consumption. We now know that there is no significant difference between acute and chronic liver disease, which supports that the 6-month abstinence period should not be a rule in well-selected cases<sup>19</sup>. However, traditionally, due to the established sobriety intervals, many patients are excluded from the LT opportunity, and this forces the committees to modify the selection criteria. In addition, it should be noted that a stable and sustained abstinence in patients with this disorder is achieved after 5 years, rarely achieved with an alcoholic liver disease.

In addition to the severity of acute alcoholic hepatitis, a detailed history of alcohol consumption, history of other substance abuse (including tobacco), history of substance treatment, and periods of abstinence should be included. It is necessary to consider the factors associated with recurrence, such as years and amount of consumption, time of abstinence, poor adherence to treatment received, social, legal, and personal problems, and family history of alcohol consumption or exposure. In addition, it is relevant to assess any comorbidity related to mental disorders, personality, and psychological resources to cope with abstinence, as well as the support network and job and family stability<sup>20,21</sup>. It is also advisable to use therapeutic contracts and obtain information from third parties (family

members and support network). It is required to establish adequate awareness of alcohol consumption and its involvement in liver disease in order to achieve sustained abstinence, promote therapeutic adherence, and achieve the goals of LT<sup>22</sup>.

The committee in charge should analyze the medical and psychosocial report in an objective manner, and make an impartial evaluation, in addition to applying the optimal selection criteria<sup>6,23</sup>.

The selection criteria for patients with acute alcoholic hepatitis are based on the prospective study by Mathurin et al.<sup>24</sup> and include:

- Severe acute alcoholic hepatitis unresponsive to steroids (Lille score at 7 days  $> 0.45$ ).
- Excellent psychosocial status agreed by the transplant committee.
- First episode of hepatic decompensation.
- Document signed by the candidate to maintain abstinence after LT and agreement for rehabilitation therapy.

According to these criteria, only 2-3% of patients are eligible for LT without a major impact on the waiting list<sup>25</sup>.

Every day more and more transplant centers around the world are accepting this indication. In the United States, transplant centers for acute alcoholic hepatitis increased from 14 in 2014 to 47 in 2019<sup>5</sup>.

There has been an evaluation of the survival rate of patients with transplant for severe acute alcoholic hepatitis in prospective case series studies, retrospective cohorts, and surveys of transplant centers and multi-center committees. It was found to be 94%, 84% and 75% at 1, 3 and 5 years, respectively, similar to those for other etiologies (Table 1)<sup>26-31</sup>.

LT in acute alcoholic hepatitis is possible if a multidisciplinary evaluation and adherence to criteria are performed on an individualized basis; we consider this strategy to be the key piece in the course and prognosis (Fig. 1).

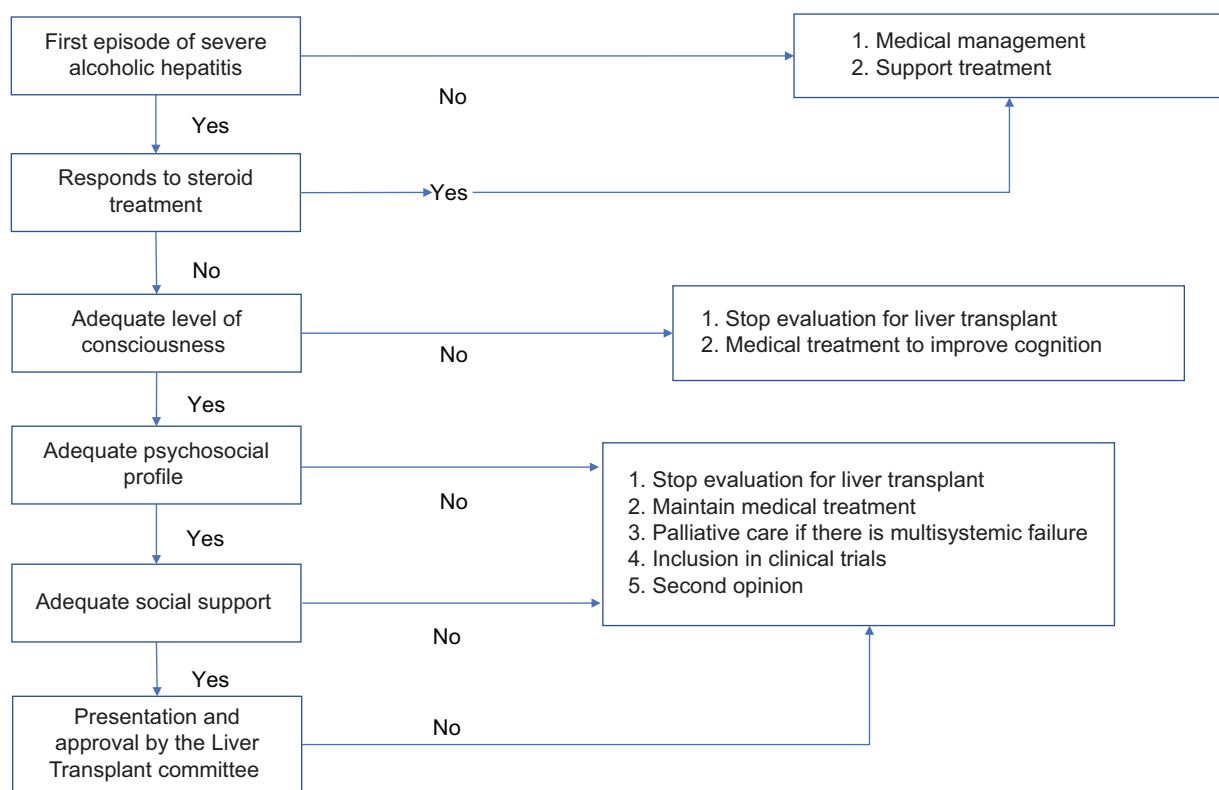
We consider that the 6-month rule alone does not guarantee sustained abstinence, and continuing with this criterion as an absolute rule limits access to LT in selected patients with good prognosis. The Italian paper concluded that those patients with acute alcoholic hepatitis who do not respond to medical treatment should not be excluded from the LT list just because they have a period of less than 6 months of abstinence. Alcohol use disorder should be considered as a multifactorial disease and a better understanding by society should be promoted.

**Table 1.** Liver transplantation experience in acute alcohol hepatitis

| Study                        | Year of publication | Number of LT due to AAH | Age | Sex male | *Abstinence time before transplant | MELD in LT | Histology compatible with AAH | Survival at one year | Relapse in alcohol consumption | Time to recurrence |
|------------------------------|---------------------|-------------------------|-----|----------|------------------------------------|------------|-------------------------------|----------------------|--------------------------------|--------------------|
| France-Belgium <sup>24</sup> | 2011                | 26                      | 47  | 58%      | < 90 days                          | 34         | 100%                          | 77%                  | 10%                            | 860 days           |
| Mount Sinai <sup>29</sup>    | 2015                | 9                       | 41  | 56%      | 33 days                            | 39         | 100%                          | 89%                  | 12.5%                          | 180 days           |
| Johns Hopkins <sup>30</sup>  | 2016                | 46                      | 50  | 72%      | 50.5 days                          | 33         | 70%                           | 97%                  | 17%                            | 256 days           |
| ACCELERATE-AH <sup>28</sup>  | 2017                | 147                     | 43  | 73%      | 55 days                            | 38         | 58%                           | 94%                  | 11%                            | 160 days           |
| India <sup>31</sup>          | 2019                | 39                      | 42  | 75%      | 120 days                           | 26         | 40%                           | 84%                  | 12.8%                          | 570 days           |

AAH: acute alcohol hepatitis; MELD: Model for End-stage Liver Disease; LT: liver transplant.

\*Data reported in median.

**Figure 1.** Evaluation algorithm for liver transplantation in alcoholic hepatitis.

All patients should undergo a medical and psychosocial evaluation process regardless of the length of abstinence<sup>32,33</sup>.

## Liver transplantation in Mexico

In our country, liver transplantation began in 1976 and is currently the standard treatment for patients with chronic liver disease. According to the registry made by the National Transplant Center (CENATRA, Centro Nacional de Trasplantes), the number has increased from 25 in

1999 to 225 in 2019, with a total of 2585 transplants performed; of these, 92% were from cadaveric donor and only 8% from living donor. However, the incidence of chronic liver disease is increasing in the Mexican population and our liver transplantation program has one of the lowest rates per million inhabitants in the Americas<sup>34,35</sup>.

The overall survival of liver transplant patients has been reported by only one center in our country at 1, 3 and 5 years, being 94%, 88% and 88%, respectively, similar to that of well-developed countries, with hepatitis C virus being the main etiology<sup>36</sup>.

In an epidemiological transition study of cirrhosis in Mexico from 2000 to 2019, it was observed that alcohol liver disease accounted for 23% of patients with cirrhosis, and it was the most important cause in men. With these changes in etiology, we will see more and more patients with alcohol-related diseases every day<sup>37</sup>.

In Mexico there are no reports of cases of LT due to acute alcoholic hepatitis. It is important to start by promoting and improving clinical care and research for this group of patients, and it is also important to establish specific criteria to define acute alcoholic hepatitis in the CENATRA database, such as: a) acute alcoholic hepatitis without alcoholic liver disease; b) acute alcoholic hepatitis with alcoholic liver disease; c) date of last alcohol consumption; d) data on the course and outcome of patients on the waiting list and after transplantation. This will allow objective results to be evaluated and selection criteria to be improved over time<sup>33</sup>.

The interest of our work is to promote equal access to LT for acute alcoholic hepatitis, similar to other etiologies, such as obesity and cirrhosis without significant weight loss or acute liver failure and suicide attempt due to drug overdose with an uncontrolled psychiatric illness<sup>38</sup>.

## Perspectives

One of the main obstacles to overcome is payment coverage by insurers in case of acute alcoholic hepatitis, which makes it necessary to establish service equity and eliminate stigmas related to this group of patients<sup>39,40</sup>.

The effort by all transplant centers in the world to accept a select group of patients with acute alcoholic hepatitis will generate more experience and evidence that will allow these patients to have the same equality of care in the future as those with other etiologies.

## Conclusions

In case of acute alcoholic hepatitis refractory to medical treatment, a well-selected group of patients should be considered as candidates for LT as equally as those of other etiologies, who have a similar post-transplant prognosis.

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## Conflicts of interest

The authors declare that they have no conflicts of interest.

## Ethical disclosures

**Protection of people and animals.** The authors declare that no experiments were carried out on humans or animals for this research.

**Data confidentiality.** The authors declare that no patient data appear in this article.

**Right to privacy and informed consent.** The authors declare that no patient data appear in this article.

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