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An 'alcohol contract' has no significant effect on return to drinking after liver transplantation for alcoholic liver disease

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Summary

Return to drinking after liver transplantation for alcoholic liver disease (ALD) remains a source of unease with varying reported rates of return to drinking and impact this has on graft function. In 2005, the UK Transplant liver advisory group recommended an 'alcohol contract' in which ALD patients listed for transplantation confirmed in writing their commitment to abstinence. We aimed to measure the rates and consequences of return to drinking alcohol in a UK transplant programme and assess the effect of the 'alcohol contract'. Consecutive patients transplanted for ALD during 1996–2011 were included. Every patient listed after Feb 2007 signed up to the 'alcohol contract'. We compared rates and pattern of return to drinking and survival before and after the introduction of the contract. Overall, 52 (37%) patients returned to drinking alcohol; 37 (39%) before and 15 (34%) after the contract. There was no significant difference in the rate of return or pattern of drinking. Median survival was 176 months (145–207 95% CI). There was no significant difference in survival, mortality rates, or in the causes of death in either group. We report high rates of return to drinking alcohol in a UK liver transplant programme. Despite this, the impact on patient and graft survival is low. There is no evidence that an 'alcohol contract' has had any effect on alcohol consumption.

Introduction

Alcoholic liver disease (ALD) remains a leading cause of cirrhosis in Europe and North America. It is a significant threat to public health and a leading cause of death; worryingly this is disproportionately high amongst younger people [1]. Currently, ALD is the second commonest indication for liver transplantation [2,3]. Despite this, it is seen by many as a controversial indication.

The controversy centres around the concern that patients will return to drinking. This remains a source of unease for the transplant community and the donating public. In part, there is a concern that return to drinking will impact on patient and/or graft survival. In the context of an organ shortfall, it is paramount to ensure optimal utility is achieved from each graft. However, there are widely varying reports of rates of return to drinking and the impact this has [4]. In part, the controversy relates to the perception that ALD is a 'self-inflicted' illness and that this weakens the entitlement to future access to a scarce resource [5,6].

In response to this controversy, and to standardize the listing and follow-up of patients with ALD, the UK Transplant liver advisory group recommended in 2005, the introduction of an 'alcohol contract' in which ALD patients listed for liver transplantation confirmed in writing their commitment to abstinence [7]. The aim of this study was to measure the rates and consequences of alcohol intake after liver transplantation in a UK transplant programme and assess the effect of the 'alcohol contract'.

Patients and methods

Patients

From a prospectively maintained liver transplant database, consecutive patients transplanted for ALD during a fifteen year period (1996–2011) were identified. All patients had a long history (at least 5 years) of heavy and persistent alcohol consumption with clinical, radiographic and often histological evidence of cirrhosis. Patients were required to be abstinent of alcohol for a period of time prior to transplantation. Patients in whom hepatocellular carcinoma (HCC) was incidentally discovered during dissection of the explanted liver were included; those with known HCC were excluded. Patients with co-existing chronic hepatitis C were excluded. Liver transplantation was undertaken as an elective procedure in all patients. The standard procedure in all cases was orthotopic liver transplantation with veno-venous bypass. Primary immune suppression included corticosteroids and calcineurin inhibitors (tacrolimus or cyclosporin) for all, with the majority also receiving azathioprine. Patients who did not survive to hospital discharge were excluded from further analysis. Other demographic and psychosocial information collected during the transplant assessment was evaluated. This included presence of social support (whether they were married/living with a companion or single/separated) and current or prior use of other substances.

Alcohol contract

In February 2007, the 'alcohol contract' was introduced in our unit [7]. Subsequently, every patient who was listed for transplantation confirmed, in writing, their commitment to future abstinence from alcohol, before and after transplantation. With this commitment, they agree to engage with counselling from the addictions psychiatry team or an alcohol rehabilitation programme if this is considered necessary by the transplant team. This agreement also seeks explicit consent to undergo random blood or urinary testing for alcohol.

Liver histology

Histological assessment of the explant was undertaken. In addition, pre-transplant histology was assessed, where available. The presence of cirrhosis and histological features including Mallory-Denk bodies, the presence of steatohepatitis, ballooning degeneration and steatosis were recorded. All histological assessment was undertaken by dedicated liver histopathologists.

Follow-up and survival

All patients were followed up regularly by transplant hepatologists at our institution. The frequency of this follow-up depended on clinical circumstances and time from transplant. With time, the frequency of follow-up falls, often with shared-care arrangements with local services. As a minimum, patients were seen weekly for the first six-weeks after discharge, at least monthly until 6 months and three- to 6-monthly thereafter. Data on mortality and survival were available in all cases. The cause of death was recorded, where available, from the case notes or death certificate. Alcohol intake during the follow-up period was evaluated from information in the medical records. This relied on the clinic doctor enquiring about alcohol consumption, as part of their assessment. From this, patients were considered to have remained abstinent or have returned to drinking. Amongst those returning to drinking, the pattern of drinking was assessed as harmful (more than 168 g/week, or with evidence of physical harm), modest (less than 168 g/week) or occasional (less than weekly). The protocol for blood alcohol testing was that it should be performed randomly at out-patient clinic visits and/or whenever there was a clinical suspicion of return to drinking alcohol.

Statistics

Descriptive statistics are provided as the median and interquartile range or percentage for the quantitative and qualitative variables, respectively. Comparisons between groups were performed with the Chi-squared, Fisher's exact test or Mann–Whitney *U*-test as appropriate. *P*-values <0.05 (two tailed) were considered significant. Survival rates were estimated by the Kaplan–Meier method. Analyses were performed using IBM SPSS Statistics for Windows, Version 19.0 (IBM Corp., Armonk, NY, USA).

Results

Patients

Between 1996 and 2011, 149 patients were transplanted for ALD, 26% of a total of 581 at our institution. Most patient were male ($n = 102$, 68%) with a median age 54 (47–58). Those who did not survive to hospital discharge ($n = 9$, 6%) were excluded from further analysis. Incidental HCC was present in 7 (4.9%).

Potential confounders of alcohol outcomes

A period of abstinence is required prior to transplantation. In the UK, this period is not specified. In our unit, patients were abstinent for a median period of 18 months (12–26) at the time of transplantation. There was no difference in the length of abstinence before or after the contract was introduced (Table 1). The median duration of abstinence

Table 1. Characteristics, follow-up and mortality.

	Overall (n = 140)	Before contract (n = 96)	After contract (n = 44)	P value
Age	54 (47–58)	54 (47–54)	55 (49–58)	0.51
Male gender	98 (70%)	68 (70%)	30 (68%)	1.0
Incidental HCC	7 (5%)	5 (5%)	2 (5%)	1.0
Dead	41 (29%)	38 (40%)	3 (7%)	0.001
Median length of abstinence (pre-transplant) [months]	18 (12–26)	18 (12–27)	17 (12–17)	0.67
Social support – Married/living with companion	122 (87%)	86 (90%)	36 (82%)	0.28
History of other substance use	17 (12%)	11 (11%)	6 (13%)	0.78
Median length to death (months)	63 (36–119)	69 (37–133)	26 (10–41)	0.132
Median length to follow-up (months)	72 (42–136)	120 (22–209)	39 (22–46)	0.00
Median length to death/ follow-up (months)	71 (41–135)	96 (70–157)	39 (21–46)	0.00

was not significantly different (P = 0.7) in those who returned to drinking [15 months (12–21)] compared to patients who remained abstinent [18 months (12–30)].

There was no difference in the presence of social support (whether patients were married/living with a companion or single/separated) nor in the rate of those that reported other substance use pre-transplant before or after the contract was introduced (Table 1). The presence of social support was not significantly different (P = 0.6) in those who returned to drinking (n = 44, 85%) compared to those who remained abstinent (n = 78, 88%). The rate of those reporting other substance use pre-transplant was not significantly different (P = 0.43) in those who returned to drinking (n = 8, 15%) compared to those who remained abstinent (n = 9, 10%).

Follow-up and survival

Given the temporal implementation of the alcohol contract, the median time to length of follow-up was significantly longer in the cohort prior to the introduction of the alcohol contract (Table 1). Overall, 52 (37%) patients returned to drinking alcohol. There was no statistically significant difference in the rate of return to drinking, or in the pattern of whether this drinking was harmful, modest or occasional, before or after the introduction of the alcohol contract (Table 2). Blood alcohol concentration was only ever measured in 76 (54%) and was positive in 7 (5%), with no difference in performance or detection before or after the contract. All but one patient with a positive blood alcohol subsequently disclosed heavy drinking. Only 5 of the 20 patients who returned to harmful drinking had a positive blood alcohol level; all 20 had blood alcohol measured at some point.

In total, 41 deaths (29%) occurred. Mortality was significantly higher in the cohort prior to the introduction of the contract (Table 1). Indeed, there were only three deaths in the cohort since the introduction of the contract, from malignancy (n = 1, lung cancer), cardiovascular (n = 1, myocardial infarction) and sepsis (n = 1). However, given these low numbers, no further analysis on mortality before and after the contract was undertaken. Given the temporal relationship of the contract introduction, any mortality difference is likely related simply to the difference in time after transplantation (Table 1). Instead, we looked at whether there was a mortality effect related to a return to drinking. There was no significant difference in mortality rate between the 16 deaths (31%) in those returning to drinking and 25 (28%) in those remaining abstinent. Kaplan-Meier analysis (Fig. 1) revealed overall median survival was 176 months (145–207 95% CI). This was not significantly different amongst those returning to drinking (165 months; 143–187 95% CI) and in those who remained abstinent (190 months; 85–215 95% CI). There was no significant difference between the causes of death amongst those returning to alcohol or not (Table 3). Only two

Table 2. Return to drinking.

	Overall (n = 140)	Before contract (n = 96)	After contract (n = 44)	P value
Any return to drinking	52 (37%)	37 (39%)	15 (34%)	0.71
Abstinent	88 (63%)	59 (61%)	29 (66%)	0.65
Occasional	16 (11%)	14 (15%)	2 (5%)	0.10
Modest	16 (11%)	8 (8%)	8 (18%)	0.09
Harmful	20 (14%)	15 (16%)	5 (11%)	0.61
Blood alcohol concentration performed	76 (54%)	54 (56%)	22 (50%)	1.0
Blood alcohol concentration positive	7 (5%)	5 (5%)	2 (5%)	1.0

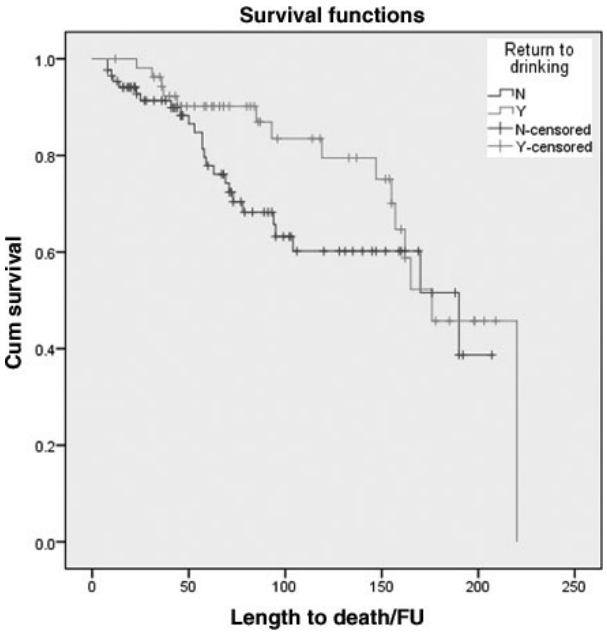

Figure 1 Kaplan–Meier survival curve.

deaths could be directly attributed to a return to drinking alcohol; one patient died from a head injury whilst intoxicated, another died from decompensated recurrent ALD.

Liver histology

Of those included in analysis (n = 140), explant histology reports were available in 132 (94%). Pre-transplant histology was obtained in 88 (63%). Liver cirrhosis was confirmed in all cases. In those with steatohepatitis, prominent Mallory-Denk bodies, ballooning degeneration or severe steatosis, the histological assessment was considered consistent with 'active' ALD. In all others, the histological assessment was considered 'inactive' ALD. There was a trend towards a higher rate of return to drinking in those with histological features consistent with 'active' ALD at the time of explant (although not pre-transplant histology), but this relationship was not statistically significant for any level of drinking (Table 4). There was no difference in this relationship before or after the introduction of the contract.

Table 4. Liver Histology and return to drinking

	'Inactive' ALD cirrhosis	'Active' ALD	*P* value
Pre-transplant histology (n = 88)	79 (90%)	9 (10%)	
Any return to drinking	29 (37%)	3 (33%)	1.0
Abstinent	50 (73%)	6 (67%)	1.0
Occasional	7 (9%)	1 (11%)	1.0
Modest	11 (14%)	1 (11%)	1.0
Harmful	11 (14%)	1 (11%)	1.0
Explant histology (n = 132)	105 (80%)	27 (20%)	
Any return to drinking	36 (34%)	14 (52%)	0.12
Abstinent	69 (66%)	13 (48%)	0.12
Occasional	10 (10%)	6 (22%)	0.09
Modest	11 (10%)	5 (19%)	0.31
Harmful	15 (14%)	3 (11%)	0.77

Discussion

In this study, we report a significant rate (37%) of return to drinking alcohol after liver transplantation. However, the actual impact on graft and patient survival appeared low. Furthermore, we were unable to find any evidence that the introduction of the UK 'alcohol contract' has had any impact on the rate or pattern of alcohol drinking. To our knowledge, this is the first published report of the effect of an 'alcohol contract' in liver transplantation.

Previous studies offer widely varying reports on the rate of return to drinking after liver transplantation. Depending on the study design and definition of relapse, return to drinking occurs in between 10% and 95% of recipients [8,9]. A meta-analysis of published studies derives alcohol relapse rates with a cumulative incidence at 5 years of 28% returning to any alcohol, and 12.5% returning to heavy alcohol use [10]. While our rates are higher than this, they are similar to those in one of the few large prospective stud-

Table 3. Cause of death.

	Overall (n = 41)	Before contract (n = 38)	After contract (n = 3)	Return to any drinking (n = 16)	Remain abstinent (n = 25)	*P* value†
Malignancy	11	10 (26%)	1 (33%)	3 (19%)	8 (32%)	0.48
Cardiovascular	9	8 (21%)	1 (33%)	4 (25%)	5 (20%)	0.72
Infection	13	12 (32%)	1 (33%)	5 (32%)	8 (32%)	1.0
Alcohol-related	2	2 (5%)	0	2 (13%)	0	0.15
Unknown	2	2 (5%)	0	0	2 (8%)	0.51
Other*	4	4 (11%)	0	2 (13%)	2 (8%)	0.64

*Includes (1) bleeding DU (2) 2 late HAT (3) HRS/secondary biliary cirrhosis.

†Comparing causes of death in those that return to drinking with those that remain abstinent.

ies reported. By multiple and repeated methods to identify alcohol use, to fully characterise patterns and predictors of alcohol consumption, by 5 years after transplantation 42% had returned to any alcohol with 26% drinking heavily [11].

Previous studies have also varied widely in the reported prognostic value of the length of abstinence prior to transplantation and the likelihood of return to drinking. Some studies have suggested that a shorter duration of abstinence prior to transplantation may predict a return to drinking [12]. This notion has led to the application of a "6-month rule" where potential recipients are required to be abstinent for a minimum specified period before transplantation, in many jurisdictions [13]. However, other studies have failed to correlate length of abstinence with a return to drinking after transplantation [14,15]. In the absence of a robust evidence base, it is not clear that the "6-month rule" identifies those at most risk of relapsing without potentially inappropriately discriminating against those who may remain abstinent [13]. Given this conflicting evidence, in the UK, a duration of abstinence is not specified [7]. In our cohort, the median duration of abstinence was no different in those who returned to drinking than in those who did not. Furthermore, it was no different before or after the introduction of the alcohol contract. This is unsurprising, given that there was no change in the requirement for and duration of abstinence prior to liver transplantation during the study period. Social support, particularly being married or living with a companion, has also been reported as a predictor of return to drinking, in retrospective [12] and prospective studies [11]. Similarly, an association between a history of other substance use and a return to drinking has been described [11]. We were unable to support either of these associations, although this may, in part, reflect the limitations of retrospective data collection and the relatively small numbers involved. Alternatively, it may reflect a more conservative bias in selecting patients for transplantation who are less likely to exhibit potentially poor prognostic criteria.

Arguably more important than rate is the impact of this return to alcohol. At a registry level, graft and patient survival for patients undergoing transplantation for ALD is favourable compared to other indications, until around 10 years [2]. In our cohort, the impact of returning to drinking on survival post-transplant appeared to be low. This is in keeping with most reported studies, which fail to find a significant impact of return to drinking on short term survival (up to 5 years) [16–18]. However, in one of the largest published studies, heavy drinking was associated with poorer longer-term survival. In this retrospective analysis of over 300 patients, survival at 5- and 10-years was significantly worse in those who resumed heavy drinking than in those who remained abstinent [12]. Notably, this study found that recurrent ALD accounted for the majority of deaths amongst those that returned to heavy drinking, unlike our study where malignancy, infection and cardiovascular disease were far commoner in both groups. A previous single-centre Spanish study had also reported worse outcomes in heavy drinking, albeit in a much smaller cohort [19].

The novel finding in this study is that the introduction of an 'alcohol contract' has had no effect on the rates or impact of alcohol consumption after liver transplantation. Whilst this may initially seem disappointing, given repeated advice and counsel against alcohol consumption with a written commitment and resolve to abstinence, it is perhaps unsurprising. Although the contract was a new process, the goal of abstinence has always been advised in the context of end-stage ALD requiring transplantation, in our unit. Similarly, while it signals an agreement to engage with addiction counselling or alcohol rehabilitation, it is clearly not legally binding nor enforceable. However, it may serve some other benefits. Its introduction was intended to standardize the process of listing and follow-up in these patients. As yet, there are no other reports with which to compare, but the contract has ensured a strong and consistent approach within our unit. In turn, this may serve to improve public perception and engagement with transplantation and organ donation. When public opinion is canvassed, there is little overall support for transplantation for ALD, a "self-inflicted" illness [5]. The contract, a written commitment to 'future responsibility', may partially mitigate against the concept of blame and consequent perceived unfairness in organ allocation which can impact negatively on donor rates [20].

The alcohol contract seeks specific consent for blood alcohol testing. However, in our experience this was an inadequate method of detecting return to drinking. In part, this may relate to the infrequency with which it was performed. We were also interested in determining whether liver histology could determine the likelihood of return to drinking to help direct resources at those patients at highest risk of returning to drinking. At explant, the majority of our patients had bland ALD cirrhosis, compatible with end-stage ALD modified by a period of abstinence. In a smaller number, there were features compatible with 'active' ALD. We failed to find any difference in the rates or return to drinking in either group. This is compatible with previous studies that have failed to identify any difference in rates of return to drinking alcohol in patients with histological features of superimposed alcoholic hepatitis compared to those with bland ALD in a small [8] then larger cohort [21]. In our study, we included any features consistent with active ALD, rather than necessarily having the full histological constellation of alcoholic hepatitis. We appeared to find a trend towards a return to drinking, but this was not significant and proved insensitive and unhelp-

ful as a tool to target resources aimed at reducing alcohol consumption. In addition, given the insensitivity of explant and pretransplant histology, it would seem inappropriate to discriminate against potential transplant candidates at the time of assessment on the basis of liver histology alone.

In terms of targeting alcohol support resources, such as relapse prevention work, the use of novel techniques for the detection of alcohol consumption in transplant patients has been reported recently. Urinary ethyl glucuronide, an alcohol metabolite, has been used as a screening tool in patients pre- and post-liver transplantation [22,23]. More recently, methanol measurement has been shown to be more sensitive than blood alcohol analysis [24]. While these have the potential to meet an unanswered need, their usefulness in targeting alcohol support resources in transplant recipients has yet to be proved. However, it seems likely that more effective objective measures of recent alcohol consumption coupled with robust support from specialist alcohol services could have more of an effect on alcohol consumption after transplantation than simply signing a contract.

As with any retrospective study, there are limitations to our data. Return to drinking alcohol was based on historical self-reported data retrieved from medical records. This relies on accurate recall and recording and is not sufficiently comprehensive to allow a sophisticated picture of the exact timing and pattern of relapse. In turn, recording of such data is often limited by clear definition of a relapse and the potential failure to distinguish occasional lapses from more harmful patterns of drinking [25]. We therefore necessarily adopted a pragmatic approach in terms of stratifying the return to drinking. Furthermore, in the context of transplantation, there is arguably a vested interested in concealing drinking [26]. However, none of these factors should be materially different before or after the contract. In addition, given that the 'alcohol contract' is a relatively recent introduction, there is a temporal limitation to our data. Much less follow-up data is available on those in the era of the contract; many more of these may yet develop recurrent alcohol problems.

In conclusion, we report high rates of return to drinking alcohol in a UK liver transplant programme. Despite this, the impact on patient and graft survival is low. There is no evidence that an 'alcohol contract' has had any effect on alcohol consumption, but it may serve to improve public perception. More objective measures of alcohol consumption along with enhanced robust support from alcohol services may have a more significant impact.

Authorship

SM: designed study, collected and analyzed data, wrote manuscript. BM, AME and SL: collected data, contributed to manuscript. SK: analyzed data, contributed to manuscript. MH: contributed to manuscript.

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