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Comparing smoking treatment programs for lighter smokers with and without a history of heavier smoking

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Abstract

The study examined the impact of counseling intensity (high vs. low) combined with either bupropion or the nicotine patch. Two hundred sixty participants smoking 6–15 cigarettes per day (cpd) were enrolled in a yearlong study to examine the effects of treatment. Four groups of smokers under medication-blinded conditions were compared for treatment completion and abstinence at three follow-up points from the initiation of treatment (weeks 12, 26, and 52). Both counseling groups had similar treatment completion rates (i.e., defined by a combination of counseling attendance and medication adherence levels). There was a main treatment effect for abstinence favoring the high counseling condition in early follow-up (week 12) and for continuous abstinence. Participants with a history of heavier smoking (≥ 20 cpd) and African American smokers were least likely to be smoke free at the end of the study. The study has implications for identifying the treatment needs of lighter smokers.

Keywords

Lighter smokers; African American smokers; smoking cessation counseling; nicotine patch; bupropion

1. Introduction

The smoking characteristics and treatment needs of lighter-smokers seeking formal treatment have been understudied. While the rate of decline in smoking has essentially leveled off, there are indications that the combination of increased awareness of health concerns, work place bans on smoking, general increased environmental restrictions on smoking (e.g., malls, restaurants, public conveyances), and increased cost of cigarettes have contributed to more smokers smoking fewer cigarettes. The mean number of cigarettes smoked per day (cpd) has

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All work was performed at the University of Pennsylvania

dropped from 19.1 in 1993 to 16.8 in 2004 (MMWR, 2005). The Centers for Disease Control (CDC) report that the percent of current daily cigarette smokers who smoke 14 or fewer cpd has increased from 23.5% in 1993 to 33.2% in 2004 (MMWR, 2005). Data further suggests that former heavier smokers are joining the ranks of lighter smokers. Fargas (1999), as part of the California Tobacco Survey (n=1,682) noted that nearly 18% of adult non-abstinent smokers surveyed by telephone had reduced the number of cigarettes smoked over a one-year period from an average of 25.7 cpd to 12.7 cpd (a 48% decrease). Most of those surveyed who had reduced the number of smoked cigarettes had been either moderate (•15 cpd) or heavy smokers (>25 cpd). At the same time, and as expected, lighter smokers (<15 cpd) who stopped smoking had the highest overall cessation rate. This finding is consistent with the frequently cited observation (Surgeon General, 1989; McWorter, Boyd, & Mattson, 1990) that lighter smokers are more successful in discontinuing smoking than heavier smokers. Unknown is the difference in abstinence rates among lighter smokers with and without a history of heavier smoking (i.e., • 20cpd) who enter formal treatment.

The efficacy and safety of various nicotine replacement products as well as the medication bupropion has been well demonstrated as first line treatments for heavier smokers. These treatments have been shown to be most efficacious when used in combination with intensive counseling (The Tobacco Use Clinical Practice Guideline Panel, 2000). Most earlier clinical trials that established the efficacy of these products didn't include smokers at less than 15 cpd, reported results on smokers who averaged more than 20 cpd, and didn't break down results based upon level of smoking (e.g., see Fiore et al., 1994, Hurt et al., 1997; Jorenby et al., 1999). Thus, the efficacy of these pharmacotherapies in combination with varying levels of counseling has not been empirically examined for lighter smokers (defined for study purposes as 6–15 cpd). Despite the increased knowledge of effective treatment for heavier smokers, there is a dearth of information on the most effective treatments for <16 cpd smokers. While the health risks associated with smoking are believed to be dose related lighter smokers still remain at substantial risk for major health problems (Hurt et al., 2000).

Another more recent first line product for smokers, varenicline, wasn't considered for the present study because efficacy and safety studies weren't completed until well after the start of the present study (see Gonzales et al., 2006; Jorenby et al., 2006).

Poor therapeutic outcomes with currently used, more minimal treatments (over-the-counter or prescription) suggest the possible benefits of more intensive counseling approaches, particularly for more problematic individuals (e.g., history of major depression or current depressive symptoms). Pierce and Gilpin's (2002) examination of California Survey quitters in 1999 reported no long term advantage for use of any pharmaceutical aid (nicotine replacement product or bupropion) in comparison to self-only attempts in the absence of adjunctive counseling among lighter smokers (< 15 cpd).

An "intensive" medically based psycho educational counseling model (Mayo, 2000) that has been shown to be efficacious with heavier smokers, when used in conjunction with bupropion and/or the nicotine patch for achieving continuous abstinence (compared to placebo) may prove to be effective with lighter smokers (Jorenby et al., 1999). At the same time, it may be argued that lighter smokers may not require a high intensity psychosocial intervention. Accordingly, the presented study compares the efficacy of a higher intensity counseling model (High C) with that of a lower intensity medically based medication management counseling model (Low C) used in conjunction with bupropion or the nicotine patch. The primary goal was to determine the combination or combinations of high or low intensity adjunctive counseling and pharmacotherapy (either bupropion or the nicotine patch) that are most effective for lighter smokers.

Four groups of smokers were compared for treatment completion and abstinence at three follow-up points from the initiation of treatment (weeks 12, 26, and 52). Levels of psychosocial counseling and medication type were the main explanatory variables. Urn randomization was used to insure a relatively even distribution among the treatment cells for level of smoking (6–9 cpd vs. 10–15 cpd), history of heavy smoking (≥ 20 cpd), and elevated scores for depressive symptoms. It was hypothesized that the High C model would have the highest rates of treatment completion and abstinence. No hypothesis was made about medication type. A secondary hypothesis was that participants with a lifetime history of prior heavy smoking (≥ 20 cpd), would be less likely to complete treatment and would have lower smoking cessation rates at 12, 26, and 52 weeks post-treatment initiation than participants without a history of heavy smoking.

2. Material and methods

2.1 Sample population, setting, and clinical trial

The sample consists of 260 self-referred lighter smokers to an urban university setting after indicating an interest in becoming abstinent and passing both an initial telephone screen and in-person confirmatory interview. The first participant was enrolled in February 2005 and the last follow-up was completed in March 2008. A total of 302 met confirmatory screening criteria and 260 were enrolled. Participants were recruited primarily through television and newspaper advertising. The confirmatory interview consisted of a medical examination, structured psychological interview (MINI; Sheenan et al., 1997), and biochemical testing (i.e., carbon monoxide reading of expired air (CO), blood alcohol concentration, and urine drug test).

Inclusion criteria have been previously described (Gariti et al., 2008). In brief, to be eligible participants were between the ages of 18–75 years, smoked between 6–15 cpd, indicated a desire to stop smoking, and were in reasonably good health, including being psychiatrically stable. Exclusion criteria included: pregnancy, any contraindication to the nicotine patch or bupropion, current use of a smoking cessation product or other tobacco use, history of psychosis, mania (Bipolar 1), eating disorder, substance abuse/dependence within the past 6 months or current use of cocaine. Current use of an anti-depressant was also exclusionary. Anxiety disorders and depressive disorders were not exclusionary provided they weren't rated as severe on formal diagnostic testing. A Global Assessment of Functioning (GAF; First, Spitzer, Gibbon, & Williams, 1994) score of 50 or lower was also exclusionary (indicative of serious symptoms).

All participants signed informed consent. The Institutional Review Board of the University of Pennsylvania approved the study.

2.2 Study Design

The study was a prospective, random assignment experiment that employed a 2×2 double blind, double-dummy design for the medication component of the study. Participants were randomized to receive one of two levels of counseling intensity in combination with one of two pharmacotherapies. The medication treatment period was 9 weeks with a target quit date set for day 8 in each condition. The four treatment conditions were: 1). a transdermal nicotine condition consisting of nicotine patch detoxification for 8 weeks plus 9 weeks of placebo bupropion combined with 10 weeks of 10–15 minute sessions of individualized, manually-driven psycho-educational counseling (Patch-High C); $n = 65$); 2). a transdermal nicotine condition consisting of nicotine patch detoxification for 8 weeks plus 9 weeks of placebo bupropion combined with four 5–10 minute visits of manually-driven medication management counseling sessions (Patch-Low C; $n = 62$); 3). a bupropion condition consisting of sustained-release bupropion for 9 weeks plus 8 weeks of placebo patch combined with 10 weeks of 10–

15 minute sessions of individualized, manually-driven psycho-educational counseling (Bup.-High C; n= 63); and 4). a bupropion condition consisting of sustained-release bupropion for 9 weeks plus 8 weeks of placebo patch combined with four 5–10 minute visits of individualized, manually-driven medication management counseling sessions (Bup.-Low C; n= 70). Completion of treatment and smoking cessation at 12, 26, and 52 weeks post-treatment initiation were the primary measures of efficacy.

2.3 Assignment to Treatment Conditions

An independent data analyst assigned eligible participants to one of the four treatment conditions using an urn randomization procedure (Wei, 1978). The urn randomization procedure helped to ensure relatively equal sample sizes in the treatment groups and balance the groups on characteristics of interest: 1). presence or absence of a history of smoking 20 cpd for one month or greater; 2). currently smoking < 10 cpd vs. 10 cpd; and 3). a high vs. low depression score (16 vs. < 16) on the Center for Epidemiological Studies-Depression Inventory (CES-D; Radloff, 1977). A computer program provided by a colleague, Dr. Robert Stout of Brown University, was used to implement the urn randomization (Stout, Wirtz, Carbonari, & Del Boca, 1994).

2.3 Counseling Types

Both the High C and Low C programs fully met Tobacco Use Clinical Practice Guidelines (2000) for brief strategies to help patients willing to quit tobacco use as well as incorporated the recommended common elements of effective counseling for achieving and maintaining sustained abstinence. Only the High C program fully met guideline criteria for an intensive smoking cessation intervention. The Low C program met for the recommended minimum number of sessions (4), but usually fell below the recommended total contact time of more than 30 minutes. Additionally, only the High C program exceeded the recommended greater than 10 minutes for the longest session.

The 10 session Mayo “Smoke-Free and Living It” high intensity (High C) counseling manual (2000) is very similar to the standardized approach used in the Hurt et al. (1997) and Jorenby et al. (1999) trials. The main exception in the current trial was the absence of post-medication counseling during follow-up. The manual/booklet was given to the participant for in-session and post-session review. Each week the counselor and participant discussed agreed upon chapter(s) and topics (e.g., motivation, triggers, withdrawal, stress, problem solving, use of social support, etc) on achieving and maintaining abstinence through tools, techniques, and life style change along with encouraging medication adherence.

By contrast, the lower intensity four-session medication management-counseling model (Low C) focused more on medication adherence rather than on smoking cessation tools, techniques and life style changes, per se. The Low C model provided a NCI booklet “Clearing the Air” (USDHHS, 2004) on successful quitting including the use of supportive others. Use of the booklet was encouraged at each session.

Both counseling models included brief direct advice to stop smoking, basic problem solving, reinforced the benefits of abstinence, provided praise and encouragement, reviewed medication adherence and side effects.

The strategy of implementation in the Low C model was designed to mirror a community practice model that operates in an environment with severe time constraints. The Low C model is a briefer version of a medical management model that was used in Project COMBINE (NIAAA) to compare a basic medication monitoring alone condition for problematic drinkers to more intense levels of behavioral treatment (Anton et al., 2006). The COMBINE medical

management model was developed for the purpose of providing some basic form of intervention that supports the use of pharmacotherapy that could be easily implemented into medical practice. The goal of the model is to promote abstinence by facilitating compliance with medication, providing educational materials, supporting participant efforts, and making recommendations for achieving and maintaining abstinence.

The prime difference between the High C and Low C model is that the counselor is a more active teacher in the higher intensity model. Both booklets contained the same basic material and suggestions. All sessions were taped and 10% of all sessions were reviewed for treatment fidelity. Master's level nurse practitioners or nursing clinical specialists were assigned to each model and delivered all sessions. The Low C sessions ended after treatment week 6.

2.5 Medications and dosing

Both bupropion (Zyban, GlaxoSmithKline) and patch products (Nico Derm CQ, GlaxoSmithKline) and their respective placebo formulations were purchased and prepared through Penn's Research Investigational Drug Service (IDS). Each participant was given an active form of one medication and the placebo version of the second medication. The assigned nurses/counselors gave instruction on the proper use of both bupropion and the patch as neither the nurses nor the participants knew which of the two formulations contained the active formulation. Bupropion was prescribed at a standard dose of 150 mg/d $\times$ 3 days followed by 300 mg/d for the next 60 days. The smoking quit date was day 8 and corresponded with the first day of wearing the patch. Except for participants who were smoking 10 cpd or fewer, the patch was prescribed at the nicotine "weaning" dosing schedule of 21 mg/day for 4 successive weeks, followed by 14 mg/day for the next 2 weeks, and 7 mg/day for the final 2 weeks (total is 56 days). For those who had been smoking 10 cpd or fewer, the dosing schedule was 14 mg/d for 6 weeks followed by 7 mg/day for the final 2 weeks. A two-week supply of bupropion and a one-week supply of patch were given to participants at the end of their first visit with the nurse counselor in week 1. An additional one-week supply of medication was dispensed on the day 11 check up visit (week 2) with the nurse. A three-week supply was given in week 3 so that the participant had enough pills and patches to extend through six weeks and the final three-week supply was given to participants at the week 6 visit.

"Special consideration" in the use of pharmacotherapy was recommended as a required guideline for those smoking 10 cpd or fewer (Clinical Practice Guideline Panel; Fiore, 2000). Dose adjustments were made if a participant wasn't able to tolerate manufacturer recommended dosing levels. For safety reasons and to guard against treating the non-addicted with a medication (e.g., "chippers"), eligibility for inclusion was set at a minimum of 6 cpd.

2.6 Assessments

In addition to the mentioned medical and psychiatric examinations, other baseline assessments included: socio-demographic information, smoking history, smoking time line follow-back (TLFB; Sobell et al., 1979; Gariti et al., 1998), Fagerstrom Test of Nicotine Dependence (FTND, Heatherton et al., 1991), Hughes & Hatsukami withdrawal scale (1984), University of Rhode Island Change Assessment (URICA; Prochaska & DiClemente, 1984) motivation/readiness to change questionnaire, Perceived Self-Efficacy Questionnaire to resist smoking situations (Yates & Thain, 1985), The Center for Epidemiological Studies Depression Scale (CES-D; Radloff, 1977), and serum cotinine testing. During treatment assessments included: TLFB for medication adherence and smoking, pill/patch count, serum cotinine testing (day 11), adverse events, CO reading, and withdrawal, and motivation measurements. Post treatment follow-up measurements included: TLFB reports, urine cotinine testing, CO readings, and withdrawal, motivation and self-efficacy scores (week 12 only).

2.7 Primary Measures of Outcome

We employed a twofold definition of treatment completion that included both medication and counseling session adherence. With respect to medication adherence, participants who reported consistently taking the active pills and wearing the active patch as prescribed 80% of the time for the full 9 weeks of medication were considered completers of pill or patch treatment provided that there was agreement with direct observation and pill/patch counts. Adequate adherence with counseling requirements was defined by attendance of at least seven of the ten required High C sessions or three of the four Low C sessions. Participants had to meet both requirements to be designated as full treatment completers.

Participants who discontinued the study because of either dissatisfaction, adverse effects from the pill or patch and other extenuating life circumstances such as serious illness, injury, or relocation were not replaced. An early dropout was defined as no visits past the first two weeks of treatment. All participant data lost to follow-up was conservatively classified as smoking.

Seven-day point prevalence abstinence was the primary measure of abstinence at follow-up weeks 12, 24, and 52. Abstinence was defined as self-report of no tobacco smoking (not even a puff) of use confirmed by a CO reading of 9 ppm and a semi-quantitative immunoassay dipstick (NicAlert™) reading of $\bullet$ 200 ng/ml. (zone 3) confirmed a by gas chromatography/mass spectrometry (GC/MS) reading of < 50 ng/ml in situations where the NicAlert method did not confirm both a negative self-report and negative CO reading. Note: different cotinine testing methods have different cut-off scores. Self-report of continuous abstinence from the quit date (day 8) through week 52 was a secondary measure of abstinence. As suggested by a workgroup for the Society for Research on Nicotine and Tobacco, failure to achieve continuous abstinence is defined as 7 consecutive days of smoking or smoking at least 1 day on each of 2 consecutive weeks post quit date (Hughes et al., 2003). Note: cotinine measurement was used only if there was no reported use of a nicotine replacement product within 7 days of testing.

2.8 Adverse Events

All self-reported and observed adverse events/side effects were recorded on case report forms. Pre-existing problems were not considered to be an adverse event unless the problems worsened.

2.9 Data analysis

The proportions of treatment completers in the different groups were compared using logistic regression models, with level of psychosocial counseling and medication type as the main explanatory variables. Background characteristics were added as co-variables in subsequent analyses. Although an interaction between medication and psychosocial counseling was not expected, a model allowing for such an effect was examined.

The abstinence status at the 12-week, 26-week, and 52-week time points comprise a set of repeated binary responses for each participant. Rates of abstinence were addressed using mixed-effects logistic regression models. As in standard (i.e. non-repeated measures) logistic regression models, the log-odds of the probability of a response, e.g., cessation, are modeled as a linear function of explanatory variables. The terms corresponding to these variables comprise the fixed effects. In the presented study, the main explanatory variables were level of psychosocial counseling, medication group, and time. The standard models assume one observation per individual, so that conditional independence between observations, given explanatory variables, is reasonable. To extend the standard model to the repeated measures setting, additional terms, random effects, are included for each individual to model the correlation between observations on the same individual. Interpretations of how the probability of cessation varies as a function of level of psychosocial counseling, medication group, time,

and the interactions of these factors are straightforward. Background characteristics were added as co-variables in subsequent analyses.

A logistic regression model with level of psychosocial counseling, medication group, and baseline history of heavy smoking as the main explanatory variables, was used to assess the effect of prior heavy smoking on treatment completion. Although the effects of prior heavy smoking were not expected to vary across the treatment or counseling groups, interaction terms were examined to allow for those possibilities. The influence of a history of prior heavy smoking on the rates of smoking cessation across the 12-week, 26-week, and 52-week time points, was addressed by including the history of heavy smoking variable as a fixed effect in the mixed-effects logistic regression models similar to those assessing abstinence.

Safety data were summarized by frequencies of events and mean changes from baseline.

3.0 Results

3.1 Participant Characteristics

As seen in Table 1 there were no significant differences between treatment conditions on pretreatment characteristics supporting the use of the urn randomization procedure. Treatment cells were relatively equally balanced. African Americans and females were highly represented in the study cohort. The number of reported cigarettes smoked per day was consistent with biochemical measurement and lower level FTND dependence scores. Nearly a third smoked less than 10 cpd. Half of the study group had a history of pack a day smoking. GAF and CES-D-scores were indicative of a satisfactory level of mental health functioning. URICA decile rank scores and Self-Efficacy scores reflected slightly less than average motivation/readiness to change and a slightly positive level of confidence to resist smoking situations respectively.

There were significant differences in background characteristics between participants with a history of heavy smoking and those without. Those with a history of heavy smoking were older (M 45.6 yrs. (SD 12.3) vs. M 41.8 yrs. (SD 11.9), $p = 0.008$); not employed (46.0% vs. 32.5%, $p = 0.03$); had both a higher level of cpd (M 11.6 cpd, (SD 2.9) vs. M 10.0 cpd. (SD 3.0), $p < 0.0001$) and a lower percent in the 6–9 cpd grouping (22.8% vs. 41.5%, $p = 0.002$); and a higher Fagerstrom score (M 4.1 (SD 1.8) vs. M 3.5 (SD 1.9), $p = 0.01$).

3.2 Research Participation

Table 2 shows that there was no difference in treatment group follow-up rates at week 52. The overall follow-up rates were 90% at week 12, 86% at week 26, and 83% at week 52. There were no group differences in follow-up rates at any follow-up point. Obtained biochemical measurement of claimed abstinence at weeks 12, 26, and 52 were 90%, 86%, and 86% respectively. Two participants died prior to the week-52 follow-up period of non-study related problems. Data for the deceased participants weren't carried over from the prior follow-up period. One participant was administratively dropped from participation at week 1 when it was determined that his smoking status was misrepresented during screening (later supported by a baseline serum cotinine of 260 ng/ml indicative of heavier smoking). The participant was replaced.

3.3 Treatment Adherence

Table 2 shows a higher proportion of kept clinical sessions in the Low C group than the High C group ($p < 0.001$). The Low C patch group had both a significantly higher proportion meeting criterion for medication adherence ($p = 0.039$) as well as higher proportional days taking the active medication as prescribed ($p = 0.02$). However, both counseling groups had comparable full treatment completion rates (High C 59.1% vs. Low C 51.6%, $p = 0.16$). Days of taking the

active medication increased by 7%–10% per group when early dropouts were not included in calculations.

There was a significant interaction between medication type and counseling type ($p = 0.005$). The Low C patch group had the highest proportion meeting criteria for full treatment completion. No other smoking or background characteristics were significant in logistic regression modeling.

There was no significant differences for full treatment completion between those with a history (hx.) of heavier smoking and those without (with hx. 51.2% vs. without hx 59.8%, $p = 0.16$) or by counseling type (with hx. Low C 55.2% vs. with hx. High C 46.8%, $p = 0.34$; without hx. Low C 64.1% vs. High C 55.6%, $p = 0.33$).

3.4 Safety, Adverse Events and Withdrawal

Table 2 shows the percent of new or worse adverse events reported by treatment condition. The most frequently reported symptoms were dry mouth, anxiety, insomnia, and headaches. Most symptoms were mild to moderate (96.9%). Only 5 of 260 participants (1.9%) stopped or had their medication discontinued due to reported side effects. All but one was an early dropout. There was one report of probable mild nicotine toxicity. The initial patch dose was decreased from 21 mg to 14 mg and the reported adverse effects (nausea, diarrhea, insomnia, tachycardia, and headache) were no longer evident. The average percent of replacement for the active nicotine patch condition was 80.4%. The reported percentage only includes those who were active patch adherent from their quit day (day 8) to the week 2 visit (day 11) and self-reported no smoking confirmed by a negative CO reading. There was no difference in nicotine replacement levels by race ($t = -0.42$, $p = 0.67$). Nicotine withdrawal symptoms were analyzed both daily and weekly for all available participants (i.e., smoking or not) starting one-week pre-randomization through the end of treatment. There were no group differences in either the medication groups or the counseling groups for withdrawal scores over time. A maximum daily score was calculated by taking the maximum daily withdrawal score for each week. A mean score was the 7-day mean for each week. Reported withdrawal scores were consistently slight to mild.

3.5 Longitudinal Effects of Treatment

The High C group had higher point prevalence abstinence rates at all follow-up points, but this difference was only statistically significant at week 12 (High C 32.8% vs. Low C 21.2%, $p = 0.03$). Among full treatment completers abstinence rates again favored the High C group at all follow-up points (High C 56.6%, 52.4%, and 56% vs. Low C 43.4%, 47.6%, and 44% but was only significant at week 12 ($p = 0.05$)).

There was a main effect for counseling type but not for medication type (see Table 3). No other smoking or background characteristics were significant in logistic regression modeling.

There was a difference in continuous abstinence post quit date among the counseling types (but not medication types) at the week 52 follow-up (High C 13.3% vs. Low C 5.3%, $p = 0.03$). There also was a difference allowing for a grace period from week 6 through week 52 (High C 16.4% vs. Low C 6.8%, $p = 0.02$). General Estimating Equations (GEE) modeling showed a significant correlation for failure to remain abstinent among African American smokers ($Z = -2.21$, $p = 0.03$) and those with a history of heavier smoking ($Z = -2.89$, $p = 0.004$). Allowing for a 6-week grace period to achieve abstinence the results remained similar, although race was no longer significantly related to outcome.

In a comparison of participants with a history of heavier smoking to those without a history of heavier smoking, a significant difference occurred at week 12 favoring those without a history

of heavier smoking (with hx. 20.2% vs. without hx. 33.1%, $p=0.02$). Participants with a history of heavier smoking were 47% less likely to be smoke free at week-12 than those without a history of heavier smoking.

Among full treatment completers there was a significant difference in abstinence rates at all follow-up time points again favoring those without a history of heavier smoking (week 12 without hx. 36.8% vs. with hx. 14.7%, $p<0.0001$; week 26 without hx. 29.2% vs. with hx. 12.9%, $p=0.002$; week 52, without hx. 24% vs. with hx. 13%, $p=0.02$). No other smoking or background characteristics were significant in logistic regression modeling.

4. Discussion

As the percent of lighter smokers has greatly increased, the current study was designed to inform the treatment community about the most effective counseling type plus patch or bupropion combination for lighter smokers coming to formal treatment and to provide information on the characteristics of treatment recipients that are most predictive of positive or negative outcomes.

Both counseling groups had comparable albeit modest full completion rates. Both smoking cessation products were well tolerated and seem safe for lower level smokers. All groups reported slight to mild withdrawal scores over the course of treatment. However, there were higher than expected reports of new or worse adverse effects (see Jorenby et al., 1999 for comparison). Nevertheless, the vast majority of symptoms were mild to moderate. Medication stoppage was rare. The highest level of counseling adherence plus medication adherence occurred in the lower intensity Low C plus patch group. The difference does not appear related to differences in early dropouts and treatment group assignment, discomfort with side effects, withdrawal scores, or other demographic or smoking characteristics. Support for the hypothesis that the higher intensity group (High C) would have the highest rate of full completion was not seen.

The lack of difference for abstinence in medication type is quite different than the earlier Jorenby et al. (1999) study of heavier smokers that made a direct comparison between the patch and bupropion. Bupropion was a clear winner in the earlier study. In the current study there wasn't any difference in abstinence rates among the medications over time other than a trend favoring the patch at week 26.

Counseling type appears more relevant than medication type in the current study. Higher intensity counseling consistently showed the best outcome over time suggesting that counseling type is quite relevant in the treatment of lighter smokers. More treatment tended to be better, meaning there was a dose response relationship between the level of counseling and efficacy. However, the hypothesis that the High C model would have the highest rates of abstinence at all follow-up points was only partially supported by point prevalence analysis. Secondary analysis using continuous abstinence measurement supported the overall hypothesis. Participant views on counseling type and medication type await further analysis to better understand these findings.

In general, overall abstinence results for the group of lighter smokers studied do not appear to be any better than those achieved by comparable studies of heavier smokers (e.g., Jorenby et al., 1999; Fiore et al., 1994). Support for this observation was reported in a secondary analysis of smokers using the nicotine lozenge. Shiffman (2005) found no differences in outcome between those who smoked 1–15 cpd and those who smoked more than 15 cpd ($M=24$ cpd).

The hypothesis testing lower treatment completion rates and abstinence rates among those with a lifetime history of prior heavy smoking was only partially supported. Those with a history

of heavy smoking were not less likely to complete treatment, but had a significantly lower smoking cessation rate at week 12 than those without a history of heavy smoking. Among participants who were both counseling and medication adherent, those with a history of heavier smoking were significantly less likely to be smoke free at all follow-up points. GEE analysis further suggests that those with a history of heavy smoking and African American smokers were the least likely to be abstinent by the end of the study. The findings most strongly suggest that the treatment needs of those with a history of heavier smoking are different than those who were always lighter smokers. The literature also suggests that African American smokers have a harder time achieving and maintaining abstinence (Choi et al., 2004).

4.1 Study Limitations

A prime limitation of the study is that the counseling types differed in the number of sessions and time spent with participants as well as there being some overlap in the common elements of counseling. Second, the extensiveness of nurse training and subsequent monitoring is likely to far exceed what prevails in the community. Thus, the study qualifies as an efficacy, rather than an effectiveness study and the results may not be entirely generalizable to treatment conducted outside of a research setting. The population studied also may differ considerably from other urban settings.

We recognize that it is not possible, given the research design of this study, to definitively conclude that the addition of higher intensity counseling contributed to improved outcomes over that obtained by the pharmacotherapies in isolation. The primary question addressed in the study was to determine the combination of psychosocial and pharmacotherapeutic treatment that is most efficacious for lighter smokers who are trying to discontinue smoking. As indicated, the results suggest that counseling type may be a more important variable than choice of medication type per se. The study appears useful in suggesting that the intensity of counseling not be reduced. Finally, it is important to recognize that this study is a starting point for research on the effectiveness of different treatments for lighter smokers.

4.2 Conclusions

Overall, the data does not suggest that lighter smokers entering formal treatment have an easier time with smoking cessation than heavier smokers. A combination of counseling plus medication can be effective if adequately applied. Counseling models that are applicable to heavier smokers should be considered for lighter smokers. Those with a history of heavier smoking are particularly vulnerable to relapse and most likely will need special attention.

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Table 1

Baseline characteristics of sample by counseling type plus medication type

	Low C Bupropion n = 70	Low C Patch n = 62	HighC Bupropion n = 63	High C Patch n = 65	p-value
Demographics					
Age (years, mean, sd)	43.3 (12.5)	45.8 (12.6)	42.4 (12.6)	43.1 (11.3)	0.427
Female (%)	62.9	56.5	49.2	58.5	0.457
African American (%)	67.1	66.1	68.3	70.8	0.950
Married (%)	26.1	25.8	22.2	15.4	0.424
Employed (%)	70.3	57.9	58.1	55.6	0.316
Smoking Characteristics					
CPD (mean, sd)	10.6 (3.2)	11.0 (3.0)	10.9 (3.0)	10.6 (3.0)	0.877
6–9 CPD (%)	36.4	25.8	31.7	33.9	0.621
Serum cotinine (mean, sd) ¹	203 (107)	229 (143)	199 (106)	213 (126)	0.535
CO level (mean, sd)	9.2 (5.0)	10.7 (7.1)	10.3 (6.3)	10.0 (6.1)	0.554
FTND (mean, sd) ²	3.7 (1.8)	3.9 (2.0)	4.0 (1.7)	3.6 (2.1)	0.614
Prior quit attempts (mean, sd)	3.8 (4.0)	5.0 (5.5)	4.2 (3.9)	4.4 (5.1)	0.561
Hx >= 20 CPD (%)	47.1	56.5	52.4	46.2	0.621
Mental Health					
No diagnosis (%)	50.7	50.0	47.6	46.2	0.950
GAF (mean, sd) ³	69.3 (8.0)	69.1 (9.0)	68.1 (6.9)	69.0 (9.0)	0.864
CES-D (mean, sd) ⁴	7.8 (7.9)	8.7 (7.7)	7.0 (6.0)	6.4 (6.9)	0.305
Motivation					
URICA (mean, sd)	10.0 (1.5)	10.0 (1.6)	9.9 (2.0)	10.3 (1.4)	0.659
Decile rank ⁵	4.2 (2.8)	4.1 (2.7)	4.4 (2.7)	4.7 (2.7)	0.577
Self-Efficacy (mean, sd) ⁶	65.3 (14.0)	67.0 (18.8)	69.3 (14.7)	67.0 (12.9)	0.517

¹ ≥ 250 ng/ml is considered a high score

² 3–4 considered lower level dependence (range 0–10)

³ 70 considered satisfactory mental health status (range 1–100)

⁴ < 16 considered to reflect non depressed score (range 0–60)

⁵ 4 considered to reflect less than average motivation/readiness to change (range 1–10)

⁶ 70 considered to reflect some confidence to resist smoking situations (range 11–98)

Table 2

Trial completion, treatment adherence, and adverse events in each treatment group

	Low C Bupropion n = 70	Low C Patch n = 62	High C Bupropion n = 63	High C Patch n = 65	p-value
Completed week 52 research visits (%)	84.3	79.0	82.5	86.2	0.742
Early Drop-outs					
Drop-outs (%) ≤ 2 visits in first 2 weeks	24.3	16.1	20.6	16.9	0.618
Clinical Visits Attended					
Clinical sessions (%)		81.6		66.7	<.001
(Low C vs. High C)					
Clinical sessions (%)	77.9	85.9	66.8	66.6	0.001
Medication					
Taking active meds ($\geq 80\%$ of time)	53.8	72.9	65.5	50.0	0.039
Taking active med (% of days)	64.1	80.9	74.7	65.7	0.020
Adverse Effects (only new or worse than baseline)					
Anxiety (%)	37.5	54.0	40.4	34.0	0.183
Dizziness (%)	23.2	26.0	32.7	13.2	0.127
Dream abnormalities (%)	25.0	44.0	28.8	30.2	0.179
Dry Mouth (%)	53.6	44.0	48.1	45.3	0.760
Headache (%)	42.9	56.0	30.8	37.7	0.068
Insomnia (%)	41.1	50.0	46.2	37.7	0.602
Nausea (%)	19.6	28.0	21.2	11.3	0.207
Rhinitis (%)	25.0	26.0	21.2	20.8	0.892
Application-site reaction (%)	14.3	30.0	21.2	43.4	0.005

Table 3

Descriptive outcomes by counseling groups and medications

Abstinent (%)	Counseling Main Effects n = 260		Medication Main Effects n = 260		
	Low C	High C	p-value	Bupropion	Patch
Week 12					
Self-Report + CO + Urine Cotinine	21.2	32.8	0.03	27.1	26.8
Week 26					
Self-Report + CO + Urine Cotinine	18.9	25.0	0.24	18.0	26.0
Week 52					
Self-Report + CO + Urine Cotinine	16.9	21.9	0.356	15.9	23.0

P values include urn randomization variables (i.e., history of heavier smoking, elevated CES-D score, and 6–9 cpd vs. 10–15 cpd) along with gender and race