Alcohol abstinence criteria

When alcohol abstinence criteria create ethical dilemmas for the liver transplant team

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In the setting of transplant medicine, decision making needs to take into account the multiple clinical and psychosocial case variables, rather than turn to arbitrary rules that cannot be scientifically supported

The yearly demand for liver transplants far exceeds the supply of available organs (living and cadaveric donation).[1] Additionally, alcoholic cirrhosis has been a controversial indication for transplant as these recipients can be viewed as having caused their own illness—an illness that is preventable by abstaining from alcohol (or using alcohol in moderation). While not categorically denying liver transplantation to those with alcoholic cirrhosis, many hospitals have incorporated a six month alcohol abstinence criterion (''six month rule'')[2] in an effort to select optimal candidates. The six month rule has two purposes; namely, allowing the liver a chance to recover in the absence of alcohol (to possibly avoid the need for transplant), and also observation of the patient to verify that he/she remains alcohol free, with the hope of reducing the risk of relapse. Everhart *et al*,[3] determined that 85% of US liver transplant programmes and 43% of third party payers require a defined period of abstinence—for example, three or six months—as part of the waiting list process.

Liver transplantation does not cure alcoholism, as evidenced by the fact that roughly 20% of these patients use alcohol following transplant, with one third exhibiting ''repetitive or heavy drinking''.[4] Arguments abound as to the scientific merit of a six month abstinence criterion in reducing the risk of alcohol relapse following transplant. Some propose that a minimum of six months abstinence itself predicts a lower relapse rate,[5] while others argue that six months is not predictive or that other factors—for example, illicit drug use—in combination with a minimum number of months abstinent is predictive.[6 7] Even the United Network for Organ Sharing (UNOS) admits that a six month rule is impossible to defend as a listing criterion.[8] As the following case examples will show, such conflicting information about the six month rule adds to the complexity of transplant decision making. While these cases are hypothetical, the authors have encountered all of them many times during their career in transplant medicine; thus we suspect others have also encountered them.

EXAMPLES

Case #1

John, a 22 year old single male, blood type B+, was brought to the emergency department by his neighbour. He is jaundiced, encephalopathic, and requires emergent intubation. He is transferred to the intensive care unit (ICU) and evaluated by the hepatology team. Toxicology tests find a slightly elevated alcohol level but no other drugs of abuse. After three days in the ICU, the team determines that urgent liver transplant is the only lifesaving option. The exact cause of his liver failure cannot be determined. His Model End Stage Liver Disease (MELD) score is 25 (significant liver dysfunction). The transplant team social worker is unable to locate any family or friends who can provide information with regard to his psychosocial and chemical dependency history. Should this patient be listed for liver transplant?

Case #2

Mary, a 45 year old female with a history of alcoholic cirrhosis, MELD score of 22 (significant liver dysfunction), blood type A+, presents for re-evaluation for liver transplant. She has been abstinent from alcohol for three months, but the transplant centre's listing criteria require six months' abstinence. The patient's spouse and 16 year old daughter plead with the transplant team to approve her for the waiting list. The social worker advocates for the patient, arguing that the patient has been active with Alcoholics Anonymous (AA) and has been maintaining contact with her AA sponsor twice weekly. She had been enrolled in a formal rehabilitation programme but did not complete it as she became too ill and required hospitalisation. Should this patient be listed for liver transplant?

Case #3

George, a 50 year old male with alcoholic liver disease, MELD 16 (moderate liver dysfunction), has been on the liver transplant waiting list for 10 months. Before being put on the waiting list, he completed a 30 day outpatient alcohol rehabilitation programme. At his recent clinic visit, he admitted to the transplant social worker that he had ''slipped'' once, having drunk a glass of wine on Father's Day (one month ago). The social worker reports this to the transplant team. Should George be removed from the transplant waiting list and evaluated for potential re-listing after five more months' documented abstinence?

Case #4

Kathy, a 55 year old female with primary sclerosing cholangitis and a MELD score of 17 (moderate liver dysfunction) presents to the hepatology team for transplant evaluation. She has no psychiatric history, but drank heavily during her college years. She completed an alcohol rehabilitation programme when she was 30 and has documented sobriety for the past 25 years. Her husband of 20 years meets the criteria for being alcohol dependent, and thus the patient is determined by the transplant team social worker to lack a ''sober support system''. She has no children or local relatives. The transplant team refers the patient's spouse for alcohol rehabilitation. Should the patient be deferred for the waiting list until her spouse is declared a sober support—for example, until her spouse completes rehabilitation and maintains abstinence?

DISCUSSION

The UNOS liver transplant data for alcoholic and non-alcoholic patients indicates similar causes and frequency of graft dysfunction and loss for both groups.[9] Lim and Keefe[4] reviewed UNOS one year and five year survival rates after transplant and found similar outcomes for those with an underlying diagnosis of alcoholic cirrhosis, autoimmune hepatitis, and chronic viral hepatitis. Compliance with immunosuppressive medication regimens also appears to be similar among those transplanted for alcoholic cirrhosis and other liver diseases.[10 11] Drinking alcohol

following transplant has been observed in both alcoholic and non-alcoholic liver disease patients, with up to nearly half of non-alcoholic patients reporting occasional social drinking.[7 12] While social drinkers may not escalate into alcoholics, these transplant patients are, nonetheless, ignoring the advice of their transplant teams—that is, to avoid alcohol.[12] One of the reasons for this is that following transplant, many transplant patients may ingest acetaminophen for pain relief, and this, in combination with alcohol, can be toxic to the liver. While the threshold of ''safe'' post-transplant alcohol use is unknown,[12 13] post-transplant alcohol use by all patients, not just those whose transplant indication was alcoholic cirrhosis, is an active concern of transplant teams.

As mentioned, most liver transplant centres in the US incorporate the six month rule, or other quantitative abstinence rules as a listing criterion. Notably, all transplant centres in the state of Ohio must follow the Ohio Solid Organ Transplant Consortium's requirement of abstinence from all substances of abuse for at least three months, along with active participation in a recovery programme for at least three months if a patient has not been abstinent for two years.[14] This abstinence requirement also includes a requirement for a ''sober, stable social support network''. Similarly, there are four transplant centres on the east coast of the US that comprise a consortium called the Boston Center for Liver Transplantation. This consortium requires ''documented abstinence for a period of approximately six months or longer'' and ''documented regular participation in a group or individual counseling program'' prior to a patient being placed on a waiting list.[15]

The greatest benefit of a defined abstinence period is the recovery of a patient's liver so that he/she no longer requires transplant (a complex surgery requiring lifelong multiple, expensive postoperative medication, which can have significant side effects). This hope is confounded, however, by the fact that many patients present beyond the chance for natural liver recovery and transplant is their only option. In these situations, one must reflect on using a rigid rule that quantitatively defines abstinence, and the potential for the rigid rule to exclude patients from an intervention that can be life saving and life improving. Referring to case #1, while alcohol was indeed found during toxicology screening, this data point *alone* does not tell the whole story about the patient (clinically or psychosocially). To base a life and death treatment decision on this one data point alone is ethically problematic, as the consequence of withholding transplant is negative and irreversible—death. In such situations, the transplant team should err on the side of preserving the patient's life, giving him the benefit of the doubt, and placing him on the liver transplant waiting list. After transplant, the patient should be thoroughly assessed for alcohol dependence/abuse, and, if diagnosed, he should be referred for rehabilitation, and placed in a transplant support group specifically designed for patients with a history of alcoholic liver disease. Post-transplant counselling should include education about the nature of his liver disease and transplant, and proper stewardship of the organ he received.

In case #2, the patient had made a diligent attempt at satisfying the abstinence requirement, but the severity of her illness makes it impossible to attain a full six months sobriety. While she was enrolled in a formal rehabilitation programme, she was unable to complete it due to hospitalisation as a result of her rising MELD score (increasing liver dysfunction). In many areas of the US, her blood type places her in a position in which she would likely be transplanted quickly, if in fact she were listed (something her family is pleading for). Again, the question becomes: *must the patient be held to a rigid rule of quantitative abstinence (six month rule)?* Abiding by the rigid rule would likely erase the patient's chance at a lifesaving opportunity. *Should she be required to wait another three months before being placed on the waiting list?* This patient, like many others in her situation, may not survive another three months, and, if she does, she may not be suitable for transplant for other reasons—for example, she may be too critically ill. As with case #1, we argue that the number of months abstinent *alone* should not be the deciding factor as to whether to place a patient on the liver transplant waiting list. The team should reflect on each patient's multiple variables,[4] including active involvement in an alcohol rehabilitation programme until hospitalisation; known psychosocial history; stable and supportive family; patient's prior expressed commitment to transplant (verbal comments or written contract), and the patient's motivation for transplant—for example, roles as mother and spouse. After transplant, the patient should be placed in a transplant support group specifically designed for patients with a history of alcoholic cirrhosis.

Case #3 is a reminder that alcoholism, by its nature, consists of the innate potential for patients to be tempted to resume alcohol consumption.[16] This said, the concepts of ''slips'' and ''relapse'' must be addressed by hospital transplant policies. Understanding a slip as ingestion of a single, isolated alcoholic beverage, and relapse as a pattern of repetitive intake of significant amounts of alcohol,[4] we propose that patients who relapse while on the transplant waiting list should be removed from the list and required to complete a formal alcohol rehabilitation programme (even if they had completed one in the past) so as to treat their drinking problem, and clarify whether they have insight about it (hopefully lowering future relapse potential). Patients refusing to enrol clearly do not evidence a commitment to treating their alcoholism or a commitment to the transplant process, and, thus, they should not be returned to the waiting list. Patients unable to complete the rehabilitation programme because of decompensation (worsening clinical status) should be evaluated by a chemical dependency counsellor in an attempt to determine their commitment to transplant and potential for alcohol relapse. Patients determined to be at low risk for relapse should be returned to the transplant waiting list.

For relapsed patients who are too ill to enrol in a formal alcohol rehabilitation programme, we advise that the patient be taken off the list and not put back on the list until the patient can enrol in such a programme and demonstrate a commitment to abstinence and transplant as determined by the evaluation of a chemical dependency counsellor. As above, patients determined to be at low risk for relapse should be returned to the transplant waiting list. Such a policy respects the scarcity of organs and the need for their proper stewardship.

In case #3, the patient experienced a slip and admitted it to the transplant social worker. There is no evidence that the slip progressed to relapse. Admission of the slip could be viewed as the patient seeking help—something that should be commended, not punished.[17] We agree with Weinrieb *et al*[2] that patients who slip will likely be more inclined to seek out help, rather than hide, if the six month rule is not hanging over their heads. Hiding the slip will result in not seeking help, and this could cause slips to progress to relapse. To this end, we argue that an isolated slip amid a period of confirmed abstinence should not be answered with being taken off the list, but instead the patient should be immediately referred to a chemical dependency counsellor for therapy and education. This type of response by the transplant team will likely encourage trust in the doctor–patient treatment alliance, and show that the team is still

committed to transplant as long as the patient is also so committed.

For patients who are not yet listed for transplant and experience a slip during their attempt to accrue a defined period of abstinence, we argue that they should not necessarily be returned to a zero starting point, but rather, as above, the patient should be immediately referred to a chemical dependency counsellor for therapy and education. Slips that progress to relapse should be handled as we described earlier. Slips amid questionable commitment to transplant should be handled by requiring an additional documented period of abstinence. We do not condone slips or dismiss them as unimportant; rather, we admit they can signal life stressors that potentially need addressing by the patient with the help of counselling.

Case #4 raises the issue of a ''sober support system'' being a variable related to transplant outcome. A patient's support system is expected to be both competent and reliable, especially in matters of medication dispensing, transportation to medical appointments, meals, and even child care. A non-sober support has the potential to insert unreliability and incompetence into these important tasks, potentially risking the health and safety of the patient following transplant. Financial compromise can also occur if non-sober supports lose their job or spend patient needed money to support their addiction. While all these are valid concerns, they must be reflected on in conjunction with the patient's capacity to benefit from transplant, the patient's *personal* psychosocial history—for example, absence of drug/alcohol history—and his/her *personal* commitment to transplant.

Indeed, the non-sober support system—for example, spouse, relative, friend—should be referred for rehabilitation as part of an ethic of care; however, this referral should not necessarily result in deferral of placing the patient on the waiting list, especially, if such a deferral would likely result in clinical decompensation. The patient should not be penalised for the behaviour of others. Every effort should be made to substitute a sober support system for the patient so that transplant can proceed, even if this means the patient has to temporarily re-locate or have in home assistance from others. It is hoped that others in the transplant community could rally around the patient at this time of need in an attempt to facilitate transplant. If there is reason to believe the patient would have a successful transplant outcome in spite of the fact their support system is not ''sober'', the patient should be allowed the possibility of transplant and placed on the organ waiting list. As with all cases described, each patient has their own unique set of variables, and thus each patient needs to be viewed as an individual (not a generic illness category—for example, alcoholic cirrhosis, hepatoma) in order to facilitate ethical decision making.

Rigid rules are sometimes employed in an effort to solve or prevent problems; however, they sometimes *cause* problems as well. The six month rule does not simplify transplant decision making: rather, as shown, it can actually complicate the process. Admitting that as the duration of the abstinence period lengthens the individual is less likely to relapse, the number of months abstinent, alone, does not predict relapse with 100% accuracy. Stressful life events and chronic stressors may play a role in relapse, making relapse a possibility at any future point in the patient's lifetime.[18] With no single factor alone capable of relapse prediction, use of the six month rule as a rigid, stand alone transplant eligibility criterion (the ''magic number'') is ethically problematic. Exceptions to rigid rules need to be considered.[9] Separately, alcoholism and liver disease are complex entities. Together, in the setting of transplant medicine, decision making needs to reflect these complexities and take into account the multiple clinical and psychosocial case variables,[19] rather than turn to arbitrary rules that cannot be scientifically supported.[20] Proper stewardship of resources means that we do not allocate when it is inappropriate and that we *do* allocate when it is appropriate and the resources are available.

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