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Alcohol, Other Drugs, and Health: Current Evidence

JULY–AUGUST 2017

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INTERVENTIONS & ASSESSMENTS

Screening and Computer-Guided 30-Minute Therapist Emergency Department Brief Intervention Plus 40-minute Booster May Reduce Drug Use Days

Large single and multi-site studies of drug brief intervention (BI) have found no efficacy. This trial enrolled 780 emergency department patients with past 90-day drug use (either weekly or more, or less with a consequence, identified by screening) who were randomly assigned to a tablet computer or computer-guided therapist BI (and 4-page change plan summary), or to usual care (3-minute review of an HIV prevention brochure and resource lists). All were subsequently randomized to a brief informational session versus a 40-minute motivational counseling booster. Mean age was 31; 45% were male, 52% black, 74% unemployed, 91% used marijuana, 19% used another illegal drug; it is not clear how many met criteria for a *DSM* substance use disorder. Follow-up was 85% at 6 months and 87% at 12.

- Primary outcome analyses (adjusted) found a significant effect size of 0.24 (95% confidence interval -0.41 to -0.07) for the therapist group compared with usual care at 6 and 12 months (difference in mean self-reported past 90-day drug use days between groups divided by standard deviation). There was no significant effect on drug use days in the computer-only group, or for either group at 3 months.
- Of note, 84–87% of participants provided urine samples for urine marijuana testing that was largely concordant with self-reported marijuana use.
- In unadjusted analyses, the 12-month decrease in drug use was approximately 6% greater in the therapist with booster group (27-28% [an approximately 11-14 day decrease to 31-37 days/90]) compared with usual care (20.9% [a 12 day decrease to 44 days/90]).

Comments: In this well-implemented trial, there was a small difference (roughly 0-2/90) in drug use days in a sample of people primarily using marijuana favoring the therapist intervention, a small-to-moderate 0.2 effect size statistically. With that, one wonders if loss to follow-up or self-report among those without urine tests could have flipped the main results to null. There may be reasons explaining positive effects—such as a computer and in-person combined intervention, the other intervention components, or the severity of drug use. But regardless, in the context of other null studies, questions will remain regarding the reproducibility and value of such an intervention to achieve a several-day greater decrease in drug use days.

Richard Saitz, MD, MPH

Reference: Blow FC, Walton MA, Bohnert AS. A randomized controlled trial of brief interventions to reduce drug use among adults in a low-income urban emergency department: the HealthiER You study. *Addiction*. 2017;112(8):1395-1405.

No Effect of High-Dose Baclofen for the Treatment of Alcohol Dependence

There is inconsistent evidence regarding the efficacy of baclofen, a potent stereo-selective GABA-B agonist, for the treatment of alcohol use disorder. Researchers conducted a multi-site double-blind placebo-controlled trial of high-dose baclofen (up to 150 mg), low-dose baclofen (30 mg), or placebo. Participants (N=151) were 18-70 years old, with *DSM IV* alcohol dependence, consuming ≥14 units/week (women) or ≥21 units/week (men) over a consecutive 30-day period with ≥2 heavy drinking days in the past 90 days. The trial consisted of a 6-week titration period, followed by a 10-week dose-stabilization period.

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No Effect of High-Dose Baclofen for the Treatment of Alcohol Dependence (continued from page 1)

- In the high-dose baclofen group, the mean dose was 94 mg/day.
- There were no between-group differences in the primary outcome: time to first return to heavy drinking (defined as one heavy drinking day).
- There were no between-group differences in the proportion of participants returning to heavy drinking: 50% in the high-dose baclofen group, 48% in the low-dose group, and 47% in the placebo group. There were also no between-group differences in cumulative abstinence duration (62, 65, 62 days, respectively).
- Similarly, there were no between-group differences in the study outcomes when analyses were restricted to the 10-week period with a stable dose.

Comments: This trial did not show an effect of either low or high doses of baclofen in patients with alcohol dependence. Although post hoc analyses suggested a dose-response effect, most participants did not reach the target dose due to side effects. Given these results, the prescription of high-dose baclofen for the treatment of alcohol use disorder is not currently supported by the evidence.

Nicolas Bertholet, MD, MSc

Reference: Beraha EM, Salemink E, Goudriaan AE, et al. Efficacy and safety of high-dose baclofen for the treatment of alcohol dependence: a multicentre, randomised, double-blind controlled trial. *Eur Neuropsychopharmacol*. 2016;26(12):1950-1959.

HEALTH OUTCOMES

Alcohol Use Increases Cardiovascular and Renal Event Risk among Young-to-Middle-Aged Smokers with Hypertension

To assess the combined impact of alcohol use and smoking on cardiovascular and renal events, researchers analyzed prospective data from 1204 white young-to-middle-aged participants (mean age 33 years, 73% male) with stage 1 hypertension (mean blood pressure 146/94). Alcohol and tobacco use were assessed by interview. The combined major adverse cardiovascular and renal event outcome included fatal and non-fatal myocardial infarction, acute coronary syndromes, cardiac revascularization procedures, hospitalization for heart failure, fatal and non-fatal stroke, aortic or lower limb revascularization, atrial fibrillation, and chronic kidney disease stage 3 or higher.

- Among the 1204 participants, 74 (6%) had a fatal or non-fatal major adverse cardiovascular and renal event (32 acute coronary syndrome, 11 stroke, 3 heart failure, 3 aortic aneurysm repair, 6 peripheral revascularization, 12 atrial fibrillation, and 7 renal disease) over 12.6 years of follow-up.
- In unadjusted analyses, smoking and alcohol use (0, <50g/day, ≥50g/day) were linearly associated with increased risk of adverse outcomes.
- Any alcohol use, smoking, or combination of alcohol use and smoking were associated with increased risk of adverse outcomes in adjusted models (Table).

Table. Hazard ratio (95% confidence interval) of adjusted* models for substance use groups** (reference group: nonsmokers who did not drink alcohol)

Outcome	Any Alcohol Use	Any Smoking	Any Alcohol Use + Any Smoking	Heavy Smoking (> 10 cigs/d) + Any Alcohol Use
Major adverse cardiovascular and renal event, including atrial fibrillation	1.8 (1.1 - 3.2)	1.5 (1.2 – 1.8)	4.0 (2.0 – 8.2)	7.8 (4.2 – 14.4)
Major adverse cardiovascular and renal event, without atrial fibrillation	2.3 (1.2 – 4.3)	1.5 (1.2 – 1.9)	-	7.3 (3.8 – 14.1)

(continued page 3)

Alcohol Use Increases Cardiovascular and Renal Event Risk among Young-to-Middle-Aged Smokers with Hypertension (continued from page 2)

* Models adjusted for age, sex, coffee intake, physical activity, body mass index, family history of cardiovascular disease, glucose, lipids, average 24-hour blood pressure, incident hypertension, and longitudinal changes in blood pressure and body weight.
** Any alcohol use (n=569), any smoking (n=254), any alcohol use + any smoking (n=142), any alcohol use + heavy smoking (n=51).

Comments: This study suggests an interactive effect between alcohol use and smoking to increase risk for cardiovascular and renal events in hypertensive smokers 45 years old or younger. The outcome variable is quite heterogeneous so it is difficult to know which specific cardiovascular events are most susceptible to the combination of smoking and drinking. Further, adjusted results were not presented for levels of drinking. Nonetheless, the results support existing clinical recommendations to control blood pressure and encourage tobacco cessation and lower-risk (which includes no) drinking.

Kevin L. Kraemer, MD, MSc

Reference: Palatini P, Fania C, Mos L, et al. Alcohol intake more than doubles the risk of early cardiovascular events in young hypertensive smokers. *Am J Med*. 2017 [Epub ahead of print]. doi: 10.1016/j.amjmed.2017.02.041.

More Evidence that Concurrent Opioid and Benzodiazepine Use Increases Risk of Overdose

Clinical guidelines recommend that clinicians avoid prescribing opioids and benzodiazepines concurrently. In this study, researchers used national health claims data from 315,428 privately insured adults who received at least 1 opioid prescription to assess the association of concurrent opioid and benzodiazepine prescriptions with emergency department and inpatient admission for opioid overdose. Concurrent opioid and benzodiazepine prescription was defined as overlap of at least 1 day in prescription coverage.

- The concurrent use of opioids and benzodiazepines rose from 9% in 2001 to 17% in 2013.
- In analyses adjusted for year, age, sex, and co-morbid conditions, concurrent opioid and benzodiazepine use was associated with increased risk for overdose among all people with opioid use (odds ratio [OR], 2.14), those with intermittent use (OR, 1.42), and those with chronic use (OR, 1.81), when compared with people with opioid use who did not have benzodiazepine use.
- Results did not change substantially if the degree of time overlap for concurrent prescription was increased from 1 day to >25% overlap.
- The researchers estimated that the elimination of concurrent opioid and benzodiazepine prescribing would lower emergency department and inpatient admissions for overdose by about 15%.

Comments: This study provides more evidence of increased risk for opioid overdose with concurrent use of opioids and benzodiazepines, this time in a privately insured adult population. Equally worrisome is the near doubling in prevalence of concurrent use from 2001 to 2013. Prescribers and patients need to be better informed about the risk of using opioids and benzodiazepines concurrently.

Kevin L. Kraemer, MD, MSc

Reference: Sun EC, Dixit A, Humphreys K, et al. Association between concurrent use of prescription opioids and benzodiazepines and overdose: retrospective analysis. *BMJ*. 2017;356:j760.

Prescribed Opioid Use May Lead to Nonmedical Use by Adolescents

Nonmedical use of prescription opioids is associated with prescribed use among adolescents, but the relationship has not been clearly elucidated. This study used independent cross-sectional data from the nationally representative Monitoring the Future survey to investigate trends in medical and nonmedical use of opioids by US high school seniors from 1976 to 2015.

- Peaks in lifetime prevalence of opioid prescription occurred in 1989 and 2002 and remained high until a decline starting in 2013.
- Nonmedical use of opioids was associated with medical use for the entire duration of the study.
- Medical use of opioids was significantly more likely to precede nonmedical use among adolescents who reported both.

Comments: Medical use of opioids by adolescents is common, although recent efforts to reduce opioid prescribing appear to be having an impact. The role of exposure to prescription opioids in the pathway to opioid use disorder remains poorly understood, although this study suggests a possible link through non-medical use. Leftover opioids may later be used with the intention of treating pain or "recreationally," or medical use may "prime" adolescents for non-medical use. These findings raise caution about prescribing opioids to adolescent patients, and underscore the need for anticipatory guidance and advice for all adolescents treated with prescription opioids.

Sharon Levy, MD, MPH

Reference: McCabe SE, West BT, Veliz P, et al. Trends in medical and nonmedical use of prescription opioids among US adolescents: 1976–2015. *Pediatrics*. 2017;139 (4).

HIV AND HCV

Baclofen Has No Effect on Days of Abstinence from Alcohol Among Patients Receiving Treatment for HCV

Baclofen has been considered a promising treatment option for alcohol use disorder (AUD) in patients with liver disease since it is metabolized through the kidneys. Prior literature on the effect of baclofen for treatment of AUD has shown mixed results with many published studies limited by small sample sizes. This 12-week placebo-controlled randomized clinical trial assessed the effect of baclofen 10 mg 3 times daily on abstinence from alcohol among 180 patients receiving treatment at US Veterans Administration hepatology clinics. Participants had co-morbid hepatitis C and AUD and reported consuming >7 standard drinks in a week for each of the preceding 2 weeks or 1 heavy drinking* day in a week for each of the preceding 2 weeks. At baseline, participants consumed an average of 32 standard drinks in a week. The mean age was 57 years, 98% were male, and participants were primarily Caucasian (57%) or African American (36%).

- At 12 weeks, all participants experienced significant increases in percentage of days abstinent from alcohol (from 37% to 69%). Compared with placebo, baclofen did not improve the percentage of days abstinent.
- There were no differences between the 2 groups on the following secondary outcomes: percentage of participants who achieved complete abstinence or had no heavy drinking between weeks 4 and 12 of the study, alcohol craving, anxiety, depression, and post-traumatic stress disorder.
- Of patients who completed week 4, 9% achieved complete abstinence (10% in the placebo group and 8% in the baclofen group).

* >4 drinks in a day for men and >3 drinks in a day for women.

Comments: Although the findings in this study may have been affected by patients with lower alcohol consumption, recruitment from hepatology rather than alcohol treatment settings, and inclusion criteria of HCV rather than cirrhosis, these findings add to the body of literature suggesting that baclofen, at least at standard doses, is no better than placebo at increasing abstinence or reducing alcohol consumption or cravings.

Jeanette M. Tetrault MD

Reference: Hauser P, Fuller B, Ho SB, et al. The safety and efficacy of baclofen to reduce alcohol use in veterans with chronic hepatitis C: a randomized controlled trial. *Addiction*. 2017;112 (7):1173–1183.

Buprenorphine Treatment Retention Associated with Improved Hepatitis C Treatment Outcomes

In the United States, hepatitis C virus (HCV) is the leading cause of liver failure and the main risk factor is injection drug use. Opioid agonist treatment in the form of methadone or buprenorphine is the most effective treatment for opioid use disorder. Researchers investigated characteristics associated with successful treatment for HCV among a cohort of patients in New York City who received buprenorphine treatment in primary care.

- Of 390 patients who initiated buprenorphine treatment between 2009 and 2014, 123 (32%) were found to have chronic HCV infection.
- Of those with chronic HCV infection, 52% were referred for treatment, 33% had an HCV-specific evaluation, 17% were offered treatment, and 8% initiated treatment. Of the 10 patients who initiated treatment, 7 achieved cure.
- Compared with those who did not, patients who remained in buprenorphine treatment for ≥6 months were more likely: to be referred for HCV specialty care (63% versus 34%); to receive HCV-specific evaluation (41% versus 21%); to be offered HCV treatment (22% versus 9%); and to initiate treatment (9% versus 6%).

Comments: This study shows how buprenorphine treatment can facilitate the identification and treatment of other chronic medical problems. Treatment outcomes would likely have been improved further by providing HCV-specific evaluation and treatment at the buprenorphine treatment site.

Darius A. Rastegar, MD

Reference: Norton BL, Beitin A, Glenn M, et al. Retention in buprenorphine treatment is associated with improved HCV care outcomes. *J Subst Abus Treat*. 2017;75:38–42.

PRESCRIPTION DRUGS & PAIN

Patients Treated by Higher-Intensity Opioid-Prescribing Emergency Physicians Are More Likely to Develop Persistent Opioid Use

Increasing prescribing of opioids for acute and chronic pain has led to increasing harms, including opioid use disorder, overdose, and death. Researchers used a database of Medicare beneficiaries to investigate the association between emergency physician opioid-prescribing patterns and the risk of long-term use. They included patients who had not received an opioid prescription in the 6 months prior to the index visit and excluded those in hospice or with a cancer diagnosis. Emergency physicians were classified based on the proportion of visits that led to a filled opioid prescription compared with colleagues at their own institution; those in the highest quartile were defined as "high-intensity" prescribers and those in the lowest quartile as "low-intensity." The sample included 215,678 patients treated by a low-intensity opioid prescriber and 161,951 treated by a high-intensity prescriber between 2008 and 2011.

- The average rate of opioid prescribing by high-intensity prescribers was 3.3 times higher than that of low-intensity prescribers (24% of visits versus 7%).
- Long-term opioid use (defined as ≥180 days of opioids dispensed in the 12 months after the index visit) was significantly higher among those treated by a high-intensity prescriber (adjusted odds ratio [aOR], 1.30). For every 49 patients prescribed an opioid in the emergency department, 1 developed subsequent long-term use.
- Patients treated by a high-intensity prescriber were more likely to have a hospital encounter for fall or fracture in the 12 months after the index emergency department visit (aOR, 1.07). There was no increase in short-term emergency department visits for inadequately treated pain among those seen by a low-intensity prescriber.

Comments: This study reinforces previous observations that short-term opioid prescribing can lead to long-term use. While we cannot tell how many of the people with long-term use developed problems with opioids, these findings argue for more judicious use of opioids, even in situations where the intent is to prescribe only a short course of treatment.

Darius A. Rastegar, MD

Reference: Barnett ML, Olenski AR, Jena AB. Opioid-prescribing patterns of emergency physicians and risk of long-term use. *N Engl J Med*. 2017;376(7):663–673.

Patients with Opioid Use Disorder Diagnosed Before and After Chronic Pain Diagnoses Have Differing Patterns of Other Diagnoses

Research in substance use disorder (SUD) treatment settings has identified high rates of chronic pain among patients with opioid use disorder (OUD), but less information is available about the prevalence of chronic pain and other clinical characteristics of those identified with OUD in general medical settings. This study compared electronic health record (EHR) SUD, mental health, and other health condition diagnoses among 4 groups of patients with OUD in a general healthcare system: those with OUD and no chronic pain; those with OUD diagnosis prior to a pain diagnosis; those with OUD and pain diagnoses at the same time point; and those with a chronic pain diagnosis prior to OUD.

- Of 4.6 million patients seen between 2006 and 2015, 5307 had a diagnosis of OUD (0.1%).
- Two-thirds (64%) of patients with OUD had a chronic pain diagnosis; of these, 62% had a chronic pain diagnosis prior to OUD diagnosis.
- Patients with OUD diagnosed prior to chronic pain had higher rates of other SUD diagnoses, as well as higher rates of HIV and hepatitis C.
- Patients with pain diagnoses prior to OUD had the highest rates of mental health disorders as well as multiple chronic medical problems.

Comments: Although it was limited by the unknown accuracy of EHR diagnoses, this study was able to identify patterns of mental health, SUD, and chronic medical diagnoses in different groups of patients with OUD and chronic pain. The high rates of chronic pain diagnoses among patients with OUD likely reflects the general medical setting, with low overall rates of OUD diagnoses and likely low rates of OUD treatment availability. The interplay of chronic pain and OUD in this setting indicates the complexity facing general medical care providers.

Joseph Merrill, MD, MPH

Reference: Hser YI, Mooney LJ, Saxon AJ, et al. Chronic pain among patients with opioid use disorder: Results from electronic health records data. *J Subst Abuse Treat*. 2017;77:26–30.

Worsening, Fluctuating Pain Increases Return to Prescription Opioids after Buprenorphine-Naloxone Taper, but Additional Drug Counseling Might Help

Patients with opioid use disorder (OUD) who have chronic pain and receive addiction treatment are at the greatest risk of return to opioid use. To determine whether pain trajectory (i.e., worsening) and volatility (i.e., fluctuating) predict opioid use after buprenorphine-naloxone (BUP-NLX) taper, this secondary analysis examined 125 patients with OUD and chronic pain who received a BUP-NLX taper in phase 2 of the multisite Prescription Opioid Addiction Treatment Study (POATS). POATS recruited from community clinics affiliated with a national clinical trials network in 10 US cities.

- Opioid use increased during the 4-week taper period, from 22% of urine screens positive in week 13 to 31% in week 16.
- While baseline pain severity was not predictive, increasing pain over time (time slope odds ratio [OR], 2.38), as well as greater pain volatility (OR, 2.43) during BUP-NLX treatment predicted any opioid use during the taper phase. Increasing pain over time (incidence rate ratio [IRR], 1.4), as well as greater pain volatility (IRR, 1.66) during BUP-NLX treatment similarly predicted more days per week of opioid use.
- Additional drug counseling lowered opioid use (OR, 0.17) in the subgroup with chronic pain, even though it did not demonstrate effects in the overall study.

Comments: This study suggests that the dynamics of chronic pain (i.e., worsening or fluctuating) are better predictors of return to opioid use than its static severity. This finding makes intuitive sense as an exacerbating or waxing-waning pattern makes it difficult for patients to acclimate to a stable level of pain. An unexpected finding was the benefit of additional drug counseling in the subgroup with chronic pain, which perhaps teaches coping skills to prevent it from triggering recurrent use. This finding merits replication.

Peter D. Friedmann, MD

Reference: Worley MJ, Heinzerling KG, Shoptaw S, Ling W. Volatility and change in chronic pain severity predict outcomes of treatment for prescription opioid addiction. *Addiction*. 2017;112(7):1202–1209.

Call for Papers

Addiction Science & Clinical Practice (*ASCP*), founded in 2002 by the National Institute on Drug Abuse (NIDA) and now published by leading open-access publisher BioMed Central, is seeking submissions.

Editor-in-Chief
Jeffrey H. Samet, MD, MA, MPH

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Journal of Substance Abuse Treatment
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Journal of Viral Hepatitis
Lancet
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Psychiatric Services
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Many others periodically reviewed (see www.aodhealth.org).

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This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of Boston University School of Medicine and Boston Medical Center. Boston University School of Medicine is accredited by the ACCME to provide continuing medical education for physicians. Boston University School of Medicine designates this enduring material for a maximum of 1.5 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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.

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