Alcohol, Other Drugs, and Health: Current Evidence

JULY–AUGUST 2011

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INTERVENTIONS & ASSESSMENTS

FDA Approves Long-Acting Injectable Naltrexone for Opioid Dependence

In October 2010, the Food and Drug Administration (FDA) approved a long-acting injectable formulation of naltrexone (XR-NTX) for the prevention of relapse to opioid dependence following opioid detoxification. This approval was based, in part, on a 24-week double-blind randomized controlled trial comparing 380 mg XR-NTX with placebo among 250 subjects with opioid dependence conducted at 13 clinical sites in Russia. Both groups received 12 counseling sessions (1 every 2 weeks). The primary outcome was abstinence confirmed by self-report and urine drug tests. The study population was 88% male, 41% HIV-infected, and 91% hepatitis-C antibody positive and had a mean of 9–10 years of opioid dependence.

- The trial was completed by 46% of the subjects: 53% in the XR-NTX group and 38% in the control group (p=0.02).
- Confirmed abstinence for weeks 5–24 was 36% in the XR-NTX group compared with 23% in the placebo group (p=0.02).
- Secondary outcomes of opioid craving, number of days retained in treatment, and receipt of all injections were better in the XR-NTX group compared with placebo.
- Serious adverse events were uncommon, although any adverse event was reported by 50% of the XR-NTX group and 32% of the placebo group (p=0.001). Only 2 subjects in each group discontinued the trial because of adverse events.

Comments: This study provides support for the use XR-NTX in places where opioid agonist treatment (methadone or buprenorphine) is not available or in patients who cannot tolerate or prefer not to take these treatments. FDA approval based on data from 1 industry-sponsored and designed study, conducted in a setting where treatment conditions are substantially different from the US, has been questioned because of generalizability concerns, because less than half of the subjects completed the trial, and because there was no surveillance for overdose (a known risk among detoxified opioid-dependent patients). Before wide dissemination in the US, a trial comparing XR-NTX with opioid agonist treatment, the current standard of care, is warranted.

Alexander Y. Walley, MD, MSc

References: Krupitsky E, Nunes EV, Ling W, et al. Injectable extended-release naltrexone for opioid dependence: a double-blind, placebo-controlled, multicentre randomised trial. *Lancet.* 2011;377(9776):1506–1513.

Wolfe D, Carrieri MP, Dasgupta N, et al. Concerns about injectable naltrexone for opioid dependence. *Lancet.* 2011;377 (9776):1468–1470.

Low-dose Topiramate for Alcohol Dependence

Topiramate 150–300 mg per day can reduce alcohol craving and relapse in patients with alcohol dependence, but adverse effects at these dosages lead to frequent discontinuation. In this paper, researchers randomized 90 alcohol-dependent patients who completed a 7–10 day inpatient detoxification protocol to open-label low-dose topiramate (up to 75 mg per day) (n=30) or to no medication (n=60). All participants received 4–6 weeks

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Low-dose Topiramate for Alcohol Dependence (continued from page 1)

of inpatient cognitive behavioral therapy following detoxification. Participants were assessed 3 times during inpatient treatment and provided self-reported alcohol use weekly for 16 weeks after discharge.

- Depression, anxiety, and obsessive-compulsive drinking scores were significantly lower in the topiramate group than in the control group at the second and third inpatient assessments.
- Relapse to any drinking 16 weeks after discharge was lower in the topiramate group (67%) than in the control group (86%) (hazard ratio, 0.52; p=0.014).
- The most common adverse effects in the topiramate group were dizziness (20%), somnolence (23%), psychomotor slowness (13%), and nausea (17%). Only somnolence differed significantly from the control group.

Comments: Low-dose topiramate appeared to decrease mood symptoms and alcohol relapse over a short timeframe in this small nonblinded trial set within a rather intensive treatment program. Although low-dose topiramate has potential for treating alcohol dependence, larger blinded trials in the outpatient setting, with longer follow-up and comparisons to other agents, are needed.

Kevin L. Kraemer, MD, MSc

Reference: Paparrigopoulos T, Tzavellas E, Karaiskos D, et al. Treatment of alcohol dependence with low-dose topiramate: an open-label controlled study. *BMC Psychiatry.* March 14. 2011;11:41.

Brief Intervention May Have Efficacy for Alcohol Dependence in Emergency Departments

The evidence for alcohol screening and brief intervention (BI) efficacy is mixed for people in emergency departments (EDs) and almost nonexistent for people who meet criteria for alcohol dependence. In this study, patients with suspected alcohol-related presentations to the ED of a university hospital and another general hospital were screened for alcohol use disorders. Some patients were hospitalized, some were not. Assessments were conducted by an alcohol specialist nurse in the university hospital and a research nurse in the other hospital. Patients with an AUDIT* score >16 were further assessed with the SADQ.** Those who scored positive for dependence and no intravenous drug use at the university hospital, but not the other hospital (n=100 at each), received BI (at least 1 intervention; median, 4). The research nurse completed 6-month follow-up interviews with 52% of patients who received BI and 50% of those who did not.

- In a descriptive analysis, 37% of patients in the BI group and 0% in the comparison group reported abstinence.
- In statistical analyses adjusted for baseline imbalances, patients in the BI group reported lower severity-of-dependence and AUDIT scores. They also reported fewer drinks per day (8 versus 23) and drinking days (3.7 versus 5.6) in the past month.
- There was a trend toward lower ED and hospital utilization among BI subjects, but the difference was not significant.

Comments: The study has some limitations, the main ones being substantial loss to follow-up and lack of randomization. The researchers appropriately suggest this study be followed up by a randomized trial. But, the work is important because it suggests patients with alcohol dependence (at least those with alcohol-related acute presentations), who have traditionally been excluded from BI trials, may benefit from identification and BI.

Richard Saitz MD, MPH

Reference: Cobain K, Owens L, Kolamunnage-Dona R, et al. Brief interventions in dependent drinkers: a comparative prospective analysis in two hospitals. *Alcohol Alcohol.* 2011;46(4):434–440.

*Alcohol Use Disorders Identification Test.
**Severity of Alcohol Dependence Questionnaire.

Home- versus Office-based Buprenorphine Induction: Impact on Opioid and Other Drug Use

Home-based buprenorphine induction is gaining increasing attention, yet adequate description and evaluation of this novel strategy is lacking. Prior analysis showed that 30-day treatment retention was similar among patients choosing home-based versus office-based induction. In this subgroup analysis of the same observational cohort, 79 patients who chose either home-based or office-based induction were assessed to determine the association between induction strategy and drug-use outcomes over 6 months. Data analysis included mixed nonlinear models.

- Compared with office-based induction, participants choosing home-based induction:
  - had no significant differences in self-reported opioid use.
  - had a greater reduction in self-reported use of other drugs (adjusted odds ratio, 0.05).

Comments: Although limited by small sample size, lack of randomization, and self-reported drug use rather than urine toxicology testing, these results suggest that location of induction may have no effect on drug use outcomes. Larger experiments with assessment of safety and patient satisfaction are needed.

Jeanette M. Tetrault, MD

Reference: Cunningham CO, Giovanniello A, Li X, et al. A comparison of buprenorphine induction strategies: patient-centered home-based inductions versus standard-of-care office-based inductions. *J Subst Abuse Treat.* 2011;40(4): 349–356.

Supervised Injecting Facilities Associated with a Reduction in Overdose Mortality

Supervised injecting facilities (SIFs) have the potential to improve access to health care and drug treatment and reduce needle sharing and overdose deaths. This study used coroner death reports and census data to examine the impact of a newly established SIF in Vancouver, Canada, on illicit-drug overdose mortality in the surrounding area, where 70% of the clients resided. The SIF provided clean needles, referral to primary health services, and emergency care but did not provide any drugs. Mortality data for the period before establishment of the SIF (January 2001–September 2003) and after (September 2003–December 2005) were compared.

- In the city blocks within 500 meters (0.31 miles) of the SIF, overdose mortality declined from 254 to 165 deaths per 100,000 person-years (a decline of 35%).
- In the remainder of Vancouver, overdose mortality declined from 7.6 to 6.9 deaths per 100,000 person-years (not significant).
- There was no change in enrollment in methadone maintenance programs in any Vancouver area before or after establishment of the SIF.

Comments: Despite its pre/post design, this study provides evidence that SIFs are associated with reduced overdose deaths, which is only 1 of a number of potential benefits. The authors did not address the main argument against these facilities, which is that they may encourage injection drug use, but the fact that overdose deaths did not increase in other areas is reassuring.

Darius A. Rastegar, MD

Reference: Marshall BD, Milloy MJ, Wood E, et al. Reduction in overdose mortality after the opening of North America's first medically supervised safer injecting facility: a retrospective population-based study. *Lancet.* 2011;377 (9775):1429–1437.

Treatment of Tuberculosis with Rifampin Induces Opioid Withdrawal in Patients Maintained on Buprenorphine

Potential buprenorphine interactions with medications for tuberculosis (TB), HIV, and other common comorbid illnesses among opioid-dependent patients are important to identify. Rifampin, a cytochrome P 450 enzyme-inducing medication used to treat TB, has the potential to decrease buprenorphine levels, leading to clinical withdrawal symptoms and possibly relapse. In this pharmacokinetic study, investigators compared the impact of 15 days of either rifampin (n=12) or rifabutin (n=9), another TB medication, coadministered with buprenorphine-naloxone (BUP/NLX) in BUP/NLX-maintained patients with TB.

- Both rifampin and rifabutin decreased buprenorphine pharmacokinetic measures, including area under the curve (AUC), maximum plasma concentration (C_{max}), and trough plasma concentration (C_{24}).
- Rifampin, but not rifabutin, was associated with significant decreases in pharmacokinetic parameters of norbuprenorphine (an active buprenorphine metabolite), including AUC, C_{max}, and C_{24}.
- Clinical opioid withdrawal was observed in 6 of the 12 rifampin-administered subjects as early as 6 days after starting rifampin. Withdrawal was not observed in rifabutin-administered subjects.
- Increased BUP/NLX offered to participants in withdrawal alleviated symptoms with dose increases of 25–100%.

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Rifampin for Comorbid TB Induces Opioid Withdrawal in Buprenorphine Patients (continued from page 3)

Comments: This important study describes withdrawal symptoms among BUP/NLX-maintained patients being treated for TB with rifampin. Rifabutin did not cause withdrawal, however, it is expensive, which may preclude widespread use. Clinicians need to be aware of the BUP/NLX-rifampin interaction and pre-empt possible relapse or treatment dropout with patient counseling. Although dose adjustments of BUP/NLX may alleviate withdrawal symptoms in patients treated with rifampin, longer term studies are needed to confirm the efficacy of this approach.

Hillary Kunins, MD, MPH, MS

Reference: McCance-Katz EF, Moody DE, Prathikanti S, et al. Rifampin, but not rifabutin, may produce opiate withdrawal in buprenorphine-maintained patients. *Drug Alcohol Depend.* May 18, 2011 (E-pub ahead of print). doi: 10.1016/j.drugalcdep.2011.04.013.

How They Do It: Physicians Describe Building a Physician-Patient Relationship with People Who Use Illicit Drugs

Primary care clinicians receive little guidance on building a doctor-patient relationship with people who actively use illicit substances. To describe the approach experienced family physicians (FPs) use with female patients who are illicit drug users, investigators performed qualitative analyses of in-depth interviews with 10 FPs. Purposeful sampling ensured variation among participants. Sampling ceased once no new emergent themes were identified during interviews.

- A 2-phase doctor-patient relationship was identified:
  - Engagement Phase—The physician established the relationship over multiple interactions. A "testing period" typically occurred, during which trust was established. Other features included creating a calm presence to deflect patients' chaos, communicating acceptance to patients, and demonstrating to patients that they would not be abandoned.
  - Maintenance Phase—Physicians reported the importance of continuity of care and "meeting people where they're at." Continuity was characterized as "intense and frequent visits over short periods of time, followed by extended absences." "Meeting people where they're at" was described as not pushing patients too hard and allowing them to set their own priorities.

Comments: This study suggests strategies for the novice health-care provider to engage and maintain active illicit drug users in care. The depiction of continuity as periods of intensity followed by absences is a helpful reminder to welcome patients back to care when they're ready. Whether these longitudinal patient-physician relationships improve health outcomes for patients with active illicit substance use ought to be studied.

Hillary Kunins, MD, MPH, MS

Reference: Woolhouse S, Brown JB, Thind A. 'Meeting people where they're at': experiences of family physicians engaging women who use illicit drugs. *Ann Fam Med.* 2011;9 (3):244–249.

HEALTH OUTCOMES

Higher Prescribed Opioid Doses Are Associated with Overdose Deaths

Opioid prescribing has risen dramatically in the past 2 decades accompanied by a rise in unintentional overdose deaths. This study used Department of Veterans Affairs prescription and diagnosis data from patients who received medical care in 2004 or 2005 to compare the 750 subjects with unintentional opioid overdose death by the end of 2008 with a random sample of 154,684 subjects who received opioids for pain. Patients prescribed methadone were not included.

- The estimated overall risk of overdose was 0.04%.
- In the unadjusted analysis, subjects who overdosed were more likely to have had chronic or acute pain as well as a substance use disorder or psychiatric diagnosis and were less likely to have had cancer.
- In adjusted analyses of subgroups with chronic pain, cancer, acute pain, or substance use disorders, an increased risk of overdose death was seen in morphine dose equivalents of ≥50 mg per day in all 4 groups.

Comments: This study confirms prior observations of an (continued on page 5)

Higher Prescribed Opioid Doses Associated with Overdose Deaths (continued from page 4)

association between opioid dose and overdose risk and points out that this is also a concern for patients with cancer. Although the overall risk of fatal overdose appeared to be low, a limitation of this and other studies is how the cause of death is determined; deaths are not always investigated, particularly when the decedent is older or had chronic medical problems.

Darius A. Rastegar, MD

Reference: Bohnert AS, Valenstein M, Bair MJ, et al. Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA.* 2011;305(13):1315–1321.

Opioid-Related Death in Patients with Nonmalignant Pain

To assess the association between opioid dose and opioid-related death in patients with nonmalignant pain, researchers used administrative and pharmacy records to conduct a case-control study of 607,156 patients aged 15 to 64 years who received a prescription opioid between 1997 and 2006. Cases were opioid-related deaths as determined by a coroner. Controls were matched to cases based on age, gender, receipt of opioids during the year of the index date (date of case's death), comorbidity, and disease-risk index results. For cases and controls, the average daily opioid dose at the index date was calculated and converted into morphine equivalents in milligrams (mg). Four hundred ninety-eight opioid-related deaths and 1714 patients met criteria for inclusion as cases and controls, respectively.

- The average age of cases at the time of death was 43 years. The majority of deaths were accidental.
- Compared with controls, cases were more likely to have received psychotropic drugs, methadone, benzodiazepines, and antidepressants; to have used multiple physicians or pharmacies for opioid prescriptions; and to have current or past alcohol dependence.
- In analyses controlling for confounders, when compared with a reference of <20 mg morphine equivalents, increasing daily opioid dose was associated with greater risk of opioid-related death:
  - 20–49 mg (odds ratio [OR], 1.3).
  - 50–99 mg (OR, 1.9).
  - 100–199 mg (OR, 2.0).
  - ≥200 mg (OR, 2.9).

Comments: This study showed increasing risk of opioid-related death as the daily dose increased, including a 3-fold increase in risk at doses (≥200 mg per day) that exceed recommendations for nonmalignant pain. Although the absolute risk of opioid-related death is low, the results argue for clinical caution when prescribing opioids for nonmalignant pain; for identifying risks such as alcohol dependence or use of other psychoactive medications; and for assuring appropriate opioid dosage and mitigation of use in patients taking other prescribed medications.

Kevin L. Kraemer, MD, MSc

Reference: Gomes T, Mamdani MM, Dhalla IA, et al. Opioid dose and drug-related mortality in patients with nonmalignant pain. *Arch Intern Med.* 2011;171(7):686–691.

Predictors of Seizures and Delirium Tremens in the Course of Alcohol Withdrawal

Identifying predictors of alcohol withdrawal seizures (AWS) and delirium tremens (DTs) among patients hospitalized for alcohol withdrawal could be helpful to clinicians. Researchers in Germany retrospectively studied a cohort of 827 adult patients admitted to a hospital intensive-care unit for alcohol detoxification (elective and emergency admissions). Patients received score-guided treatment with clomethiazole started simultaneously with an antiepileptic (valproic acid or carbamazepine) as well as clonidine when noradrenergic hyperactivity was present and haloperidol when there were hallucinations. The researchers used stepwise logistic regression models to identify predictors of AWS and DTs.

- Of the 827 patients, 5.6% had DTs and 7.4% had AWS.
- Significant predictors of AWS, independent of medication administered, were past structural brain lesions* (odds ratio [OR], 6.5), AWS as the cause of admission (OR, 2.6), and delayed peak of withdrawal severity since admission (OR for every 10-hour increase, 1.23).
- Significant predictors of DTs, independent of medication administered, were past structural brain lesions (OR, 5.8), lower platelet count (OR per increase of 100.000, 0.42), and lower serum potassium level (OR per increase of 1 mmol/l, 0.33).

Comments: The authors provide 2 nomograms to help clinicians predict the risk of AWS and DTs using available clinical data. By identifying patients at higher risk for AWS

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*Past cerebral trauma or hemorrhage, benign or malignant tumor, past neurosurgical interventions, epilepsy.

Predictors of Seizures and DTs in Alcohol Withdrawal (continued from page 5)

or DTs, clinicians could monitor them more closely and treat them earlier and more aggressively if needed. It is important to point out, however, that although analyses were adjusted for the amount of medication received, these results reflect predictors in a cohort receiving a specific treatment and may differ when other medications for alcohol withdrawal, such as benzodiazepines, are prescribed. Results should be replicated in a prospective cohort of patients receiving benzodiazepines.

Nicolas Bertholet, MD, MSc

Reference: Eyer F, Schuster T, Felgenhauer N, et al. Risk assessment of moderate to severe alcohol withdrawal--predictors for seizures and delirium tremens in the course of withdrawal. *Alcohol Alcohol.* 2011;46(4):427–433.

Subtle Change in Drinking Guidelines Could Have Increased Alcohol-related Harm

In 2010, the US Departments of Agriculture and Health and Human Services considered changing recommended drinking levels in the *Dietary Guidelines for Americans.* "Moderate" drinking guidelines had been 1 drink or less for women (2 for men) on any 1 day. The proposed change was 1 drink or less for women (2 for men) per day on average and 3 (4 for men) or fewer on any 1 day.* Researchers assessed the impact the proposed guidelines would have on alcohol-related harm by assessing risks in a nationally representative longitudinal sample of adult drinkers (2 survey assessments 3 years apart, n=26,438). People drinking amounts within the proposed guidelines, but exceeding the established guidelines, were deemed to be in the "gray zone" of consumption.

- Compared with those drinking lower risk amounts, those in the gray zone had a significantly increased incidence of alcohol dependence (adjusted odds ratio [OR], 1.5; population attributable fraction† [PAF], 9%) in 3 years.
- The OR and PAF were 1.8 and 9%, respectively, for alcohol-related interpersonal problems.
- The OR and PAF were 2.3 and 3%, respectively, for past-year dependence and 1.2 and 5%, respectively, for job loss.

*The same as current National Institute on Alcohol Abuse and Alcoholism (NIAAA) limits.
†The proportion of drinkers who would experience alcohol-related harm due to gray-zone consumption.

Comments: The proposed guidelines did not go into effect, and this analysis suggests that decision avoided substantial population harm. To some, a change to an average daily limit may seem subtle. But, as suggested by Naimi, it would have been interpreted as condoning up to 3 drinks daily for women (4 for men) as long as average limits were not exceeded. He provides the following analogy: the change would be like a guideline for low-risk drinking and driving that condones drinking up to a blood alcohol concentration of 0.079%, a level at which there is substantial impairment (despite the 0.080% legal limit for driving in the US). Simply put, dietary guidelines that recommend what to eat and drink for health should not be the same as limits that indicate health risks.

Richard Saitz MD, MPH

References: Dawson DA, Grant BF. The "gray area" of consumption between moderate and risk drinking. *J Stud Alcohol Drugs.* 2011;72(3):453–458.

Naimi TS. "Gray area" alcohol consumption and the U.S. Dietary Guidelines: A comment on Dawson and Grant (2011). *J Stud Alcohol Drugs.* 2011;72(4):687.

Lower Risk of Heart Disease from Alcohol, Even with Hazardous Drinking?

Researchers assessed the relationship between coronary heart disease (CHD) and alcohol consumption using data from the 2001–2002 National Epidemiologic Survey on Alcohol and Related Conditions study (NESARC, n=43,093). The sample included 16,147 people who were abstinent, 15,884 who drank moderate amounts, 9578 who drank hazardous amounts, and 1484 who were alcohol dependent.* Participants were asked whether they had CHD in the last 12 months as confirmed by a doctor.

- Both moderate and hazardous drinking were associated with decreased odds of CHD when compared with abstinence, whereas odds of CHD were not significantly different between abstinent and alcohol-dependent participants.
- In multivariable analyses controlling for sociodemographic, psychiatric, and addictive risk factors, both moderate and hazardous drinking were associated with a decreased likelihood of CHD.

*Moderate drinking was defined as having at least 1 drink in the past year but not meeting criteria for hazardous drinking or dependence. Hazardous drinking was defined as exceeding weekly limits (men, >14 drinks per week; women, >7 drinks per week) or exceeding daily limits (men, ≥5 drinks per day; women, ≥4 drinks per day) in the past year. Dependence was diagnosed using DSM-IV criteria.

Comments: The authors conclude that alcohol may be cardioprotective not only in individuals who drink moderately but also in those who drink amounts

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Hazardous Drinking and CHD (continued from page 6)

traditionally considered to be hazardous. However, the method used to diagnose CHD raises concerns: only 1% of subjects reported having had myocardial infarction in the past year, the primary "hard" endpoint for CHD, whereas most reported angina pectoris, a "softer" endpoint for CHD. Further, subjects who quit drinking due to illness or those with hazardous drinking who died earlier than healthy subjects may have confounded results. Another possibility is that the definition of "hazardous drinking" in this study was too inclusive, including some people who might better be classified as moderate drinkers. If indeed hazardous drinking does not increase the risk of CHD, it is possible that the increase in cardiovascular disease from heavy drinking reported in other studies may be due to arrhythmias, cardiomyopathy, or other effects of alcohol, and not from coronary artery disease.

R. Curtis Ellison, MD

Reference: Le Strat Y, Gorwood P. Hazardous drinking is associated with a lower risk of coronary heart disease: Results from a national representative sample. *Am J Addict.* 2011;20(3):257–263.

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