CASE STUDY

Mood Management and Nicotine Patch for Smoking Cessation in Adults With Bipolar Disorder

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Cigarette smoking is three times more prevalent in bipolar disorder than in the general population, and quit rates are low (Lasser et al., 2000). Only two small ($n = 5$) pharmacotherapy studies (Weinberger et al., 2008; Wu et al., 2012) have examined interventions for smokers with bipolar disorder. Targeted behavioral interventions designed to address barriers to quitting in bipolar disorder may improve quit rates. Cognitive-behavioral mood management interventions have demonstrated some success in treating depressed smokers (Haas, Muñoz, Humfleet, Reus, & Hall, 2004) and may be useful for smokers with bipolar disorder, but no studies have tested this proposition. Consequently, we examined the feasibility of a mood management intervention for smokers with bipolar disorder in a proof-of-concept study.

Participants were adult smokers (≥ 18 years old) who met *DSM-IV* criteria for bipolar I disorder; smoked ≥ 10 cigarettes/day for the past 90 days, with expired air carbon monoxide (CO) level ≥ 10 ppm; scored ≥ 6 on a 10-point scale of motivation to quit smoking; were nicotine dependent, minimally symptomatic (i.e., Montgomery–Asberg Depression Rating Scale [MADRS; Montgomery & Asberg, 1979] ≤ 12 ; Young Mania Rating Scale [YMRS; Young, Biggs, Ziegler, & Meyer, 1978] ≤ 12), and taking psychotropic medications that had been stable for at least 3 months. Individuals were excluded if they had current alcohol or other substance dependence; had an unstable medical condition; were pregnant, lactating, or planned to become pregnant during the study interval; had received treatment for smoking cessation within 30 days of screening; or tested positive for drugs other than cannabis. Individuals who tested positive for cannabis were enrolled only if they agreed to refrain from marijuana in the 24 hr prior to study visits. This study was approved by the University of Cincinnati Institutional Review Board, and participants provided written informed consent.

Manual-guided mood management counseling was offered in 12 weekly, 60-min sessions by a licensed clinical psychologist (JLH) and two advanced clinical psychology doctoral students supervised by the psychologist. The treatment consisted of 15 min of standard counseling and 45 min of targeted mood

management based on cognitive-behavioral therapy principles. Standard counseling components included self-monitoring of smoking triggers, stimulus control strategies, and relapse prevention techniques. Mood management components included mood monitoring, cognitive restructuring, and stress management, as suggested in previous studies for depressed smokers (e.g., Brown et al., 2001; Haas et al., 2004). Lifestyle topics relevant to managing bipolar disorder (e.g., a regular sleep–wake schedule) were also included. Secondary intervention components addressed substance use and nonadherence to psychotropic medication using motivational interviewing (Miller & Rollnick, 2002) and encouraged nicotine replacement therapy (NRT) adherence using compliance enhancement strategies (Carroll & O'Malley, 1996). Homework assignments focused on identifying smoking triggers, mood monitoring, and practice of strategies covered in session.

The target quit date occurred at Week 4 to allow time for skill acquisition. Open-label nicotine patch was provided for 8 weeks using standard dosing. The primary treatment outcome was CO-verified (≤ 8 ppm), 4-week prolonged abstinence. A secondary outcome was 50% reduction in cigarettes per day between baseline and end-of-treatment. Participants were compensated \$20 for each completed visit.

We screened 119 individuals for more than 13 months in order to enroll 10 participants (mean age = 44, $SD = 13$) who met eligibility criteria. The most common exclusions were psychiatric (31%), medication- (29%) and substance-related (13%). The 10 participants were predominantly non-Hispanic Caucasian (70%), male (70%), not currently married (90%), low income (50%), and averaged approximately one pack of cigarettes per day.

Nine participants (90%) completed treatment. Participants attended an average of 10 out of 12 sessions and rated the helpfulness of the counseling at 3.3 (where 1 = not at all helpful and 4 = extremely helpful). Participants also indicated that 30-min sessions were preferred over 60-min sessions. From the survey, the patients reported that what they liked most about the treatment was the therapist support and standard tobacco intervention strategies, with no reference to the targeted mood

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management components. The experience of the study therapists who delivered the intervention also suggested that several participants did not see a connection between mood and smoking.

Two participants (20%) achieved CO-confirmed, 4-week prolonged abstinence. On the secondary endpoint, seven of nine study completers (77%) achieved $\geq 50\%$ reduction in self-reported smoking (supported by $\geq 50\%$ reduction in CO). Only four of the nine treatment completers (44%) used at least 80% of the nicotine patches during the final 4 weeks of treatment. Effects of the intervention on alcohol and other substance use and psychotropic medication nonadherence could not be assessed, as these issues were nearly absent. Ratings increased slightly for depression (MADRS = 2.3 points, $SD = 6.5$) and mania (YMRS = 2.2 points, $SD = 5.0$) from baseline to end of treatment. Two participants reported clinically significant increases in depressive symptoms. Another participant reported a brief period of suicidal ideation, but not of severity that required clinical intervention. None of these participants quit smoking. No participants developed hypomania or mania.

We concluded that this newly developed approach to smoking cessation in bipolar disorder showed promise in facilitating smoking abstinence. Treatment acceptability, as indicated by retention and satisfaction, was also good. At the same time, the mood management component of the treatment was not uniformly face-valid. Additionally, participants indicated that they preferred 30-min to 60-min sessions, and some topics (i.e., psychotropic medication nonadherence, alcohol, and illicit drug use) were not applicable to these participants. Although conclusions are very limited due to the small sample size and the open-label nature of the study, our preliminary findings suggested four modifications to the treatment protocol: (a) alter intervention content so that it addresses mood-related motivations for smoking but does not focus exclusively on that topic, (b) remove content focused on psychotropic medication nonadherence and non-nicotine substance use, (c) enhance methods for improving NRT adherence, and (d) use shorter sessions. Less restrictive inclusion criteria may be warranted to improve recruitment feasibility and generalizability. Given the considerable dearth of research in this area, results of this proof-of-concept study provide valuable information regarding the successes and challenges of this study and treatment design and may guide researchers in the planning of much-needed studies to enhance treatment outcomes for smokers with bipolar disorder.

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DECLARATION OF INTERESTS

JLH has served as a consultant for Pfizer. RMA provides consultancy and advisory services to Pfizer and has received research support from Lilly, Pfizer, Nabi Biopharmaceuticals, and Sanofi-Aventis. MPD has received honoraria for speaking or consulting during the past 12 months from Pfizer, Bristol-Myers Squibb, and Merck, and research support from AstraZeneca, Otsuka, Eli Lilly, Forrest, Sumitomo, Amylin, Repligen, Pfizer, GlaxoSmithKline, Janssen, and Johnson and Johnson. SMS provides consultancy and/or advisory services to American Association of Child and Adolescent Psychiatry,

CME Outfitters (CME companies get support from different pharmaceutical companies that can and does change), and Adamed. In addition, SMS has chaired symposia for Consensus Medical Communications, mentored a young investigator meeting—American Psychiatric Association—and directed a discussion on Web MD. Finally, SMS has received funding from Eli Lilly, Janssen, AstraZeneca, Martek Biosciences, Nutrition 21, Repligen, National Institute on Drug Abuse, National Institute on Alcohol Abuse and Alcoholism, National Institute of Mental Health, and National Alliance for Research on Schizophrenia and Depression for research activities within UC or UC Health. LS has no competing interests to disclose.

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