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# Alcohol and Health: Current Evidence

JULY - AUGUST 2006

## Assessments and Interventions

### Combining Medication With Specialist Behavioral Intervention for Alcoholism: the COMBINE Study

To study the effects of pharmacotherapy with behavioral intervention for alcohol dependence, researchers randomized 1383 recently abstinent patients with alcoholism to 1 of 9 treatments for 16 weeks: placebo; naltrexone (100 mg per day), acamprosate (3 g per day), or both; or combined behavioral intervention (CBI) alone, with active pills, or with placebo. CBI was offered by a specialist and included elements of cognitive behavioral therapy, motivational interviewing, and 12-step facilitation in up to 20 50-minute sessions.

All but the CBI alone group also received "medical management" (MM). MM included 9 counseling and education sessions (45-minute initial session and approximately 20-minute follow-up sessions) that were provided by a generalist healthcare professional and focused on medication side effects, adherence, and alcohol abstinence. Follow-up was 94% at 16 weeks and 82% a year later.

Drinking outcomes improved substantially in all groups. For example, the range of mean percent days abstinent across groups was 23%–30% at baseline, 67%–81% at 16 weeks, and 59%–69% a year later. Key findings at 16 weeks include the following:

- Naltrexone/MM was more effective than placebo/MM at increasing percent days abstinent (81% versus 75%) and delaying a return to heavy drinking\* (hazard ratio 0.7). Combining naltrexone/MM with CBI did not further improve these outcomes.
- CBI/MM with active or placebo pills was also more effective than placebo/MM at increasing percent days abstinent (e.g.,

79% versus 75%). However, CBI alone (without MM or pills) was less effective than placebo/MM (67% versus 74%).

- Acamprosate did not significantly affect drinking outcomes.

One year after treatment, drinking outcomes did not significantly differ among groups.

*Comments:* This large, rigorous, and complex study showed that (1) naltrexone and specialist counseling have similar modest efficacy when each is offered with medical management, and (2) specialist counseling alone has less efficacy than when combined with medical management. These findings support the use of naltrexone and intensive medical management in primary care settings as a potential alternative to specialized treatment. Delivering the type of medical management provided in this study, however, requires substantial training and a collaborative care model. This requirement and other concerns (e.g., need for chronic treatment; acamprosate's perplexing lack of efficacy) require further investigation.

Kevin L. Kraemer, MD, MSc

\* $\geq$ 5 standard drinks per day for men,  $\geq$ 4 for women

*Reference:* Anton RF, et al. Combined pharmacotherapies and behavioral interventions for alcohol dependence. The COMBINE Study: a randomized controlled trial. *JAMA*. 2006;295(17):2003–2017.

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## Acamprosate May Work Only When Abstinence Is the Goal

The Food and Drug Administration's approval of acamprosate to maintain abstinence in patients with alcohol dependence is based on data from international randomized, placebo-controlled clinical trials. To evaluate acamprosate's efficacy in U.S. patients, researchers conducted a randomized controlled trial of the drug (the first in this country) in 21 alcohol treatment clinics. Subjects, recruited primarily by newspaper advertisement, were assigned to receive either the standard 2 g of acamprosate per day (n=258), 3 g per day (n=83), or placebo (n=260). All subjects also received self-help materials and 8 sessions of brief counseling.

- In unadjusted analyses, the percentage of days abstinent at 6 months did not significantly differ across groups.
- However, in analyses adjusted for potential confounders (e.g., readiness to change, treatment goal of abstinence), the percentage was significantly higher in subjects who received acamprosate (52% for the placebo group, 58% for subjects on 2 g of acamprosate, and 63% for subjects on 3 g).

- Patients who stated at baseline that abstinence was their goal achieved the best results (58% days abstinent for the placebo group, 70% for subjects on 2 g of acamprosate, and 73% for subjects on 3 g).

*Comments:* Acamprosate's lack of efficacy in this large, well-designed trial is surprising, though also noted in another recent study (see Anton et al on page 1). One explanation may be that the U.S. subjects had less established abstinence (i.e., abstinent for a shorter time) than did the international subjects. Lastly, the link between having abstinence as a goal and benefit from acamprosate may guide clinicians' prescribing practices and merits confirmation.

Jeffrey Samet, MD, MA, MPH

*Reference:* Mason BJ, et al. Effect of oral acamprosate on abstinence in patients with alcohol dependence in a double-blind, placebo-controlled trial: the role of patient motivation. *J Psychiatr Res.* 2006;40(5):382–392.

## Most Medical Inpatients With Unhealthy Alcohol Use Have Dependence

Practice guidelines recommend that clinicians screen and conduct brief intervention for nondependent unhealthy alcohol use. Whether a substantial proportion of medical inpatients with unhealthy alcohol use has nondependent use—and thus might benefit from brief intervention—is unknown. To explore this issue, researchers in Boston conducted alcohol screening of 5813 medical inpatients.

- Seventeen percent of inpatients screened were drinking risky amounts (>14 standard drinks per week or >=5 drinks per occasion for men; >11 and >=4, respectively, for both women and people >=66 years).
- Of those drinking risky amounts,

97% exceeded per occasion limits (>=5 drinks for men, >=4 for women and people >=66 years). And most scored >=8 on the Alcohol Use Disorders Identification Test (which strongly correlates with a diagnosis of current alcohol abuse or dependence).

- Of the 341 inpatients who drank risky amounts and received more detailed evaluation, 77% had alcohol dependence.

*Comments:* According to this study, almost 1 in 5 medical inpatients has unhealthy alcohol use, a number identical to that found in a recent systematic (continued on page 2)

## Most Medical Inpatients With Unhealthy Alcohol Use Have Dependence (continued from page 3)

review of hospital alcohol screening studies (Roche AM et al, 2006). Of note, most medical inpatients with unhealthy alcohol use have alcohol dependence. Because brief intervention—the currently recommended practice—has established efficacy only for nondependent unhealthy alcohol use, new strategies to address alcohol dependence on a medicine service are warranted.

Peter Friedmann, MD, MPH  
Rosanne Guerriero, MPH

*References:* Saitz R, et al. The severity of unhealthy alcohol use in hospitalized medical patients: the spectrum is narrow. *J Gen Intern Med.* 2006;21(4):381–385; Roche AM, et al. From data to evidence, to action: findings from a systematic review of hospital screening studies for high risk alcohol consumption. *Drug Alcohol Depend.* 2006;83(1):1–14.

## Another Single-Item Screening Test?

To increase the likelihood that clinicians will address unhealthy alcohol use with their patients, researchers are pursuing briefer and simpler intervention strategies. Through a web-based survey completed by 3909 college students in North Carolina (36% response rate), researchers examined whether one question ("In a typical week, how many days do you get drunk?") could identify drinkers at risk of injury.

Of 2488 current (past 30-day) drinkers, 54% got drunk at least once in a typical week. In analyses adjusted for potential confounders (e.g., race, current drinking), students who got drunk in a typical week were significantly more likely than those who did not to have

- been injured because of their drinking (odds ratio [OR] 5.0);
- had a fall requiring treatment (OR 2.2);
- caused or experienced “secondhand” effects of alcohol, such as being taken advantage of sexually because of another’s drinking (OR 2.6) or causing injury to another person that required treatment (OR 2.6).

Drunkenness was a better indicator of the injury outcomes than was heavy episodic drinking ( $\geq 5$  drinks in a row on at least 1 day in the past 30 days for men,  $\geq 4$  for women).

*Comments:* This study did not assess for alcohol use disorders, a significant limitation that precludes recommending the single question as a clinical screening test. But the results are interesting because they suggest that a question about drunkenness might identify college-student drinking with consequences better than a question about heavy drinking on an occasion would. For now, it seems reasonable for clinicians to ask the question when discussing drinking with college students.

Richard Saitz, MD, MPH

*Reference:* O'Brien MC, et al. Single question about drunkenness to detect college students at risk for injury. *Acad Emerg Med.* 2006;13(6):629–636.

## Intensive Referral to 12-Step Groups Improves Outcomes

Some patients with substance dependence who are referred to self-help groups, such as Alcoholics Anonymous (AA) and Narcotics Anonymous (NA), choose not to participate. In this study, researchers examined whether intensive referral is more effective than standard referral at increasing self-help involvement and subsequently improving substance use outcomes.

Researchers randomized 345 veterans entering outpatient substance abuse treatment to either standard referral, including a schedule of and encouragement to attend local 12-step meetings, or intensive referral, including

additional information and clinician support (e.g., linkage to AA/NA volunteers, follow-up on meeting attendance, encouragement to obtain a sponsor). Almost all subjects had attended 12-step meetings previously, and 46% preferred alcohol to other substances.

- At 6 months, attendance at 12-step meetings did not significantly differ among the groups. But, of subjects with less exposure to 12-step groups at study entry, those assigned to intensive referral had better attendance.

(continued on page 4)

### Intensive Referral to 12-Step Groups Improves Outcomes (continued from page 3)

- The intensive referral group had significantly greater 12-step involvement (e.g., obtained a sponsor) and improvement in substance use problems than did the standard referral group.
- The intensive referral group was also more likely to be abstinent from drugs (78% versus 70%,  $P<0.05$ ) and alcohol (76% versus 70%,  $P<0.12$ ).
- Involvement in 12-step groups partially mediated improvements in alcohol outcomes.

*Comments:* Because 12-step groups do not sponsor research,

rigorous trials of their effectiveness are difficult to perform. Nevertheless, this study provides strong evidence that clinicians should support patients' active participation in AA/NA. Linking patients with AA/NA volunteers, following up on attendance, and encouraging sponsorship are essential to successful 12-step facilitation.

Peter Friedmann, MD, MPH

*Reference:* Timko C, et al. Intensive referral to 12-Step self-help groups and 6-month substance use disorder outcomes. *Addiction*. 2006;101(5):678–688.

### Help Seeking Quadruples the Likelihood of Abstinence

To quantify the effect of help seeking on recovery from alcoholism, researchers in the United States analyzed data from 4422 adults who had participated in a nationally representative survey and developed alcohol dependence at least 1 year before their participation.

- Only 26% of subjects had ever sought help for their alcohol problems; 3% participated in a 12-step program only, 6% in formal treatment only, and 17% in both.
- Help seekers drank more and had higher lifetime prevalences of other drug use, mood disorders, and personality disorders than did subjects who had not sought help.
- In analyses adjusted for potential confounders, help seeking significantly increased the likelihood of any recovery (odds ratio [OR] 2.4) and of abstinence (OR 4.0). Any recovery was defined as, in the past year, having no symptoms of alcohol abuse or dependence and either drinking low-risk amounts\* or abstaining.
- The odds of recovery were greater for those who had participated in 12-step programs with or without formal

treatment than for those who had participated in formal treatment only.

*Comments:* Even though they had more comorbidity and therefore were at risk for worse outcomes, seekers of formal and informal treatment had better odds of recovery from alcohol dependence. This study could not separate the motivation inherent in seeking help from the therapeutic effects of help received. However, help seeking—regardless of the patient's level of readiness—should be encouraged.

Peter Friedmann, MD, MPH

\* $\leq 14$  drinks per week and  $\leq 4$  drinks on any day for men;  $\leq 7$  and  $\leq 3$ , respectively, for women

*Reference:* Dawson DA, et al. Estimating the effect of help-seeking on achieving recovery from alcohol dependence. *Addiction*. 2006;101(6):824–834.

### Should Screening for Colorectal Cancer Start Earlier for Drinkers and Smokers?

Alcohol and tobacco use may increase the risk of colorectal cancer (CRC). It is unknown, however, whether clinicians should initiate CRC screening earlier based on a patient's history of such use. To explore whether earlier screening is warranted, researchers identified 166,172 cases of CRC through a national medical registry and assessed age at diagnosis. Analyses were controlled for sex, race, and insurance status.

- CRC was diagnosed significantly earlier in current and past drinkers\* than in subjects who never drank.
- Diagnosis occurred even earlier among current and past drinkers who currently smoked (e.g., 7.8 years earlier in current drinkers who also smoked than in subjects who

never drank or smoked).

- The likelihood of distal CRC was significantly higher among current and past drinkers than in subjects who never drank (odds ratios 1.2 and 1.1, respectively) and among current smokers than in subjects who never smoked (odds ratio 1.2).

*Comments:* This large retrospective study found that CRC was diagnosed in current and past drinkers at a younger age, especially if they currently smoked.

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\*Current use defined as use in the past year; past use defined as having quit at least 1 year before CRC diagnosis

## Should Screening for Colorectal Cancer Start Earlier for Drinkers and Smokers? (continued from page 4)

While the study helps clarify the association between alcohol, tobacco, and CRC, it neither addressed whether screening could have detected the earlier diagnoses nor accounted for many important confounding factors (e.g., quantity and frequency of drinking and smoking, diet, family history of CRC, obesity, comorbidities that potentially lead to earlier gastrointestinal evaluation). Thus, more investigation is needed to determine whether CRC screening guide-

lines should be modified according to a patient's history of alcohol and tobacco use.

Kevin L. Kraemer, MD, MSc

*Reference:* Zisman AL, et al. Associations between the age of diagnosis and location of colorectal cancer and the use of alcohol and tobacco: implications for screening. *Arch Intern Med.* 2006;166(6):629–634.

## Alcohol and Health Outcomes

### Is Drinking Unsafe for Patients on Warfarin or Statins?

Experts warn that alcohol can interact with warfarin and statins. But the risks, particularly in relation to the possible health benefits of moderate drinking for people with heart disease, have not been well described. To assess the safety of drinking in warfarin or statin users, researchers studied 1244 men who had undergone coronary artery bypass graft surgery and enrolled in a randomized trial of daily lovastatin (mean dose of 4 mg or 76 mg), low-dose warfarin (1–4 mg to achieve an INR\* of 1.8–2), or placebo-warfarin. Most men (54%) drank <1 drink per week, and only 9 men drank >21 drinks per week.

During about 5 years of follow-up, alcohol use did not significantly affect the risk of having elevated INR or alanine aminotransferase (ALT):

Standard drinks per week	ALT $\geq$ 80 IU/L (% of subjects)	INR $\geq$ 2 (% of warfarin subjects only)
<1	8	67
1–6	10	66
7–13	9	68
$\geq$ 14	6	61

ALT results were similar when the analysis was restricted to patients taking the higher dose of lovastatin.

*Comments:* Because few men drank more than 21 drinks per week, this study could not inform us about the risks associated with warfarin or statin use and heavy drinking. Further, reporting abnormal creatine kinase levels by drinking categories would have helped readers to judge risk. Nonetheless, these results should somewhat reassure patients with coronary artery disease that drinking moderately while taking warfarin or lovastatin is not harmful (or at least does not increase the risk of developing two specific lab abnormalities).

Richard Saitz, MD, MPH

\*International normalized ratio

*Reference:* Mukamal KJ, et al. Moderate alcohol consumption and safety of lovastatin and warfarin among men: the Post-Coronary Artery Bypass Graft Trial. *Am J Med.* 2006;119(5):434–440.

### Alcohol and the Risk of Injury

Numerous reports have documented the association between alcohol consumption and the risk of injury. To examine whether specific patterns of consumption affect this risk, researchers assessed 8736 patients admitted to an emergency department in Switzerland (5077 with an injury). Measures included usual volume of drinking, past-month heavy episodic drinking ( $\geq$ 5 drinks on at least one occasion for men,  $\geq$ 4 for women), and recent drinking (in the 24 hours before the emergency-department visit).

- Heavy episodic drinking and recent drinking increased

the risk of injury. And as the volume of usual and recent drinking increased, the risk of injury increased.

- Risk was highest in patients who usually drank moderately (<14 drinks per week for men, <7 for women) and reported both past-month and recent heavy episodic drinking (odds ratios 6.4 for men and 7.4 for women, compared with abstainers).

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### Alcohol and the Risk of Injury (continued from page 5)

- Past-month heavy episodic drinking tended to confer a higher risk in patients who usually drank moderately than in patients who usually drank heavily.
- Almost half of the alcohol-attributable injuries among women were suffered by those who usually drank moderately, did not have past-month heavy episodic drinking, and drank >0 but <4 drinks in the 24 hours before their emergency-department visit.

*Comments:* This study indicates that patterns of drinking, particularly heavy episodic drinking, influence the risk of

injury. Interventions to reduce alcohol-related injury should focus on preventing heavy episodic drinking among both moderate and heavy drinkers.

Joseph Conigliaro, MD, MPH

*Reference:* Gmel G, et al. Alcohol-attributable injuries in admissions to a Swiss emergency room: an analysis of the link between volume of drinking, drinking patterns and preattendance drinking. *Alcohol Clin Exp Res.* 2006;30(3):501–509.

### Lifetime Drinking, Confounders, and Breast Cancer Risk

Researchers in New York examined whether confounding factors could explain the association between moderate drinking and an increased risk of breast cancer. Using data from a population-based study, they compared information on alcohol use and other lifetime exposures from 1508 women with breast cancer and 1556 matched controls. Analyses were adjusted for potential confounders (e.g., age at diagnosis, race, education, body mass index [BMI]).

- Breast cancer risk was not significantly associated with lifetime\* or current alcohol use, except for current drinking of <0.5 grams per day (odds ratio [OR]\*\* 0.7).
- In subgroup analyses, the association between breast cancer risk and lifetime alcohol intake of 15–30 g (approximately 1–2 drinks) per day was significant in women with a BMI <25 (OR 2.1), and who were postmenopausal and had never used hormone replacement therapy (OR 2.0). Further, lifetime drinking of ≥15 g per day was significantly associated with estrogen receptor positive tumors (OR 1.9) and invasive tumors

(OR 1.6), but only in women with a BMI <25.

- Results did not differ in analyses that examined alcohol intake during a particular decade of life.

*Comments:* These findings are consistent with those of most previous studies that show a weak positive relationship between alcohol use and breast cancer risk. However, there was no dose-response curve for any of the observed associations, and only the subgroup analyses were significant. Additional studies are needed to help clinicians identify women at higher risk of breast cancer from current or lifetime moderate drinking.

R. Curtis Ellison, MD

\*Calculated based on average intake during various periods across the lifetime

\*\*Odds ratios compare drinking with not drinking alcohol at least once for 6 months or more

*Reference:* Terry MB, et al. Lifetime alcohol intake and breast cancer risk. *Ann Epidemiol.* 2006;16(3):230–240.

### Discrimination Against People With Alcoholism

People with alcohol dependence often face discrimination from individuals and institutions. Through phone interviews of 1012 German adults, researchers examined whether public attitudes and beliefs about alcohol dependence (1) are more negative than those about other diseases (i.e., schizophrenia, depression, Alzheimer's disease, rheumatism, diabetes, AIDS, myocardial infarction, and cancer), and (2) affect public preferences for resource allocation.

- Only 7% of respondents would spare alcohol treatment from budget cuts if resources were scarce.

- Most (85%) thought alcoholism, more than any other disease, was self-inflicted.
- More respondents (78%) would distance themselves from people with alcoholism than from people with other diseases.
- A little over half believed that alcoholism was severe, but only 30% felt it could be treated effectively.
- Just 4% thought they were at risk for alcoholism.

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## Discrimination Against People With Alcoholism (continued from page 6)

- Respondents were more likely to choose budget cuts for alcohol treatment if they believed that alcoholism was self-inflicted and not as severe as other conditions, and that their risk of alcoholism was low.

*Comments:* This study highlights the public's lack of understanding about alcohol dependence and the severe stigma faced by people with the dis-

ease. Increasing awareness and destigmatizing alcoholism are essential to improve the delivery of quality care.

Joseph Conigliaro, MD, MPH

*Reference:* Schomerus G, et al. Alcoholism: illness beliefs and resource allocation preferences of the public. *Drug Alcohol Depend.* 2006;82(3):204–210.

## Lifetime Drinking and the Metabolic Syndrome

Whether lifetime drinking affects the risk of the metabolic syndrome is largely unknown. Researchers examined this possible relationship in a population-based sample of 2818 subjects aged 35–79 years. All subjects drank at least once a month for at least 6 months during their lifetimes and were free of cardiovascular disease and cancer when they were interviewed. Analyses were adjusted for potential confounders (e.g., age, sex, smoking status).

- As lifetime drinking intensity increased, the prevalence of the metabolic syndrome and most of its components significantly increased. (Lifetime drinking intensity was defined as the total number of drinks over a lifetime divided by the total number of drinking days over a lifetime).
- For example, prevalence ratios for the metabolic syndrome were 1.2, 1.4, and 1.6 for subjects in the second, third, and fourth quartiles of lifetime drinking intensity, respectively (versus subjects in the lowest quartile).
- As the number of lifetime drinking days increased, the prevalence of abdominal obesity in women and

low high-density lipoprotein cholesterol significantly decreased.

*Comments:* Studies of lifetime drinking are desirable, but their validity can be difficult to judge because they are rarely prospective. Results depend on the recall of amounts consumed in the distant past; any errors in these estimates get multiplied when calculating lifetime intake. At least in this study, the researchers used an intensive and extensively studied interview method with known reliability. Further, the results support past findings: increasing per-occasion amounts of alcohol are harmful, while more frequent drinking may be protective.

R. Curtis Ellison, MD

*Reference:* Fan AZ, et al. Lifetime alcohol drinking pattern is related to the prevalence of metabolic syndrome: the Western New York Health Study (WNYHS). *Euro J Epidemiol.* 2006;21(2):129–138.

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