



A pilot study of an alcoholic liver disease recurrence prevention education program in hospitalized patients with advanced liver disease

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Abstract

No systematic work has been completed to assess whether or not educational programming might exert lifestyle improvements among alcoholic liver disease (ALD) inpatients. The present pilot study sought to answer this question through the use of a small-scale two-group experiment (five-session education program versus standard care) at a state-of-the-art Liver Unit that provided tertiary care of indigent patients with advanced ALD. A total of 44 patients were initially randomly assigned to program conditions, and 25 provided 3-month follow-up data (13 in the program condition, 12 in the control condition). Patients who received the program reported high receptivity to it, and showed greater learning of program material and reported greater lifestyle changes than the control patients. For those ALD inpatients that are able and willing to participate, the program shows promising effects on self-reported lifestyle change. © 2004 Elsevier Ltd. All rights reserved.

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1. Introduction

Alcoholic liver disease (ALD) is one of the major medical complications of alcohol abuse. Alcohol is the major cause of cirrhosis in the Western world; alcoholic cirrhosis accounts for about 50% of all cirrhosis cases in the United States. Latino males account for a disproportionate percentage of ALD cases in Los Angeles County (Tao, Sussman, Nieto,

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Tsukamoto, & Yuan, 2003). ALD patients have been found to report relatively little insight into the relationship between their drinking and subsequent ALD compared to problem drinkers without ALD (Farid, Clark, & Williams, 1998). Clearly, counseling for these ALD patients is needed (Sussman, Dent, Skara, deCalide, & Tsukamoto, 2002).

Liver transplantation is an option for saving the life of someone with advanced ALD; however, there is a limited supply of donor livers and the economic costs involved are very high. Of those who receive new livers, the 2-year survival rate is 80% (Showstack et al., 1999; Tang, Boulton, Gunson, Hubscher, & Neuberger, 1998). In addition, maybe in the future, there will be drugs that can intervene at different stages of ALD (e.g., antibiotics, pentoxifylline, *S*-adenosylmethionine; Akriadiadis et al., 2000; Iimuro, Gallucci, Luster, Kono, & Thurman, 1997; Kochuk, 1997; Mato et al., 1999). While transplantation is a current, fortunate option for a percentage of ALD sufferers, and other ongoing research efforts are laudable, education is an important alternative option that might be considered to try to help prevent or arrest progression of ALD.

To our knowledge, no previous cohesive ALD recurrence prevention education program has been offered to ALD sufferers. The first program piloted was our five-session program (Project ALD-RP). This program was piloted at Ranchos Los Amigos National Rehabilitation Center (RLANRC), which treated the second greatest number of ALD cases in Los Angeles County. We wanted to examine ALD patient receptivity to this education program, how well they learned the material, how helpful they perceived the material to be to prevent recurrence of ALD, and what the short-term impact was of the material on their behavior. We hypothesized that patients who received the ALD-RP program (a) would find the program interesting and helpful to them in preventing ALD symptom recurrence, (b) would better learn program material relative to a standard care control condition, and (c) would self-report relatively greater lifestyle behavior changes at follow-up.

2. Method

2.1. Location

The study location was at the RLANRC liver disease unit with follow-up assessment of the same participants at the Roybal Comprehensive Health Center (RCHC) outpatient Liver Clinic. The RLANRC liver disease unit was a 44-bed intensive rehabilitation center that was part of the Los Angeles County Department of Health Services' system for providing care to the medically needy indigent. RLANRC serves as a tertiary center receiving referrals from six county and private hospitals in southern California. The liver unit closed its doors in November of 2003, due to lack of County funds. Recruitment of new participants for this study was stopped 1 month prior to its closure.

2.2. Pilot study design

The ALD prevention education component examined whether or not addition of a five-session education component compared to standard care-only assisted in efforts to prevent

recurrence of ALD among those recovering from ALD. A two-group experimental design (individual level of selection, assignment and analysis) was completed in this pilot study to explore the feasibility and potential efficacy of adding a systematically delivered education component to ALD treatment. As a pilot study, we focused on measurement of patient receptivity and knowledge change variables, and short-term effects on behavioral compliance.

2.3. *Participant selection*

Patients who were admitted to the liver unit with an ALD-related condition were eligible for participation if they could understand the consent form in Spanish or English, by reading it or having it read to them. They needed to complete (sign) the consent form. Any patient not capable of understanding or comprehending the consent form was excluded. Thus, patients with active alcohol withdrawal, decompensated psychosis, or hepatic encephalopathy were excluded. Patients determined to be demented or incompetent were excluded. The Reitan Trail Test was used to assess presence of hepatic encephalopathy. This test was performed daily for patients with encephalopathy. Once a patient's test normalized, indicating that the encephalopathy has cleared, he (she) would be able to provide informed consent and participate in the study (e.g., [Arguedas, DeLawrence, & MGuire, 2003](#)).

There are several reasons patients were admitted to Rancho. In all cases, these patients exhibited immediately life-threatening liver problems mostly due to heavy alcohol intake, which precluded them from staying at other general medical facilities. Typical conditions at admission included jaundice, encephalopathy, large volume ascites, diuretic-resistant ascites, spontaneous bacterial peritonitis, alcoholic hepatitis, multiple organ failure that usually precedes death, or combinations of all of the above. Some degree of acute upper gut bleeding may have occurred due to portal hypertension, although this was not a defining criterion for admission.

A total of 136 patients was screened for enrollment in this study. They were consecutive admissions to the liver unit at Rancho. Of them, 34 were either nonalcoholic liver disease patients, very demented, or in too great of subjective distress to be approached for enrollment in the study. In addition, 25 patients were enrolled in brief stays (under 8 days) and did not qualify for the study. Of 77 remaining patients, who were approached by experimenters, 30 declined participation. All of these patients indicated lack of interest in the education program as their reason for not wanting to participate. Of the remaining 47 patients, 3 left prior to being assigned to condition. A total of 57% of the remaining patients (25/44) was located and reinterviewed at an average of 3-months follow-up (13 in the program condition and 12 in the control condition). Of those 19 participants not followed-up or reinterviewed, in the experimental condition, 2 people could not be located, 2 refused to be reinterviewed, and 4 died. In the control condition, 7 people could not be located, 1 refused to be reinterviewed, and 3 died.

2.4. *Participant characteristics*

The 25 patients in the pilot study follow-up sample were very similar in composition to the full sample, had an average age of 44 years old (S.D.=9.14), and, of them, 75% were male. Of these participants, 88% were Hispanic, 8% were White, non-Hispanic, and 4% were Black.

Only 24% reported being married, and only 4% reported owning a home. Sixteen percent of the sample reported being employed with an average income of US\$1000 per month (e.g., work including restaurant employee, electrician, and packer). Only 40% of the sample ever graduated high school. Two thirds of the sample reported having become drunk at or before 18 years of age, and 50% reported having a real problem with drinking by the time they were 28 years old. The sample reported an average daily intake of alcohol of 11.18 beer equivalent units (i.e., equated to 12 oz, 5% alcohol beer; S.D.=5.89 beer equivalent units), with a 23.87 mean year history of drinking alcohol (S.D.=10.81 years). At baseline, 25% of the sample reported smoking cigarettes in the last 30 days, 4% reported using marijuana in the last 30 days, 5% reported using cocaine in the last 30 days, and between 0% and 2% reported using any other drug.

2.5. Description of conditions

Standard care included medical care on entry at the RLANRC Liver Unit. There also were consults for social work and psychological care. All patients were referred to the social worker for reasons including referral to Alcoholics Anonymous (A.A.), housing, and care after discharge. Approximately 15% of the patients were assisted by the psychologist for comorbidity issues (particularly anxiety and depression). All patients were invited to participate in daily recreational therapy (relaxation, bingo, and pool tables). Some received physical therapy. All saw the dietician for a visit. Some received nutritional supplements, all received multivitamins, and many were informed about the importance of avoiding obesity and maintaining a low-sodium diet. Some received various medications, compliance with which anecdotally was a problem. All received an offer of A.A. bedside counseling once per week. They also received information from nurses about ALD.

The *ALD recurrence prevention education program plus standard care* consisted of five sessions of education in addition to standard care. This program was one-on-one (individual education) delivered in the late afternoon/early evening (in which there were several hours of unstructured time). It was delivered over a 1- to 2-week period while the patients were residing on the unit. This program reinforced other information, and provided new information, related to alcohol, drug, and tobacco use, nutrition and exercise, sanitation, resource advocacy, and decision making. Motivational enhancement features were important. First, participants were instructed in ALD development and consequences, and they were provided with motivation enhancement information. Specifically, instruction made use of their personal ambivalence regarding continued vulnerability to ALD-related death to motivate changes in lifestyle. Second, they were instructed in consequences and cessation and relapse prevention techniques regarding alcohol and tobacco use. Third, they were instructed regarding good nutrition and sanitation (e.g., how to avoid infections such as hepatitis C, avoidance of obesity, perhaps diet supplementation). Fourth, they were instructed in resource advocacy. In other words, they learned how to obtain numerous other resources in their community to help them achieve better lifestyle habits. Finally, they were instructed in decision making/personal commitment to motivate improvement in lifestyle (see [Table 1](#) for further description of the sessions).

Table 1
Summary of the five alcoholic liver disease-recurrence prevention (ALD-RP) sessions

Session number, name, and content of facilitator's manual

- (1) Introduction and alcoholic liver disease (ALD) development and consequences: Facilitator introduces him or herself. ALD is defined. All sessions are introduced. Functions of the liver are discussed. Stages of ALD are instructed. ALD terms are defined and practiced (mix and match). Example stories of compliance to the education program and survival are discussed, and a survival curve is presented.
- (2) Alcohol and tobacco cessation and relapse prevention: Session 1 is reviewed. The relation of drinking frequency and liver injury is discussed. Drug abuse is defined. Financial cost of heavy drinking is discussed. Alcohol withdrawal symptoms and coping skills (for withdrawal and for maintenance of sobriety) are instructed. Likelihood of becoming a controlled drinker is discussed. Cigarette withdrawal symptoms and consequences are taught. The relation of smoking and ALD is mentioned. A quit date and coping with withdrawal are discussed.
- (3) Nutrition/sanitation, avoidance of obesity, and medication compliance: Session 2 is reviewed. Obesity is defined and the patient's BMI and waist size is calculated. Nutrition is discussed, including reading food labels, instruction in portions and the food pyramid, warning about sodium and bacteria, and food safety tips. Sanitation tips are instructed. Relation of exercise to ALD recurrence prevention, and general reasons for exercise, are instructed. How to begin a workout regimen is instructed (stretching, aerobics, and physical activity). Medication compliance is instructed, including discussion of a compliance scenario, and nine medication tips are instructed.
- (4) Resource advocacy: Session 3 is reviewed. Using the telephone to call for assistance is taught, modeled, and role-played. Practice in using a resources toolkit is completed. The tool kit includes phone numbers and some locations for drugs and alcohol abuse, family member's use of drugs or alcohol, local food and shelter, job placements or job training, trade or academic school, and transportation options. The tool kit also includes phone numbers and some locations for sexual or physical abuse assistance, emotional problems assistance, sexual or eating disorder recovery needs, and food distribution centers.
- (5) Decision making and personal commitment to motivate improvement in lifestyle: Session 4 is reviewed. Goal setting is instructed. Planning how to reach goals is instructed. Decision-making is instructed. Two scenarios for good decision making in high risk (drinking and overeating situations) are practiced. Finally, a personal commitment is stated. Future use and storage of patient "survival manual" are discussed.

2.6. Follow-up and tracking

At discharge from Rancho, appointments were arranged at the outpatient clinic. Follow-up meetings at Roybal were held weekly, attended by 11 staff persons, primarily physicians. For participants that did not show up to follow-up visits, directory assistance, contact persons' phone number, mailed surveys to the last known address, public information databases, and home visits (to hospitals, homes, shelters, and homeless "squats") were used to minimize participant loss. For this sample, only telephone of participant or contact person and home visits were of value in locating patients.

2.7. Measures

Measures assessed at pretest included Marlatt's Drinking Profile, which was adapted from a behaviorally oriented intake protocol used for the assessment of alcoholism in hospitalized male alcoholics, adapted to both males and females, consisting of 80 items (e.g., demographics and alcohol use history), each requiring multiple responses (Miller & Marlatt,

1984). Reliability (test–retest) and measures of content and criterion validity have been established on The Drinker Profile.

Drug use behavior items were directed to ever trying and frequency of use of cigarettes, alcohol, marijuana, cocaine (crack), inhalants, stimulants, hallucinogens (LSD), and other drugs (e.g., XTC, heroin, depressants, PCP, mushrooms, and steroids). The use of simple, appropriately time-anchored, rating scale items have shown adequate psychometric properties (e.g., Sussman, Ames, Stacy, & Dent, 2001).

A process items measure provided an evaluation of the education program at immediate posttest only, and was used only in the ALD-RP education condition, including 12 adjective ratings of the overall program (enjoyable, interesting, not boring, understandable, not difficult, well-organized, believable, acceptable, realistic, helpful, not a waste of time, and important) on four-point scales (“definitely not,” “no, not really,” “somewhat,” and “yes”).

We also assessed knowledge of lifestyle behaviors that decrease or increase one’s chances of a recurrence of ALD symptoms, and assessed self-reports of one’s lifestyle behaviors related to recurrence of ALD symptoms. Knowledge was assessed through use of 19 forced-choice items (3–5 choices per item), and approximately 4 items were anchored to each session. For example, patients exposed to the program should have learned that ascites involves a swelling up of the stomach and ankles; that substance abuse disorder involves role, social, legal, and dangerous behavior-related consequences; that one with an ALD history should avoid eating oysters or clams; that a weekly pillbox contained compartments for each day of the week; and that brainstorming involves making a list of potential solutions without judging them; as examples. Lifestyle was assessed through use of 18 forced-choice items (2–4 choices per item) on diet preferences (e.g., monitoring one’s diet to make sure it is healthy; not eating excessive sodium, fast-food, canned food, or raw seafood), alcohol preferences (e.g., not drinking, attending 12-step meetings, being involved in alcohol or drug treatment, not being around drinkers), smoking (not smoking), using other recreational drugs (not using them), exercise (e.g., brisk mile walk or more), medication compliance (e.g., not using a drug without a doctor’s prescription other than a limited dosage of Tylenol), keeping sanitary conditions (e.g., washing hands), and resource attainment skill (e.g., knowing how to sign up for continuing education).

2.7.1. Skill level of personnel

One bilingual Hispanic male and one bilingual Hispanic female of approximately the same age delivered the interventions. The male delivered programming to approximately 75% of the patients. Both helped write the facilitator’s guide and subject manuals, and were very familiar with all materials and assessments.

3. Data analysis and results

We present data on the 25 patients who completed a pretest, posttest, and were followed-up after discharge from the unit. First, we examined baseline comparability across the two conditions, as a function of the 25 patients or the full pretest sample ($n=44$). No significant differences were found across condition, or by comparing the subsample to the full sample on

all measured variables (unpublished data available on request). Those 13 participants who received the program and were follow-up rated the program very highly on the 12-item, four-point process rating measure. The mean process rating was 3.82 (S.D.=0.22) out of a maximum rating of 4.00.

The next set of analyses assumed directional associations, so a one-tailed p value was used. Specifically, repeated-measures analysis of variance models were calculated. Hispanic ethnicity was included as a nuisance variable in all models, since Hispanics showed lower knowledge and protective lifestyle scores at baseline than non-Hispanics. First, it was expected that participants in the program condition would show greater learning than those in the control condition, from pretest to posttest. There was a significant time effect ($F=19.54$, $P<0001$) and a significant Time \times Condition interaction effect ($F=8.71$, $P<004$). The program condition showed a greater change in average correct score than the control condition (least squares means at pretest and posttest were 10.92 and 12.76 in the control condition, and were 9.34 and 14.86 in the program condition).

Second, it was expected that participants in the program condition would show greater self-reported lifestyle change than those in the control condition, from pretest to follow-up. There was a significant time effect ($F=26.29$, $P<0001$) and a significant Time \times Condition interaction effect ($F=3.09$, $P<05$). The program condition showed a greater change in average lifestyle score than the control condition (least squares means at pretest and posttest were 27.85 and 31.49 in the control condition, and were 27.32 and 33.06 in the program condition).

4. Discussion

Certainly, the advantage of an educational program could only be experienced by those patients who were capable of learning the information, who were residing at the hospital for the duration of the program (at least 8 days: 2 days pretest, 5 session days, 1 day posttest), and who could live long enough to be able to benefit from lifestyle change. Of 136 patients screened, and among the 44 who were selected and provided consent to participate, only 25 were followed up. Of those, 13 received the program and 12 were in the control condition. While this sample size is small, and suggests that ALD recurrence education programming is relevant to a minority of very low bottom, indigent patients, it is perhaps surprising that this program did exhibit benefits among those who participated—and one might speculate that this program may be even more useful with persons who show only warning signs of ALD.

The standard care control condition employed here actually was the state of the art in medical treatment of ALD among those for whom liver transplantation was not recommended. In addition, patients receiving or not receiving the program were on the same unit. Some contamination in transmission of information is possible. Thus, it is not surprising that some learning occurred across both conditions. For example, knowledge of cirrhosis increased in both conditions. On the other hand, some medical knowledge (e.g., ascites) and knowledge of drug abuse and successful coping did differentiate the program dramatically from the control program condition.

Likewise, changes in lifestyle were, in some cases, found to increase in both conditions. In particular, self-reports of not using a drug without a doctor's prescription, not eating food with excessive sodium, and not eating canned foods increased in both conditions. Relative benefits in the program condition appeared regarding not drinking alcohol, not hanging around people who drink alcohol, monitoring one's diet to make sure it is healthy, not eating raw seafood, exercising, taking medication exactly as prescribed, and washing one's hands when done using the washroom.

There are several limitations to this study. The sample size is very small. The patients are a relatively difficult population to work with and follow up. ALD is a chronic disorder that, when in its later phases, will be intractable, resistant to potential impacts of any psychosocial programming or lifestyle change. The patients in both conditions were at the same facility on the same ward, which closed down 1 month after termination of data collection, and it is possible that some contamination of programming occurred. Most programming was delivered by one health educator, and the health educator also engaged in the assessments. Thus, experimental demand effects are possible as well. The results of this pilot study suggest that ALD patients can be enrolled in ALD recurrence prevention education programming that, if they are enrolled, they very much like the programming and that, if they survive and can be followed up, do seem to benefit by the information they receive in terms of knowledge and subsequent lifestyle change. There is hope for ALD sufferers, and ALD recurrence education may be a useful part of rehabilitation for them, particularly among those who are in earlier phases of the disease. Much research needs to be completed in the future.

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