Alcohol, Other Drugs, and Health: Current Evidence

MARCH–APRIL 2015

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INTERVENTIONS & ASSESSMENTS

Reduce-to-Quit Approach in Smoking Cessation Using Varenicline Shows Promise

Most tobacco cessation strategies have targeted individuals willing to abstain completely from tobacco use within one month, but many people decline this treatment approach. This randomized controlled trial of a reduce-to-quit approach comparing 24 weeks of varenicline with placebo included 1510 participants from 10 countries. Individuals with suicidality, other severe mental health disorders, and past-year unhealthy alcohol or substance use were excluded. All participants received ≤ 10 minutes of counseling in 18 clinic and 10 telephone sessions. Participants were asked to reduce tobacco use by ≥ 50% by week 4, ≥ 75% by week 8, and quit by week 12. The main outcome was continuous abstinence rate (CAR) during weeks 15–24 of treatment.

- 47% of varenicline recipients (versus 31% of placebo) reduced tobacco use by ≥ 50% at 4 weeks.
- 26% of varenicline recipients (versus 15% of placebo) reduced tobacco use by ≥ 75% at 8 weeks.
- Week 15–24 CAR for varenicline group was 32% versus 7% for placebo group (risk difference [RD], 25%).
- Week 21-52 CAR for varenicline group was 27% versus 10% for placebo group (RD, 17%).

Comments: This study demonstrates that a reduce-to-quit approach using varenicline can be effective. However, the fact that frequent counseling is rarely provided in usual clinical practice may decrease the generalizability of these findings. Comparative effectiveness to a similar strategy with nicotine replacement therapy is not known. Furthermore, the exclusion of participants with past-year unhealthy alcohol or substance use makes the impact in this population unknown.

Hillary Kunins, MD, MPH

Reference: Ebbert JO, Hughes JR, West RJ, et al. Effect of varenicline on smoking cessation through smoking reduction: a randomized clinical trial. *JAMA*. 2015;313(7):687–694.

Brief Alcohol Intervention Shows Potential in Japanese Occupational Health Settings

The occupational health setting could be a place to implement brief intervention (BI) for unhealthy alcohol use. Researchers conducted a randomized controlled trial in 6 companies in Japan. Participants (N = 304) were recruited by advertisement and then screened for unhealthy alcohol use and randomized to 1 of 3 groups: BI, BI plus completion of a drinking diary every day for 3 months, and control. Follow-up took place at 3 and 12 months. The intervention was delivered by occupational health care providers (nurses and physicians).

- The follow-up rate was 93% in the BI group, 85% in the BI+diary group, and 95% in the control group.
- At baseline, the mean number of drinks over the past week was 35.2, 35, and 32.5 in the BI, BI+diary, and control groups, respectively. At 12 months, there was a significant reduction in all groups (mean number of drinks in a week: 24.1, 27.5, and 25.5), but no differences were observed between groups. Similarly, a reduction in the

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Brief Alcohol Intervention Shows Potential in Japanese Occupational Health Settings (continued from page 1)

number of heavy episodic drinking episodes over the past 28 days was observed in all groups, without differences between groups (baseline: 7.6, 8.3, 6.7; 12 months: 4.4, 4.7, 5.3).

- There was an increase in the number of alcohol-free days over the past 28 days and a significant beneficial effect in the two BI groups was observed (baseline: 4.6, 4.1, 5; 12 months: 9.0, 7.5, 6.6).
- No differences were observed on any outcome between the BI and BI+diary groups.

Comments: Despite important limitations due to design (notably it seems that the personnel who conducted the interventions also conducted the research assessments), this study suggests a possible effect of BI, among individuals concerned enough about their alcohol consumption to enroll in a trial, on the number of alcohol-free days. Adding a drinking diary did not increase the effect of the BI and had a detrimental effect on the follow-up rate.

Nicolas Bertholet, MD, MSc

Reference: Ito C, Yuzuriha T, Noda T, et al. Brief intervention in the workplace for heavy drinkers: a randomized clinical trial in Japan. *Alcohol Alcohol*. 2015;50(2):157–163.

HEALTH OUTCOMES

A Drink a Day Keeps the Doctor Away?

Two recent editorials in *Alcoholism: Clinical and Experimental Research* debated whether to prescribe 1 drink a day for lifetime abstainers starting between the ages of 40 and 50 years. Arguing for the recommendation, Rubin made the following points:

- Numerous observational studies suggest that, compared with abstinence and higher levels of use, "moderate" alcohol use is associated with decreased all-cause mortality.
- Studies suggest that, when compared with abstinence, "moderate" alcohol use is associated with decreased rates of myocardial infarction, ischemic stroke, osteoporosis, type II diabetes mellitus, rheumatoid arthritis, and dementia.
- There is no strong evidence that "moderate" alcohol use increases cancer risk.
- Risk of alcohol dependence developing in lifelong abstainers who begin drinking alcohol after age 40 years is "trivial."

Rubin concludes: "the overwhelming evidence suggests physicians should counsel lifelong non-drinkers at about 40 to 50 years of age to relax and take a drink a day, preferably with dinner." Greenfield and Kerr countered with the following points:

- Observational studies that show benefit from "moderate" alcohol use are uncontrolled and limited by misclassification (e.g., inclusion of "sick quitters" in the abstainer group) and residual confounding.
- A meta-analysis indicated no benefit of "moderate" alcohol use for all-cause or cardiovascular mortality among the studies judged to be without misclassification error.
- Another meta-analysis of 261,991 individuals indicated that those with the variant of alcohol dehydrogenase 1B gene associated with less alcohol use had reduced risk of cardiovascular disease across all levels of alcohol use. This suggested that decreasing alcohol consumption, even in people with "light" to "moderate" use, would reduce cardiovascular risk.
- Daily consumption of < 1.5 standard drinks a day accounts for 26%–35% of cancer deaths attributable to alcohol.

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A Drink a Day Keeps the Doctor Away? (continued from page 2)

- Individuals are abstinent for many reasons (e.g., religious beliefs) and may not be receptive to advice to start drinking.
- Advice to start drinking may have unintended consequences, including drinking in excess of safer limits and indirect transmission of the "wrong message" to people with current use, who might increase their consumption.

Greenfield and Kerr conclude: "we respectfully urge caution in prescribing drinking to abstainers, even lifetime abstainers, over 40 years of age" and call for a randomized controlled trial.

Comments: In my own clinical practice, I can recall only a few instances of a lifelong abstainer patient asking me if he or she should start drinking to improve their health. These queries generally were made with some levity and occurred after the news media publicized an observational study's finding of alcohol's benefit. I would respond, "No, I don't think we're quite ready to make that recommendation yet… But have you thought about exercising more?" Should I change my approach to this recommendation? Would my abstaining patients follow the recommendation if I made it? Certainly, many lifelong abstainers have done so for a reason and may not appreciate the recommendation and perhaps may even have decreased quality of life should they not enjoy the drink a day. What would be the optimal dose and duration of use? Should I urge my non-abstaining patients who drink less than one drink a day to increase their intake?

Although many observational studies suggest a health benefit of "light"-to-"moderate" drinking, the medical literature also has many examples of preventive interventions that showed a beneficial effect in observational studies but not when tested in high-quality randomized controlled trials. Further caution is warranted because alcohol is classified as a carcinogen by some national and international health organizations. Since there remains clinical equipoise (i.e., uncertainty about the potential benefit of moderate alcohol use in the context of known potential harms) in this matter, I agree with Greenfield and Kerr about the need to give serious consideration to a randomized controlled trial. The conduct of such a trial poses many challenges and might be most efficiently done in patients at high risk for cardiovascular disease or as secondary prevention.

Kevin L. Kraemer, MD, MSc

References: Rubin E. To drink or not to drink: that is the question. *Alcohol Clin Exp Res*. 2015;38(12):2889–2892.

Greenfield TK, Kerr WC. Physicians' prescription for lifetime abstainers aged 40 to 50 to take a drink a day is not yet justified. *Alcohol Clin Exp Res*. 2015;38(12):2893–2895.

More Evidence Raising Questions About Whether "Moderate" Drinking Has Any Benefit

Low amounts of alcohol are purported to have health benefits, but even if advantages exist there are many questions about dose, frequency, to whom they might pertain, and with what risks. To assess the association between alcohol consumption and mortality, investigators linked national mortality data to English population health survey data from over 30,000 people aged ≥ 50 who were followed for 7–10 years.

- Although analyses that compared those who drank with those who did not and analyses only adjusted for age showed a number of significant associations, there were no significant associations between weekly alcohol consumption and mortality for men ≥ 65 years, or women 50–64 years old, when compared with never drinking.
- Younger men drinking 9–11 US standard drinks* in a week had reduced mortality (hazard ratio [HR], 0.5).
- Older women drinking < 1–2 occasions in a month or < 9 drinks in a week had reduced mortality (HRs, 0.7–0.8).
- The above adjusted** analyses compared those who drank with never drinkers, and excluded former drinkers from the noncurrent drinking category. In analyses in which those who drank were compared with occasional drinkers (< 1-2 times in a month), there were no significant associations between alcohol consumption and mortality.

* Approximately equivalent to 1.5 oz 80-proof liquor, 12 oz beer, or 5 oz wine.
** Adjusted for age, body mass index, economic activity, ethnicity, region, marital status, social class, and smoking.

Comments: These analyses detected associations between drinking and mortality for very specific bands of age and consumption that disappeared in more sophisticated analyses. Of note, most associations were in the beneficial direction even though they were not statistically significant, and there was likely limited power. Nonetheless, the differences in results seen when the reference group is non-drinking versus never drinking, and when the analyses are adjusted for some potential confounders, are dramatic, suggesting that the worse health among non-

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More Evidence Raising Questions About Whether "Moderate" Drinking Has Any Benefit (continued from page 3)

drinkers is not because they don't drink but rather because of other negative exposures. This study contributes to the mounting evidence that the associations between drinking and health benefits seen in prior research are not causal.

Richard Saitz, MD, MPH

Reference: Knott CS, Coombs N, Stamatakis E, Biddulph JP. All cause mortality and the case for age specific alcohol consumption guidelines: pooled analyses of up to 10 population based cohorts. *BMJ*. 2015;350:h384.

Adolescent Cannabis and Tobacco Use are Associated with Poor Educational Outcomes

Observational studies suggest that heavy, habitual marijuana use in adolescence may be associated with cognitive decline and adverse educational outcomes. However, conflicting data exists. The authors of this study used data from a large population-based prospective cohort of 1155 individuals from the United Kingdom to investigate the effects of cannabis use by age 15 on subsequent educational outcomes. They also explored the relationship between tobacco use and educational outcomes to assess for possible bias. The primary educational outcomes were performance in standardized English and mathematics assessments at age 16, completion of 5 or more assessments at a grade level C or higher, and leaving school having achieved no qualifications. Exposure was measured by self-report and serum cotinine levels.

- In fully adjusted models both cannabis and tobacco use were associated with adverse educational outcomes.
- A dose response effect was seen with higher frequency of cannabis use associated with worse outcomes.
- Adjustment for other substance use and conduct disorder attenuated these effects and tobacco had a stronger association than cannabis.

Comments: This data sheds more light on a possible association between early exposure to cannabis and tobacco and subsequent poor educational outcomes. However, given the nature of the analysis, causality cannot be implied. Further research is needed at longer follow-up periods to gain more understanding of the relationship between cannabis use in adolescence and educational outcomes.

Jeanette M. Tetrault, MD

Reference: Stiby AI, Hickman M, Munafò MR, et al. Adolescent cannabis and tobacco use and educational outcomes at age 16: birth cohort study. *Addiction*. 2015;110(4):658–668.

Increased Drinking Precedes Unsanctioned Stopping of Alcohol Pharmacotherapy

Few studies have examined the process by which patients discontinue medication prior to the end of treatment for alcohol use disorder. This secondary data analysis of the 16-week Combined Pharmacotherapies and Behavioral Interventions for Alcohol Dependence (COMBINE) study examined drinking patterns before and after unsanctioned stoppage of oral naltrexone or acamprosate.

- 667 patients (54% of sample) stopped their medication early; 44% by their own choice, 19% because of an adverse effect, and 37% without a reason given.
- Decreases in the percentage of days abstinent (PDA) and increases in percentage of heavy drinking days (PHDD) occurred on average several weeks before medication discontinuation. Drinking increased at a similar rate after discontinuation.

Comparing pre- with post-discontinuation drinking levels:

- Patients who discontinued early in treatment (weeks 1–8) experienced a 14% decrease in PDAs, compared with only a 5.5% decrease among late discontinuers (weeks 9–15), but no effect was seen on PHDDs.
- Patients who discontinued by their own choice experienced a 4% increase in PHDDs, compared with a < 1% increase among those who discontinued because of an adverse effect.

Comments: This analysis found that gradual, linear increases in drinking over weeks typically precede alcohol-dependent patients' drop-out from pharmacotherapy. The investigators rightly point to a window of opportunity in which the clinician can intervene to avert relapse-related consequences and loss to care. In addition, the rate of increase in drinking did not accelerate after cessation, suggesting that medications for alcohol use disorders do not produce a rebound worsening of symptoms. Finally, discontinuation in the first 8 weeks, and the patient's decision to stop the medication on his/her own, are poor prognostic signs that should signal a need to intensify or modify treatment.

Peter D. Friedmann, MD

Reference: Stout RL, Braciszewski JM, Subbaraman MS, et al. What happens when people discontinue taking medications? Lessons from COMBINE. *Addiction*. 2014;109(12);2044–2052.

Among Adolescents, Combining Alcohol and Energy Drinks Is Associated With Other Risky Behaviors

The consumption of energy drinks has increased among adolescents in the past decade. Researchers used data from a trial for underage drinking at the University of Michigan to assess the combined consumption of alcohol and energy drinks. Subjects were 810 patients aged 14–20 seen in an emergency department (average age 18.6 years, 41% male). They were interviewed regarding alcohol and energy drink consumption, and other risk behaviors.

- Of the 810 patients screened, 439 (54%) reported past -year alcohol use. Of these, 261 (60%) reported any energy drink consumption and 61% of them reported combining alcohol and energy drinks.
- The most common reasons cited for combining alcohol and energy drinks were: hiding the flavor of alcohol (39%), liking the taste (36%), and staying awake (32%).
- On multivariable analysis, combined use of alcohol and energy drinks (compared with non-use of either) was associated with male gender, sex after use of alcohol and/or drugs, driving/riding after drinking, higher AUDIT score, and other drug use. Separate use of either (compared with non-use) was only associated with male gender.

Comments: This study suggests that combining alcohol and energy drinks is a marker for other risky behaviors. It is probably helpful for clinicians to be aware of this association when screening and counseling adolescents and young adults.

Darius A. Rastegar, MD

Reference: Bonar EE, Cunningham RM, Polshkova S, et al. Alcohol and energy drink use among adolescents seeking emergency department care. *Addict Behav*. 2015;43:11–17.

HIV AND HCV

Most Individuals with Injection Drug Use and Hepatitis C Virus Are Unaware of Their Infection

Injection drug use is the primary risk factor for hepatitis C virus (HCV) infection. This study recruited individuals in San Diego who had injected drugs in the previous 6 months. All were asked whether they had been tested for HCV previously and the result of the test; they were then tested for HCV antibodies.

- Of the 540 participants, 148 (27%) were anti-HCV positive. Of these, only 46 (32%) were aware that they were infected and only 16 (35%) of those who were aware of their infection reported having been offered treatment previously.
- In multivariable analysis, factors that were associated with awareness of HCV infection included older age, being tested for HIV previously, and being in drug treatment previously.

Comments: Now that we have very effective therapies for this deadly disease, more needs to be done to identify individuals with HCV and link them with treatment. Providers of drug treatment appear to play a valuable role in screening these individuals and can also help get them connected with HCV care.

Darius A. Rastegar, MD

Reference: Collier MG, Bhaurla SK, Cuevas-Mota J, et al. Awareness of HCV infection among persons who inject drugs in San Diego, California. *Am J Public Health*. 2015;106(2):302–303.

Hepatitis C Treatment in People Who Inject Drugs: Treatment As Prevention Based on Risk Level

With the focus of hepatitis C virus (HCV) treatment shifting from interferon-based regimens to more effective oral, direct-acting antiviral regimens, more patients are likely to be willing to engage in treatment. However, high medication cost may limit HCV treatment accessibility, particularly among people who inject drugs (PWID). Although treatment of HCV in PWID may decrease viral transmission, reinfection is a concern. Using mathematical modelling, the authors investigated the expected benefits of HCV treatment in high-risk PWID who share injecting equipment versus low-risk PWID who rarely or never share injecting equipment. Primary outcomes included the probability of becoming and remaining HCV uninfected and the expected number of prevented infections due to decreased HCV transmission. The authors studied the effects of risk behaviors on the prevalence of HCV in exchanged syringes.

- Determining which risk group to target for HCV treatment depended on the prevalence of HCV in the population; when >50% of the syringes in a population of PWID were infected with HCV, targeting HCV treatment at low -risk individuals was most beneficial. However, below this level, it was most beneficial to target HCV in high-risk individuals.
- By sensitivity analysis, the authors noted that a relatively small high-risk group could strongly impact the prevalence

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Hepatitis C Treatment in People Who Inject Drugs: Treatment As Prevention Based on Risk Level (continued from page 5)

of HCV among returned syringes, but not necessarily affect HCV prevalence among PWID.
- Modelling the combination of risk reduction strategies coupled with HCV treatment had the greatest benefit among the high-risk group.

Comments: The results from this study suggest that directing HCV treatment strategies among PWID based on risk level may enhance the population-level benefits achieved. Further studies conducted in clinical populations of PWID with differing risk profiles will add knowledge to our understanding of both the individual and public health impact of HCV treatment.

Jeanette M. Tetrault, MD

Reference: de Vos AS, Prins M, Kretzschmar ME. Hepatitis C treatment as prevention among injection drug users: who should we cure first? *Addiction*. 2015 [Epub ahead of print]. doi:10.1111/add.12842.

Buprenorphine/Naloxone Treatment Decreases Opioid Use and HIV Risk Behaviors in China and Thailand

Buprenorphine/naloxone (BUP/NX) treatment for opioid use disorder has been shown to reduce injection risk behaviors, but access in Central/Southeast Asia remains limited. This open-label trial compared incident HIV infection and mortality rates among 1251 people with injection drug use in China and Thailand. Participants were randomized to receive either short-term treatment, in which they were initiated on BUP/NX and then tapered over up to 15 days—this was repeated if needed at week 26—or long-term treatment, in which participants received BUP/NX for 46 weeks and then underwent a taper over the subsequent 6 weeks. Both groups received drug counseling.

- The study was stopped early due to lower than expected HIV infection rates. It did not show any difference in a composite outcome of HIV infection or death between the two groups.
- High-risk injection use behaviors (e.g., sharing needles) decreased in both groups.
- At weeks 24 and 48, individuals in the long-term group were less likely to have opioid use according to urine drug test and self-report than individuals in the short-term group. This difference was no longer apparent at 78 and 104 weeks.
- Approximately half of the individuals in both groups reported opioid use at week 104.

Comments: This study showed decreased HIV risk behaviors and opioid use during BUP/NX treatment; however, benefits diminished after tapering, consistent with recent US studies. This first trial of BUP/NX prescribed in China or Thailand raises questions about how to best expand capacity for such treatment in regions of the world such as Southeast Asia where injection drug use plays a dominant role in HIV transmission. Although adherence rates provide initial evidence that the intervention was feasible and acceptable to participants, additional studies of providers and key community stakeholders will be important next steps to expanded access. Additionally, the observed HIV seroconversion rate calls into question the feasibility of using this as the endpoint in future trials of opioid agonist treatment.

Jessica S. Merlin, MD, MBA

Reference: Metzger DS, Donnell D, Celentano DD, et al. Expanding substance use treatment options for HIV prevention with buprenorphine naloxone: HIV Prevention Trials Network 058 (HPTN 058). *J Acquir Immune Defic Syndr*. 2015;68(5):554–561.

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The major journals regularly reviewed for the newsletter include:

Addiction
Addiction Science & Clinical Practice
Addictive Behaviors
AIDS
Alcohol
Alcohol & Alcoholism
Alcoholism: Clinical & Experimental Research
American Journal of Drug & Alcohol Abuse
American Journal of Epidemiology
American Journal of Medicine
American Journal of Preventive Medicine
American Journal of Psychiatry
American Journal of Public Health
American Journal on Addictions
Annals of Internal Medicine
Archives of General Psychiatry
Archives of Internal Medicine
British Medical Journal
Drug & Alcohol Dependence
Epidemiology
European Addiction Research
European Journal of Public Health
European Psychiatry
Gastroenterology
Hepatology
Journal of Addiction Medicine
Journal of Addictive Diseases
Journal of AIDS
Journal of Behavioral Health Services & Research
Journal of General Internal Medicine
Journal of Hepatology
Journal of Infectious Diseases
Journal of Studies on Alcohol
Journal of Substance Abuse Treatment
Journal of the American Medical Association
Journal of Viral Hepatitis
Lancet
New England Journal of Medicine
Preventive Medicine
Psychiatric Services
Substance Abuse
Substance Use & Misuse

Many others periodically reviewed (see www.aodhealth.org).

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Target Audience

The target audience is generalist clinicians, many of whom have received limited training on detecting and treating substance abuse.

Educational Needs Addressed

Primary-care clinicians often miss the diagnosis of alcohol or drug problems and cannot stay abreast of the current substance-abuse literature in the context of a busy practice. Because of the effects of alcohol and drugs on adherence to care plans and physician-patient relationships, patients with alcohol or drug problems may receive suboptimal treatment for other conditions. Further, physicians sometimes perceive alcohol or drug dependence as less treatable than other medical conditions, and thus delegate responsibilities for screening and intervention to others. At the root of the screening and treatment gap is the inadequate provision of substance-abuse education in medical schools and mental-health fields. The newsletter addresses this not only by research dissemination but by providing free downloadable teaching tools for use by educators.

Educational Objectives

At the conclusion of this program, participants will be able to state the latest research findings on alcohol, illicit drugs, and health; incorporate the latest research findings on alcohol, illicit drugs, and health into their clinical practices, when appropriate; and recognize the importance of addressing alcohol and drug problems in primary care settings. In sum, the purpose of the newsletter is to raise the status of alcohol and drug problems in both academic and clinical culture to promote evidence-based screening and treatment and ultimately improve patient care.

Disclosure Statement

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