The Carlat Report

On Psychiatric Treatment

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The New(er) Drugs for Alcoholism

Reviewing the new medications for alcoholism brings us into a pharmacologic netherworld. Nothing is very clear, and when you think you've finally come to a conclusion, a new study comes along to cast a fresh fog over everything.

We'll start with naltrexone (brand name ReVia), currently the only medication other than Antabuse (disulfiram) to be FDA-approved for alcoholism. Naltrexone blocks opiate receptors, and presumably helps prevent relapse by depriving the drinker of a secondary opiate-induced "buzz" that would normally lead to a craving for more. It's a longer-acting version of Narcan, which is used to quickly revive drug users from a heroin-induced stupor in the ER.

Naltrexone has disappointed; Acamprosate is seeking FDA approval

The first big naltrexone paper came out with much fanfare in 1992 (*Arch Gen Psychiatry* 1992;49:876-880), and showed that after 12 weeks of treatment, only 23% of hard core VA alcoholics relapsed vs. 54% of those receiving placebo. A second positive study led to FDA approval, but since then, results have been mixed. Some of these contrary results were explained away because they came out of Europe, where patients enter clinical trials after a period of abstinence and tend not to be addicted to other substances as well. Thus, they may be less "severe" than the American subjects and thus less responsive to the effects of naltrexone.

Unfortunately, a large negative U.S. trial was published 3 years ago from a VA system, looking at 600

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All About...Antabuse!

Guess what: Antabuse (disulfiram) is back in fashion, over a half century after its initial approval by the FDA. You have probably seen some of the infomercials funded by Odyssey Pharmaceuticals and published as supplements by the usual journals. Whether the renewed interest in Antabuse has been fueled by this advertising, or whether Odyssey is taking advantage of a spontaneous groundswell of clinical interest, is immaterial. The fact is, Antabuse is a very useful tool for a subsegment of your alcohol-using patients, and you'd do well to learn about it.

Its mechanism of action is infamous. **It inhibits the metabolism of acetaldehyde**, which is a metabolic byproduct of alcohol. High levels of acetaldehyde cause extreme discomfort, including nausea, vomiting, throbbing headache, dizziness, and flushing. While cardiovascular collapse and even death are theoretical results, I have yet to meet a clinician who has actually seen a patient become severely ill from an Antabuse reaction. An

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Next Month in *The Carlat Report*: All abou **PTSD**, with articles on meds that work, effective therapies, and an interview with PTSD guru Dr. Edna Foa.

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Focus of the Month:
Treatment of Alcoholism
Guest Editor: Stuart Gitlow, M.D.

- **The New(er) Drugs for Alcoholism**
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- **Alcoholics Anonymous:** A Primer
- **Expert Q & A:** Dr. Stuart Gitlow on using Benzodiazepines in Alcoholism

The New(er) Drugs for Alcoholism

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patients, who were randomly assigned to one of three arms: 12 months of naltrexone (50 mg daily); three months of naltrexone followed by nine months of placebo; or 12 months of placebo (*N Engl J Med* 2001;345:1734-1739). The results? No difference at all among the three groups, in rate of relapse or percentage of drinking days.

So is naltrexone a fancy placebo after all? Many researchers are still standing by their med, but the recent data do not impress.

Acamprosate. Europe has been much kinder to acamprosate than it has to naltrexone. Fourteen of sixteen controlled trials have shown it to be effective for reducing drinking (*Med J Aust* 2002;177:103-107), and it is an approved medication for alcoholism throughout Europe and Latin America.

Back here in the US of A, the FDA's Psychopharmacological Drugs Advisory Board voted by an 8 to 2 margin that acamprosate is indeed effective at promoting sobriety, but nonetheless the FDA issued a "non-approvable letter" to Forest pharmaceuticals in July 2002. Apparently, an unpublished U.S. trial comparing acamprosate to placebo was unimpressive, and the FDA wants to see more data. Experts in the field are fairly certain that it will gain approval eventually.

How does acamprosate work? By calming down the glutamate system, which becomes overly excitable as a result of chronic alcohol abuse. Too much glutamate activity seems to be one of the things driving alcoholics toward that next drink.

Acamprosate is extremely well-tolerated, with much milder GI side effects than naltrexone, and no liver toxicity. One weird thing about it is that it comes in 333 mg tablets, and the recommended daily dose is a bizarre "1998 mg" per day. To make matters worse, it's supposed to be dosed as 2 tablets TID. As compared to this byzantine dosing schedule, naltrexone's a breeze at 50 mg a day, period.

It may be that combining acamprosate with naltrexone is the way to go. A recent Archives of General Psychiatry article showed a relapse rate of only 25% on the combination therapy 12 weeks after detox, as compared to 50-60% relapse rates on naltrexone or acamprosate alone (*Arch Gen Psych* 2003;60:92-99).

Zofran (odansetron). Zofran is the fabulously expensive anti-emetic used for treating nausea induced by chemotherapy in cancer patients. Over the years, it has wended its way into alcoholism research, largely because it blocks 5HT 3 receptors, and any medication that touches serotonin is fair game for any indication in psychiatry. It so happens that most of the serotonin data in alcoholics implies a serotonin *deficiency*, which would not logically endorse a serotonin-*blocking* drug like Zofran, but such technicalities can be massaged away by using terms in research papers such as "serotonin modulation" and the like.

A single controlled trial of Zofran in alcoholics has been published (*JAMA* 2000;284:963-971) and showed that it modestly reduced drinking relative to placebo, but only in the early-onset group. "Early-onset" alcoholics, also known in the field as "Type II" or "Type B" alcoholics, have onset before age 25, have a strong family history of alcoholism, and have antisocial personality traits. The optimal dose was less than 0.5 mg QD, which can only be achieved by prescribing the oral solution (4 mg/5 ml). It's worth a try when nothing else works.

Topamax. Yes, Topamax (topiramate), the drug that everybody wishes would work for everything (because it causes weight loss as a side effect--see *TCR* 1:9) has been tested in alcoholism and seems to beat placebo (*Lancet* 2003;361:1677). 150 alcoholic men and women were randomised to either Topamax or placebo; all patients also received weekly 20 minute brief therapy sessions with study nurses who were blind to the treatment. In the Topamax group, the dose was titrated up very gradually to 150 mg BID. On the average, Topamax patients had significantly fewer drinks and more days of abstinence than the placebo group at the 12 week endpoint. ❖

Medications to try for Alcoholism

Medication	Mechanism	Dosage	Notes
ReVia (naltrexone)	Opiate blocker	50 mg QD	Recent large VA study was negative
acamprosate	Modulates Glutamate	666 mg TID	Approved in many countries, but not in U.S.
Zofran (odansetron)	5HT3 Blocker	0.5 mg QD	Shown effective for early-onset alcoholics only
Topamax (topiramate)	Stimulates GABA	150 mg BID (Titrate slowly)	Only one controlled trial so far

TCR VERDICT: *Meds for Alcoholism: We're far from Panacea*

All About...Antabuse!

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accurate way of describing the Antabuse reaction to a patient is: "You'll wish you were dead, but it won't kill you."

How does the drug help? Classified as an "aversive" treatment, **Antabuse provides an extra layer of motivation to those of your patients who are already highly motivated to stop drinking**. A good Antabuse candidate screening question is: "Are you able to make a commitment to me and to yourself right here and now that you are ready to say goodbye to alcohol forever?" A "yes" answer may or may not be sincere, but it's a good start. Patients who sort of grit their teeth and say "I don't know, forever's a long time" are much less likely to benefit from Antabuse. They will either not fill the prescription or they'll make a plan to stop taking it on a Monday in order to drink on a Friday.

The typical good Antabuse candidate is a sales rep with several one to two day relapses of alcohol use divided by long periods of sobriety. He knows if he relapses, he'll end up out of a job, but finds the temptation when he is on the road, away from his usual AA meetings, to be too great to deal with. Antabuse is a good check on his impulsivity.

Research-wise, few controlled trials have been done on Antabuse; the largest and most widely cited was published back in 1986 (*JAMA* 1986;256:1449). In this study of 605 alcoholic males in the VA system, the subjects were divided into three treatment arms: 202 patients were given Antabuse 250 mg QD, 204 were given Antabuse at only 1 mg QD, and 199 were given riboflavin. The patients in the Antabuse arms were all told that they were taking Antabuse, but were not told the dose. The riboflavin group was told they were taking vitamins.

What was the point of the 1 mg arm of the study? To evaluate whether or not the active aspect of Antabuse treatment is merely the psychological threat of a reaction, in the absence of a possibility of an actual reaction.

Antabuse Dosing Guidelines

Start at 125 mg QD X 1 week, then increase to 250 mg QD.

Check baseline LFTs and periodically thereafter.

After one year of treatment, there was good news and bad news. The bad news was that there was no difference in the percentage of men remaining abstinent. The good news was that in the subpopulation of men who attended all the scheduled followup research appointments, Antabuse 250 mg significantly decreased drinking days vs. Antabuse 1 mg and vitamin. The bottom-line: Those alcoholics who are most highly motivated will do the best on Antabuse.

Now, down to the nitty-gritty of dosing and side effects.

Since Antabuse can rarely cause liver toxicity, it's good to check LFTs (liver function tests) at baseline, and then periodically thereafter. "Periodically" may mean monthly initially then every 3 months for the more obsessive among us, and less frequently for others. A recent study of liver abnormalities in patients prescribed Antabuse was very reassuring, indicating that the drug rarely worsens liver problems even when baseline LFTs are elevated (*J Clin Psychiatry* 1998; 59: 313-316). Don't give Antabuse to patients on Flagyl or to patients with severe cardiac problems.

The common side effects are initial fatigue (so start it at bedtime), a metallic taste in the mouth, and GI side effects such as nausea or diarrhea. Tell patients not to drink Nyquil or other alcohol-based medicines. There is some lore that alcohol-based perfumes and aftershaves can seep into the blood and cause a reaction, but it's likely quite rare.

Dosing is also a matter of clinician preference. The package insert recommends starting at a whopping 500 mg QD to get robust blood levels early on but nobody does this. **A common strategy is to start at 125 mg QD** (you have to split the pill in half) for a week and then increase to a maintenance dose of 250 mg QD. However, some keep it at 125 mg QD on the theory that this is enough to cause a reaction with drinking, but low enough to minimize the risk of hepatic toxicity. If a patient reports drinking on 250 with no reaction, bump it up to 500.

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TCR VERDICT: *Antabuse Works! (For the Chosen Few)*

Q&A With the Expert

This Month's Expert:

Stuart Gitlow, M.D., *On Benzodiazepines and Alcoholism*

Medical Director, Family and Children's Service
Nantucket, Massachusetts
Author, Substance Use Disorders
Lipincott, Williams, and Wilkins 2001

TCR: Dr. Gitlow, let's get right into the issue of benzodiazepines. A typical scenario for many of us in office practice is that we will see a patient recently out of detox who will say, "Well doctor, I have always had terrible anxiety whether I have been drinking or not, I have tried this and I have tried that, and if I can't take something that will help my anxiety, I am sure I am going to start drinking again."

Dr. Gitlow: The way you phrase it is almost exactly the way it is always phrased. It is phrased in a manner by the patient that is meant to make the psychiatrist think or feel that the burden or the onus is on them. And I think psychiatrists need to be aware that the patient with the substance abuse disorder is almost always going to play it exactly that way.

TCR: So how do you recommend we deal with this?

Dr. Gitlow: The trick is to turn it around and place the burden of the illness back where it belongs, which is on the patient. If a diabetic patient came in and said to me, "If you don't give me medication X, I will purposely take 50 units of insulin when I only need 10," we would say to ourselves, "What a silly thing for the patient to say. What they are saying is that they are going to purposely make their illness worse or make themselves uncomfortable as a result of something that I do which is only in their best interest." That makes no sense. And by the same token, it makes no sense for an alcoholic to say he'll drink if he can't get benzos. You really have two different choices: one would be to keep them on the benzodiazepine as the result of the veiled threat they have made; the second would be to gradually taper it off as makes sense medically. Tapering them off might make them more uncomfortable, and they might actually pick up alcohol in part as a result of that. But if you leave them on the benzodiazepine on the same dose, it has to be done with the understanding that they are going to grow increasingly tolerant to that dose and in a month or two it will be even more difficult to taper them off. So, as far as I am concerned, it never pays to go down that path. It is only making things inevitably worse for the patient, although indeed in the short term it will assist them in getting through whatever level of anxiety they are experiencing.

"Controlled use of sedatives generally fails because the individual has not learned what modalities and interactions with other people are necessary when they feel stressed or uncomfortable .

— Stuart Gitlow, M.D.

TCR: Why are benzos so risky in alcoholic patients?

Dr. Gitlow: Because when you prescribe a benzodiazepine to an alcoholic, it isn't very different from saying to them, "You may have no more than 2.5 beers a day with the intake spaced out evenly throughout the day." That would be a measured amount of a sedative used in a controlled way. The problem is that anytime controlled drinking studies have been done, they have been shown to fail. And they inevitably fail for the same reason: because the individual has not learned what modalities and interactions with other people are necessary when they feel stressed or uncomfortable. So what will happen to them ultimately is that their house will burn down or they will lose a job or their kid will move across the country or something will happen that they will see as being traumatic and they will have nobody to turn to during the time of stress. And, in the meantime, they know that this 2.5 beers a day or the 20 mg of Valium has been helping them to feel better and therefore, why won't 3.5 beers or 30 mg of Valium be even better? And of course, they will be right. It will be better and for a short amount of time it will help. But they will find that when they go back to the originally prescribed dose they get quite anxious because now they are used to the higher dose, and you know where that ends.

TCR: What do you like to use instead of benzos for these patients?

Dr. Gitlow: I tend to minimize the use of any anti-anxiety drugs until I feel that somebody has hit a solid recovery.

Q & A With the Expert

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TCR: What constitutes "solid recovery"?

Dr. Gitlow: Do they have an AA sponsor? Do they have a good AA home group, that is, a meeting that they are going to repetitively and have gotten to know the people there well. Are they participating actively in their recovery and taking responsibility for their illness? If those pieces are in place, and there is still anxiety, I'll use medication, but this necessary in only about 15-20% of my patients.

TCR: What are your favorites non-addictive meds?

Dr. Gitlow: I will look at a few different classes. Out of the SSRIs and the newer generation antidepressants, I will use Paxil (10-60 mg QHS) or Remeron (7.5-30 mg QHS), because the level of sedation they provide can be helpful for anxiety and depression in alcoholics. I also frequently use Seroquel 25-50 mg either during the day for anxiety or at night, and I've had good success with Elavil at 25-50 mg HS.

TCR: Why do you like Elavil?

Dr. Gitlow: I find that alcoholics in recovery tend to complain of nightmares on Paxil or Remeron, whereas Elavil tends to cause a little amnesia about what happened overnight, so if they are having nightmares they don't remember them.

TCR: What about Ambien or Sonata? Some psychiatrists swear that these are addictive yet others feel they are pretty benign for alcoholics.

Dr. Gitlow: I haven't seen very much in the way of abuse of either of these medications; however, the way that they work is similar to benzos. Some patients who take these compare them to having a glass of brandy before bed and I don't want them coming close to thinking that.

TCR: Any other nostrums that come to mind that you find helpful?

Dr. Gitlow: BuSpar comes to mind. I know people tend to chuckle about BuSpar as being in many ways a placebo. On the other hand, over the years, I have found a small number of patients who seem to respond very nicely, and I tend to use it in concert with an activating drug like Wellbutrin. However, BuSpar alone doesn't seem very helpful for alcoholics because they look it up online, see that it is marketed as an antianxiety drug, assume that it will work like Valium and then be annoyed when it doesn't work quickly enough.

TCR: Let's shift to a different clinical scenario: The patient who has been sober for many years and has been on a stable dose of a benzo, without signs of abuse. How do you approach such patients?

Dr. Gitlow: I will tell them that it is not in their best interest to stay on the benzo, but if they have been taking medication for many years without any evidence of increasing the dose or having problems, and if they are not comfortable with the idea of discontinuing it, I won't. But many patients like this will eventually begin to feel as if they are having a problem. They might have read something that concerns them or felt the old twinges of wanting to take an extra pill, and at that point I will generally taper them off.

TCR: More easily said than done!

Dr. Gitlow: Very true, and one of the biggest problems that I see in the field is doctors attempting to taper such a patient from a benzo too rapidly. Almost anything is too rapid if the patient is feeling significant discomfort. If somebody has been on 3 or 4 mg of Klonopin a day for 5 years, I will often do a taper that takes nine or ten months. I might taper by 0.5 mg per day each month with the very last mg being reduced by 0.25 mg a month. I continue to divide the dose evenly throughout the day, rather than removing the morning, afternoon, or evening dose. Using this approach, I have not found any patients who cannot complete the taper nor have I met a patient who didn't feel better off the medication. They all feel worse each time the drug is lowered. They all feel certain that they are going to feel worse when the taper is complete and yet every one of them at the end of taper comes in and says that they feel significantly better off the drug.

TCR: In what way do they feel better?

Dr. Gitlow: They don't feel as sedated. They don't feel as clouded in their thought process. They don't feel that they put their car keys down and can't find them anymore. They don't feel as if they have to reread paragraphs in the paper in order to figure out what it says. They will always end up feeling brighter.

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Alcoholics Anonymous: A Primer

By now, it is clear that the most effective treatment for alcoholism is consistent attendance at AA (Alcoholics Anonymous) meetings. Not only have outcome studies shown that AA attendance promotes abstinence, but in addition, therapy aimed specifically at encouraging AA attendance has been shown to robustly increase the chances that patients will actually go to meetings and get sponsors (*Alcohol Research and Health*, 1999;23:93-98).

OK, fine. You know this, but if you are like many psychiatrists, you have only the barest sense of what happens at AA meetings and how to knowledgeably discuss them with your alcoholic patients.

The colorful history of AA begins in 1935, in Akron, Ohio, when a stockbrocker (named "Bill" in AA literature) met "Bob", a local surgeon. Both had been alcoholics, though Bill was sober when they met. Bill discussed the (at that time) new idea that alcoholism was a disease, and this struck a chord with the surgeon, who became sober, and the two formed a group that eventually became AA.

An AA meeting generally begins with the leader giving a short presentation, and then asking if anybody at the meeting has achieved an anniversary of sobriety. Attendees can receive 90 day "chips", 6 month chips, and one year chips. (Your patients may mention these, and you will come across as remarkably savvy if you ask, "Hey, have you gotten your 90 day chip yet?") After this, the floor is open to others, and attendees will stand up, identify themselves as alcoholics, and share something.

Encourage your patients to be active participants in their meetings. Optimally, they should arrive early, make the coffee, meet at least three people, sit in the front row, speak at least once during the meeting, and be the last one to leave. The other extreme is the patient who arrives late and sits in the back without saying anything. This hardly qualifies as "going to a meeting."

Encourage your patients to get a sponsor who can be supportive during tough times. Of course, it is up to the "sponsee" to be proactive and to call their sponsor when the urge to drink strikes.

In any urban or suburban area, there are bound to be plenty of AA meetings available, and your patients should try out several until they find one or two where they feel most comfortable. If your patient resists attendance because the other people aren't "like" her (too blue or white collar, too ethnic, too severely alcoholic, etc...), remind her that there are likely dozens of alternative groups within driving distance.

Some patients will balk at the apparent religiosity of the 12 Steps (eg., Step 3 says, "We made a decision to turn our will and our lives over to the care of God as we understood Him.") Indeed, in some meetings, the "Higher Power" is portrayed as "God", but in other more secular groups, it is viewed more as a recognition that we are not the be-all and end-all, and that we often cannot control ourselves without "higher" help.

A wonderful way to help a freshly sober patient get over his AA jitters is to offer to introduce him to one of your patients who has been sober for a year or more and has served as a sponsor. Collect names and numbers of such patients (with their permission) and facilitate a meeting.

Doctors are welcome at meetings, except at those identified specifically as "closed meetings." Simply show up, identify yourself at the meeting by standing up and saying something like, "I'm Danny (use your first name), I'm a physician and I treat patients with alcohol issues, and I've come to learn." And learn you will. ❖

TCR VERDICT: *Become AA-Savvy: Your Patients Will Gain*

Anecdotes From the Field: The Meaning of "Rehab"

Susan Hochstedler, RN, CADAC, is a nurse at Addison Gilbert Hospital in Gloucestor, MA. She works full-time with substance abusers in The Discovery Program, an addictions day treatment program.

"Most of our clients are either alcoholics or heroin addicts, and we start with a 3 to 5 day detox, followed by rehab. The rehab program is essentially a huge overhaul of the addict's life. A big part of rehab is teaching clients how to use AA, because we find that the single most important factor in maintaining sobriety is going to AA and liking it. But beyond this, the addict's entire lifestyle needs to be reordered, because situations that used to be part of everyday life are now high risk and potential triggers of relapse. For example, we teach clients how to manage the holiday party. Many alcoholics think it's fine to drink O'Doul's and other non-alcoholic beers, but in fact it's a bad idea, because it elicits so many emotional cues. The brain is saying, 'Hey lady, you're shooting blanks, let's get the real thing.' From my experience working with these patients, there are three things that I tell MDs: 1. Don't go it alone, always work with a counselor in treating these patients; 2. When psych meds are not working for a syndrome, think substance abuse before changing the psychiatric diagnosis; and 3. Don't be afraid to use meds like Antabuse and naltrexone early after detox, because these patients need all the help they can get."

CME Post-Test

To earn CME credit, you must be a subscriber of *The Carlat Report* and complete the following quiz, answering at least 5 of the 6 questions correctly. Select the best answer, circle the letter corresponding to your choice, and mail this page to CME Coordinator, The Carlat Report, P.O. Box 626, Newburyport, MA 01950. You may also fax the answer sheet to the CME Coordinator at (978) 499-1892. Anna Jaques Hospital (AJH) is accredited by the Massachusetts Medical Society to provide continuing education for physicians. AJH designates this educational activity for a **maximum of 1 hour credit** toward the AMA's Physician Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

1. Research on naltrexone, an opioid receptor antagonist, has shown that:
- a. Naltrexone consistently is more effective than placebo
- b. Naltrexone has only been effective in combination with acamprosate
- c. Evidence for efficacy has been mixed, with a recent large VA study showing no benefit
- d. It should not be combined with Antabuse

2. A true statement about acamprosate is:
- a. It has been shown to be effective in Europe, but a U.S. study was negative
- b. Its primary action is on the serotonin system
- c. It seems to work by alleviating gastrointestinal effects of withdrawal
- d. Dosing is identical to naltrexone (50 mg QD)

3. Antabuse cannot be given safely to any patient with liver abnormalities.
- a. True b. False

4. An accurate assessment of the efficacy of Antabuse is:
- a. It works well for most patients, as long as they take it for one to two weeks
- b. It works best for early-onset alcoholics
- c. It is most effective for patients with comorbid anxiety and depression
- d. It decreases drinking days in motivated and compliant patients

5. Research on AA meetings has shown that:
- a. Therapy aimed at facilitating attendance is highly effective
- b. Only those patients who have regular contact with sponsors achieve sobriety
- c. Patients who identify themselves as "religious" benefit the most from attendance
- d. Attendance at more than one meeting per week is paradoxically anti-therapeutic

6. According to Dr. Gitlow, benzodiazepine use in alcoholics:
- a. Is safe, as long as refills are carefully monitored
- b. Inevitably leads to an escalating dose, with a more difficult withdrawal needed eventually
- c. Should only be used in conjunction with AA meetings
- d. Is dangerous because of drug interactions with Antabuse

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