A Simple Score for Predicting Alcohol Relapse After Liver Transplantation

Results From 387 Patients Over 15 Years

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Background: Alcohol relapse can negatively influence the outcome after liver transplantation (LT). The aim of our study was to identify factors that could be associated with the recurrence of harmful alcohol consumption after LT.

Methods: A total of 387 consecutive patients (23.8% women) who underwent LT for alcoholic cirrhosis in Geneva, Switzerland, and Lyon, France, between 1989 and 2005 were evaluated. Mean±SD age was 51.3±7.5 years. Follow-up time was 61.2±47.5 months. Alcohol consumption relapse and potential factors associated with it were studied.

Results: The relapse rate of harmful alcohol consumption after LT was 11.9%. In univariate analysis, alcohol relapse was significantly associated with age greater than 50 years ($P=.04$), year of LT 1995 or earlier ($P<.05$), duration of abstinence less than 6 months ($P=.02$), presence of psychiatric comorbidities ($P<.001$), presence of a life partner ($P<.05$), and a high score on the High-Risk Alcoholism Relapse (HRAR) scale ($P<.001$). Multivariate logistic regression disclosed the following independent factors of relapse: duration of abstinence of less than 6 months (odds ratio [OR], 3.3; 95% confidence interval [CI], 1.2-9.3) ($P=.02$); presence of psychiatric comorbidities (OR, 7.8; 95% CI, 3.1-20.0) ($P<.001$); and HRAR score higher than 3 (OR, 10.7; 95% CI, 3.8-30.0) ($P=.001$). In patients with none of these factors, alcohol relapse was 5%, while the presence of 1, 2, or 3 factors was associated with relapse rates of 18%, 64%, and 100% of the patients, respectively.

Conclusions: In a large cohort of patients undergoing LT for alcoholic cirrhosis, a duration of abstinence of less than 6 months before wait-listing for LT, the presence of psychiatric comorbidities, or an HRAR score higher than 3 was associated with relapse into harmful drinking. The presence of more than 1 factor dramatically increased this risk over 50%. In the pre-LT evaluation in this setting, these factors should be accurately determined.

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ONE OF THE LEADING INDICATIONS for liver transplantation (LT) in Western countries is alcoholic liver disease (ALD). Between 1988 and 2004, 31% of LTs in Europe were carried out for alcoholic cirrhosis as the primary indication, which was inferior only to virus-related cirrhosis.[1] Similarly, in the United States, ALD was the second most common indication for LT between 1988 and 2006, accounting for more than 17.1% of all cases.[2] In France, 28% of LTs were indicated for ALD in 2005.[3] The question of organ allocation to patients with ALD remains a controversial issue, in particular in the public opinion,[4] because organ allocation to patients with a self-inflicting disease may not be well accepted and because scarce resources such as liver grafts should be allocated to patients who have definitively stopped drinking alcohol.

After LT for ALD, rates of alcohol consumption of any importance range between 7% and 95%.[5] However, only a minority of patients (less than 5%) return to alcoholic intoxication associated with histologic evidence of alcoholic damage.[6,7] Moreover, numerous studies have reported on alcohol relapse after LT, but the definitions and the methods used have varied widely.[8] Recent studies demonstrate that resumption of moderate drinking has little or no influence on survival and that graft rejection rates are similar for ALD and non-ALD cases.[6] Nevertheless, it has been suggested that alcohol recidivism could significantly affect survival or lead to a reduced compliance associated with an increased graft rejection rate,[9,10] even if some authors have reported a lower rate of acute rejection.[11]

The identification of preoperative patient characteristics associated with alco-

Table 1. High-Risk Alcoholism Relapse Scale

Item	Score
Duration of heavy drinking, y	
≤11	0
11-25	1
≥25	2
Daily drinks, No.*	
≤9	0
9-17	1
≥17	2
Prior alcoholism inpatient treatments, No.	
0	0
1	1
≥1	2

*One drink = 12 g of ethanol.

hol relapse after LT constitutes a major issue for the selection and surveillance of patients. Presently, patients with alcoholic cirrhosis are considered for the waiting list at most LT centers after a 6-month alcohol abstinence period. This period may allow the patients to stabilize or improve their clinical condition,[12] and it has been associated with lower rates of posttransplantation relapse, although the controversy on this issue still remains open.[13] However, selection of candidates for LT based on this 6-month rule alone is increasingly criticized because a number of other factors known to influence alcoholic behavior are not taken into account. Thus, the aim of the present study was to characterize demographic and psychiatric features of a large cohort of patients and to analyze the possible factors associated with a relapse of harmful alcohol consumption after LT and its relevance on graft and patient survival.

METHODS

PATIENT INCLUSION

All 387 patients who underwent LT for ALD at the University Hospital of Geneva, Switzerland, and at the Edouard Herriot Hospital of Lyon, France, between 1989 and 2005 were retrospectively enrolled in this study. Indication for LT was based on (1) the presence of end-stage liver disease, in which LT was the only option for survival; (2) the absence of medical or surgical contraindications; and (3) a period of abstinence from alcohol consumption to ensure that there was no improvement in liver function without alcohol intake (a minimum of 3 months of abstinence was considered necessary).

The diagnosis of cirrhosis due to excessive alcohol intake was based on a consensus from the hepatologist, surgeon, psychiatrist, LT coordinator, and nurse involved in the patient's pre-LT evaluation. Additionally, a pre-LT liver biopsy specimen showing lesions consistent with alcoholic cirrhosis was a prerequisite. The diagnosis of alcohol abuse or dependence was made according to the criteria detailed in the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*.[14]

Other demographic and psychosocial information collected in the pre-LT evaluation included drug abuse, presence of depressive or anxiety disorders, duration of abstinence at the time of placement on the waiting list, time on the LT waiting list, Child-Pugh[15,16] score, and MELD score (Model for End-stage Liver Disease).[17]

HIGH-RISK ALCOHOLISM RELAPSE SCALE

For each patient, the pre-LT alcohol consumption level was evaluated using the High-Risk Alcoholism Relapse (HRAR) scale.[18] The HRAR scale was developed from a study of relapse following inpatient alcoholism treatment in a cohort of male US Veterans and includes 3 parameters empirically developed to estimate the risk of alcoholism relapse following an index evaluation. The scale was replicated by demonstrating predictive validity in a second cohort of similar subjects.

Three items (duration of heavy drinking, usual number of daily drinks, and number of prior alcoholism inpatient treatment experiences) are included in the scale. Each item can be scored 0, 1, or 2 for a total possible score ranging from 0 to 6 (**Table 1**).

PATIENT FOLLOW-UP AND ALCOHOL RECIDIVISM

In the post-LT follow-up, patients attended the LT outpatient clinic every week for the first 2 months, every 2 weeks until the sixth month, every 4 weeks for the first year, and every 6 months thereafter. At every visit, patients were asked about any alcohol intake, and blood alcohol level was sporadically measured. A liver biopsy was performed yearly or more frequently if needed, and a psychiatric evaluation was requested when resumption of alcohol intake was identified or suspected.

Post-LT alcohol consumption was assessed according to the time point of the relapse. Harmful drinking was defined by a declared alcoholic consumption level higher than 40 g/d associated with the presence alcohol-related damage, either physical (including histologic features of alcoholic liver injury seen on liver biopsy specimens) or mental.[19] The duration of post-LT sobriety was defined as the time until the intake of alcohol was declared by the patient or screened by a caregiver. The alcohol intake was estimated and expressed in grams per day based on the average alcohol content of 40%, 12%, and 5% for spirits, wine, and beer, respectively.

STATISTICAL ANALYSIS

The data from each patient were included until the end of the observation time. Continuous variables are presented as mean±SD values, and categorical data are presented as proportions. Retrospective analysis of the clinical and biological data of all patients was performed to identify factors affecting alcohol relapse. Comparisons between qualitative variables were performed using the χ^2 or Fisher exact test. Univariate analysis of data from all patients was performed. The continuous variables were dichotomized by splitting at mean or median, or upper normal value, and compared. Survival and survival without alcohol relapse were assessed by the Kaplan-Meier method from the date of LT to that of (1) death, (2) alcohol relapse, or (3) the final clinic visit; survival curves were compared using the log-rank test. Multivariate analysis was performed to determine the predictive factors significant for all patients using the Cox regression model. Risk factors relative to baseline hazard (odds) function for the sample were examined. A result was considered significant if its probability of occurrence by chance was less than 5% ($P<.05$). All analyses were performed using SPSS software, version 13 (SPSS Inc, Chicago, Ill).

RESULTS

DEMOGRAPHIC DATA

The characteristics of the 387 patients included in this study are summarized in **Table 2**. There was a male sex predominance (76%), and the mean age at LT was 51 years. The mean duration spent on the LT waiting list was 5 months. After LT, the mean follow-up time was more than 61 months. More than 50% of patients were classified in Child-Pugh class C, and approximately 35% of them were in class B.

The patients who underwent LT for ALD in our 2 centers represented 39.5% of all adult LT cases during the period of study. There were some patients with liver comorbidities such as viral hepatitis (hepatitis C, 8%; hepatitis B, 3%), hemochromatosis (1%), and α_1-antitrypsin deficiency (1%). In all of these patients, alcohol was considered the main cause of the liver disease.

More than 57% of the patients who underwent LT were blue collar workers, whereas white collar and service industry workers represented 32%, and patients working in the household represented about 11%. Most patients (93%) had low HRAR scores (<4), and the mean duration of abstinence at time of placement on the waiting list was 20 months. Anxiety or depressive disorders were present in 21% of the patients.

Table 2. Characteristics of 387 Patients Who Underwent Liver Transplantation for Alcoholic Liver Disease

Characteristic	Finding
Male sex	295 (76.2)
Age at transplantation, y	51.26 ± 7.51
Duration on waiting list, mo	5.05 ± 5.8
Follow-up, mo	61.18 ± 47.53
Child-Pugh[15] score	
A (5-6)	55 (14.4)
B (7-9)	135 (35.2)
C (10-15)	193 (50.4)
MELD score†	17.4 ± 6.5
Profession	
White collar	122 (31.6)
Blue collar	222 (57.5)
Household	42 (10.9)
Life partner present	289 (74.9)
HRAR score	
0-3	356 (93)
4-6	27 (7)
Sobriety duration before placement on waiting list, mo	20.27 ± 28.39
Psychiatric disorder present (anxiety or depression)	82 (21.2)
Return to harmful drinking after LT	46 (11.9)

Abbreviations: HRAR, High-Risk Alcoholism Relapse[18]; LT, liver transplantation; MELD, Model for End-stage Liver Disease.[17]

*Data are presented as number (percentage) of patients or mean ± SD values.

†Available for 273 patients.

ALCOHOL RELAPSE AND SURVIVAL

Harmful alcohol consumption after LT was declared by the patient or detected at a visit in 11.9% of the patients. The mean time from LT to harmful relapse was 32 months (range, 1-128 months). At 1, 3, 5, and 10 years after LT, the percentage (standard error [SE]) of patients free from relapse was 95.5% (1.1%), 89.8% (1.7%), 85.4% (2.2%), and 77.8% (3.7%), respectively (**Figure 1**A). The actuarial survival rates (SE) for periods of 1, 3, 5, and 10 years were 91.8% (1.4%), 87.1% (1.8%), 83.0% (2.2%), and 72.5% (3.2%), respectively (Figure 1B). Overall survival was not significantly affected by alcohol relapse (Figure 1C).

The main causes of death after LT were cancer (23 [32%] of 73 patients) and infections (n=21; 29%). Other causes of mortality included cardiac disease (n=9; 12%), graft failure (n=7; 9%), suicide (n=1; 1%), and other causes (n=12; 17%). The types of cancer were upper aerodigestive tract (18 [78%] of 23 patients), multiple liver metastases from an adenocarcinoma of unknown origin (n=2), and cerebral lymphoma, colon carcinoma, and ovarian carcinoma (n=1 for each). Four patients (17%), who died of post-LT cancer were alcohol relapsers.

PREDICTIVE FACTORS FOR ALCOHOL RELAPSE

The factors associated with alcohol relapse in patients after LT are listed in **Table 3** and **Table 4**. The following characteristic were associated with a significantly increased risk of alcohol relapse: presence of an anxiety or depressive disorder ($P<.001$); absence of a life partner ($P<.001$); elevated HRAR score ($P<.001$); duration of sobriety of less than 6 months ($P<.001$); LT in the early years of our experience (1989-1995) ($P<.05$); and an age greater than 50 years at the time of LT ($P<.001$). This percentage did not significantly differ between the 2 centers involved in the study.

Multivariate analysis for relapse to harmful drinking showed that the pre-LT diagnosis of a psychiatric disorder (anxiety or depressive disorder), HRAR score of more than 3, and a period of abstinence less than 6 months at the time of listing were independently associated with a significantly increased risk of relapse.

In the absence of any of these 3 factors, 13 (5%) of 272 patients returned to harmful alcohol consumption. If 1 factor was present, this proportion increased to 18% (16 of 92). The combination of 2 of the factors was associated with a relapse rate of 64% (14 of 22). Finally, although the number of cases was limited, all 3 patients who had all 3 risk factors resumed harmful alcohol consumption (**Figure 2**). In addition, the mean time from LT to alcohol relapse was 45, 30, 32, and 23 months in the presence of none, 1, 2, or 3 of any of these factors, respectively.

COMMENT

Because ALD is one of the leading indications for LT, the question of frequency and severity of alcohol relapse needs close evaluation. To our knowledge, the present series is the largest ever studied. The main finding of this study is that psychiatric comorbidity, HRAR score, and/or duration of sobriety at the time of listing are determinant factors for the outcome of LT for ALD in terms of relapse to heavy drinking.

We chose as the outcome of interest the return to harmful drinking, not "any drinking," because this is the most

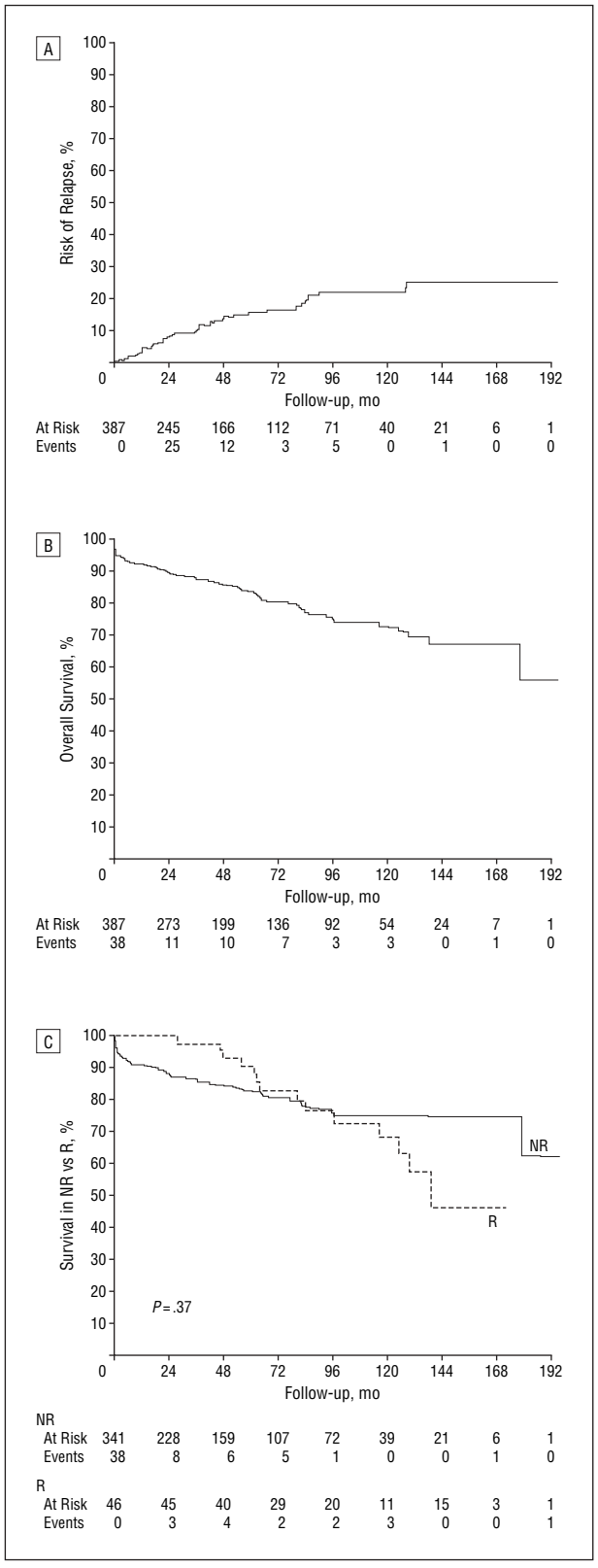

Figure 1. Survival curves. A, Cumulative proportion curve for the risk of alcohol relapse after liver transplantation during follow-up; B, overall survival; C, survival according to alcohol relapse after liver transplantation. R indicates relapse; NR, no relapse.

clinically relevant event. Moreover, alcohol relapse might not only compromise the success of LT but might also provoke a negative reaction in public opinion toward the view that ALD does not represent a priority for organ allocation.[20] Because the patients were regularly attending the LT clinic in Lyon and Geneva, with biological and clinical follow-up conducted by experienced physicians and surgeons, the probability that a case of harmful drinking relapse has been missed is unlikely.

To our knowledge, the 387 patients contributing data to this study represent the largest cohort described in the literature. Most previous reports have been conducted on relatively small numbers of patients, and only a few studies included more than 100 patients.[10,21-24] Moreover, the present study has been conducted in 2 geographically closed LT centers from 2 different wine-producing countries, probably representing homogeneous populations of patients with ALD.

The population of this study was similar to that considered in other studies focusing on the outcome after LT for ALD.[10,22,23,25-29] The percentage of male patients was predominant (76%), and the mean age at transplantation was 51 years. In spite of the strong advice from the transplantation team members for the maintenance of so-

Table 3. Univariate Analysis for Posttransplantion Harmful Drinking*

Characteristic	Harmful Drinking: Yes	Harmful Drinking: No	*P* Value
Sex			.46
Female	13	79	
Male	33	262	
Child-Pugh score[15,16]			.95
A (5-6)	6	49	
B (7-9)	16	119	
C (10-15)	24	169	
Psychiatric comorbidity			<.05
Absent	19	285	
Present	27	55	
Life partner			<.05
Absent	20	77	
Present	25	264	
Profession			.14
Blue collar	32	190	
White collar	10	112	
Household	3	39	
HRAR score			<.05
0-3	28	328	
4-6	18	9	
Duration of sobriety at listing, mo			<.05
≤6	9	43	
≥6	27	317	
Hepatitis B or C infection			.52
Absent	39	305	
Present	6	37	
Year of LT			<.05
1989-1995	31	123	
1996-2005	14	219	
Age at the time of transplantation, y			<.05
<50	16	210	
≥50	30	131	

Abbreviations: HRAR, High-Risk Alcoholism Relapse[18]; LT, liver transplantation.
*Unless otherwise indicated, data are presented as number of patients.

Table 4. Multivariate Logistic Regression Analysis for Posttransplantation Harmful Drinking

Characteristic	Odds Ratio (Confidence Interval)	*P* Value
HRAR high score (4-6)	10.7 (3.8-30.0)	<.005
Presence of a psychiatric comorbidity	7.8 (3.1-20.0)	<.001
Duration of alcohol abstinence ≤6 mo when placed on waiting list	3.3 (1.2-9.3)	.02

Abbreviation: HRAR, High-Risk Alcoholism Relapse.[18]

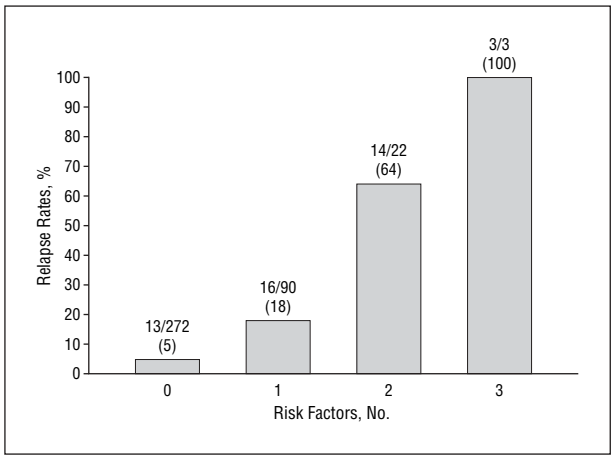

Figure 2. Relationship between the number of risk factors (alcohol abstinence period <6 months; presence of psychiatric comorbidity; and/or High-Risk Alcoholism Relapse[18] score >3) and the risk of relapse to heavy drinking after liver transplantation. In the groups of patients without risk factors and with only 1 risk factor, the percentages of relapse were 5% and 18%, respectively. However, the percentages of relapsing patients rose to 64% and 100%, when 2 and 3 risk factors were present, respectively. Percentages of relapsing patients are reported in parentheses.

briety, 11.9% of patients returned to harmful alcohol intake. This proportion is among the lowest rates reported before this study.[13,27] This is probably the result of our selection policy in our 2 centers. We do not have precise information in our LT databases on the drinking history of patients who were evaluated for participation in the study but eventually excluded, but such analysis would be of great relevance.

The finding that a psychiatric comorbidity such as a depressive or anxiety disorder is correlated with the risk of relapse to harmful drinking is important because this is an a priori treatable disease. In our study, the majority of patients with this diagnosis were under pharmacologic treatment, but the efficacy of such a therapy was not evaluated. This observation suggests that in these patients, the treatment was possibly not sufficient and that the therapy could be implemented with additional measures such as psychological support and better social integration. In accord with the findings of our study, DiMartini and colleagues[22] recently found that a history of depressive disorder was associated with a greater risk of alcohol relapse after LT. However, this association was not found in some other studies, such as those by Jauhar et al[23] and Perney et al.[29]

The duration of sobriety before placement on an LT waiting list continues to be a matter of debate, although many centers have adopted the 6-month rule as one of the inclusion criteria. The duration of sobriety was found to be a predictor of alcohol relapse in several[22,24,30-32] but not all recent publications.[23,29] In our study, the risk of relapse to harmful drinking was significantly higher in patients who were placed on the transplantation waiting list when their abstinence duration was less than 6 months (OR, 3.3; 95% CI, 1.2-9.3) (P=.02). It is important to place this finding in the appropriate clinical context and to consider that the longer the sobriety, the lower the risk of relapse, independently from the 6-month rule, which remains only 1 indicator to be interpreted together with other criteria. The 6-month abstinence rule has been progressively adopted to include patients on the waiting list. At the beginning of our transplantation programs, however, some patients were on the waiting list in spite of abstinence duration of less than 6 months, since the 6-month rule was not routinely considered (nevertheless, a minimum of 3 months of abstinence was considered necessary). In addition, the waiting time should be added to sobriety interval to obtain the duration of abstinence before LT. Nevertheless, for the LT team, it is crucial to know how long the patient has been abstinent at the time of placement on the waiting list because this is an important element of decision-making before the LT, not at the moment of the LT. Interestingly, we observed that alcohol relapse in the early years of our experience (in both centers) was higher than in more recent years, but this was not statistically significant in the multivariate analysis. Even if follow-up was longer for the oldest patients, this was probably owing to a better selection with time, especially for the exclusion of patients with recent alcohol weaning.

One of the determinant factors in the relapse to heavy drinking is the HRAR score, which is an evaluation scale for the gravity of ALD, initially developed and piloted in a group of veterans to assess the risk of relapse after alcohol rehabilitation.[18] Patients in our study were classified as having a high (4-6) or low (0-3) HRAR score, based on their daily alcohol consumption, years of drinking, and treatment history. A high HRAR score was associated with a significantly higher risk of post-LT return to harmful drinking (OR, 10.7; 95% CI, 3.8-30.0) (P<.005). Interestingly, but in contrast with the present study, a previous investigation failed to demonstrate that the HRAR scale predicts recidivism.[33] This is possibly owing to the fact that few patients undergoing LT in the earlier study had high HRAR scores, and a small number of cases emerged. It must also be stressed that this score applies equally to men and women, even though it is well known that the negative effects of the same amount of alcohol intake are more deleterious in women than in men.[34] Although this scale has not been previously validated in an LT population, its strong association with the risk of relapse after LT demonstrated in our study suggests that this parameter should be further investigated and could be included in the pre-LT assessment of patients with ALD.

Finally, a relevant goal was to assess whether resuming alcohol intake after LT might affect overall mortality. Although our data showed that this parameter was not significantly worsened by alcohol recidivism, exces-

sive drinking after LT might contribute to morbidity in terms of poor compliance, organ rejection, general complications, and histopathologic features.[10] Hence, abstinence remains crucial. It is of major importance to address the specific question of histologic outcome in this population, and this needs to be evaluated in our cohort in the near future.

Some limitations, however, should be taken into account for the interpretation of the results of the present study. Data have been collected prospectively, but this is a retrospective analysis. Moreover, the impact of alcohol use on outcomes after LT has been assessed only in patients relapsing into heavy drinking.

In conclusion, the results of the present study warrant further consideration, not only because 3 parameters (short abstinence, presence of psychiatric comorbidity, and higher HRAR score) were associated with alcohol relapse but also because the combination thereof assumed a particular importance. In fact, while 1 factor alone was associated with a risk of recidivism below 20%, the combination of 2 or 3 factors resulted in a risk of recidivism exceeding 60%. Based on these findings, we suggest that the evaluation before LT for ALD should include these 3 parameters and that a patient presenting with 2 or 3 of them should be considered at very high risk of recidivism.

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