

VISN 5 MIRECC Research Abstract

A Comparison of Bupropion SR and Placebo for Smoking Cessation in Schizophrenia **Elaine Weiner, MD**

Schizophrenic patients have a higher rate of smoking than the general population and are less likely to receive smoking cessation interventions. They may be less able to comply with traditional smoking cessation programs, yet there are studies that support the ability of schizophrenic patients to respond, when psychoeducational smoking cessation programs are modified to meet their needs. In addition to the obvious health hazards associated with smoking, the use of nicotine may also interfere with the benefits of antipsychotic medication, by lowering the blood levels of these drugs.

Bupropion hydrochloride, initially marketed as the antidepressant, Wellbutrin was recently given FDA approval for smoking cessation and is now marketed as Zyban. There are several reports, most notably the recent article in the New England Journal of Medicine, citing the possible efficacy of bupropion SR for smoking cessation in nondepressed patients (ref, NEJM, 337, 17: 1195-1202, 1997). However, there have been no studies conducted in patients with schizophrenia.

The purpose of this study is to examine whether the adjunctive use of bupropion SR in the context of a psychoeducational program modified for this specific population might improve the likelihood of successful abstinence in this population. If bupropion SR is effective for reducing cigarette smoking, then it will be important to determine to what extent decreased nicotine intake is associated with symptom and cognitive changes in patients. The effect of nicotine on antipsychotic plasma levels suggest that cigarette cessation may lead to decreased positive symptoms, through increased plasma levels. The effects of acetylcholine at both nicotinic and muscarinic receptor sites have been shown to regulate attention and memory function with the hypothesis that these functions are normalized by acute nicotine administration.

A total of forty subjects will be recruited from the Maryland Psychiatric Research Center, Outpatient Research Program (MPRC ORP), Key Point Southwest Mental Health Center, Revisions, Inc., and The Baltimore, VA. Patients must be regular half pack a day smokers and score at least a 4 on the Nicotine Dependency Test.

After obtaining consent, patients will enter a two week stabilization phase followed by a 12 week treatment phase. The treatment phase begins with a 9 session group therapy led by clinic nurses trained in the educational model of the American Cancer Association. Subjects will begin the double-blind, randomized, placebo controlled medication phase of treatment following the third group session, which is two weeks prior to the established quit day. Patients will receive either bupropion SR 150mg twice a day (starting with 150mg once a day for three days) or placebo in addition to their usual medication regimen. Patients will be offered the use of nicotine replacement in the form of Nicorette gum from quit day through week 8, the end of the group therapy course. Following completion of the group therapy course, patients will continue in their assigned medication group until study completion.

Expired carbon monoxide levels will be measured weekly during the treatment phase and monthly thereafter. Urinary cotinine levels will be obtained at the beginning, week 4 (quit day), and week 14 of the treatment phase.