Category: Alcohol

Title: Improving Naltrexone Response: An Intervention for Medical Practitioners to Enhance Medication Compliance in Alcohol Dependent Patients

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Background: Treatment noncompliance is common in both medical and psychiatric disorders. The presence of substance abuse has been one of the most frequent risk factors for medication noncompliance in medical and in psychiatric samples. In 1995, the Federal Drug Administration approved Naltrexone, an opiate antagonist, for the treatment of alcohol dependence. It is thought that Naltrexone blocks the pleasurable effect or high associated with excessive alcohol drinking. The only other FDA approved medication for alcohol dependence is Disulfiram. Only 20% of patients taking Disulfiram are compliant, whereas average treatment compliance with Naltrexone is 60%.

Objective: The study had 2 analyses, one that demonstrated that compliance with Naltrexone was correlated with its positive effect on relapse prevention (relapse is defined as drinking 5 or more drinks in one occasion); the second analysis focused on a manual driven psychosocial intervention with acronym BRENDA. The second analysis was to see if the psychosocial intervention that focused on pill taking, patient education, tighter strategies for pill taking and strategies to avoid missing doses were correlated with better outcomes.

Type of Article:

Study:

Design: The first analysis was 2 placebo-controlled double-blinded 12-week trials of 50 mg of Naltrexone or placebo. The second study was 12-week Naltrexone or placebo up to 100-mg, again double-blinded placebo-controlled and given the psychosocial intervention BRENDA.

Setting: The patients were outpatients at the Center for Study of Addictions at the University of Pennsylvania at VAMC day hospital and after care program.

Patients: 66% were Caucasians, 78% male, 47% were married. Outpatients carried the diagnosis of alcohol dependence and were excluded if they met diagnostic criteria for any other substance dependence except nicotine.

Intervention: In the first analysis pharmacotherapy or placebo plus 45-minute individualized addiction counseling sessions was used. The counseling sessions were characterized as a cognitive behavior therapy. In the second analysis, the intervention was Naltrexone 50-100 mg or placebo plus a manual-driven psychosocial intervention called BRENDA.
Outcomes measured: Patient compliance. They were considered compliant if they had 80% of their clinic visits, and they were medication compliant if they took 80% of their pills prescribed. Relapse was defined as 5 or more drinks in one sitting. A “slip” was defined as less than 5 drinks per one sitting.

Main results or findings: In the first analysis, any compliant Naltrexone treated patients vs. placebo treated patients, the relapse rate was 10% vs. 88.6%, respectively, with p value of 0.001. Furthermore, 22 of 44 of compliant placebo treated patients experienced at least one slip compared to only 16 of 60 compliant Naltrexone patients, with a p value of 0.02. Outpatients were receiving weekly substance abuse counseling as mentioned earlier. In the second analysis, 83% of BRENDA patients stayed in treatment for 12 weeks compared to 55.7% of the group that did not receive BRENDA, with a p value of 0.001, than the patients who were also more compliant in taking their medications as compared to those that did not receive BRENDA and that was 77% vs. 60.8%, with a p value of 0.01. In the second analysis, the blind has not been broken yet to ascertain the effect of Naltrexone plus BRENDA.

Conclusion: 1) A focused psychosocial intervention on medication compliance and patient education increases compliance with Naltrexone. 2) Persons who are compliant with Naltrexone are less likely to relapse.

Commentary: (Impact on Internal Medicine). The study has limitations in that the second analysis does not have the results for the effects of BRENDA plus medications in regard to the measurement of relapse. However, the results are encouraging for a focused psychosocial intervention, a.k.a. BRENDA, and medication compliance. This is at least true when compared retrospectively to other psychosocial interventions used at this treatment center. The implications for practicing internists are that Naltrexone is an effective chemical therapy for alcohol dependence. However, its efficacy is limited by patient adherence. A focused psychosocial intervention that targets medication adherence significantly improves compliance and should improve outcomes, specifically relapse prevention and abstinence. Similar studies in the treatment of medical and psychiatric conditions have borne this out as well. This should alert the internist to use pharmacotherapy in the treatment of alcohol dependence when combined with specific psychosocial interventions that include interventions that had to pay focus on medication adherence program.