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Correlates of adherence with transdermal nicotine

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Abstract

This correlational study examined the adherence rates of transdermal nicotine (TN) use among a population of males and females 18 years of age and older ($N = 619$) who received varying levels of behavioral intervention. Rates of patch adherence were assessed for demographic (e.g., gender, ethnicity, and age), income-, smoking- [e.g., baseline carbon monoxide (CO), nicotine dependence, and follow-up quit status], and treatment-related (e.g., condition, and drop status) variables. Loglinear and logistic regression analyses were performed to assess adherence rates. Results indicated that male gender [$\chi^2(2, n = 485) = 20.39$, $P = .038$], not dropping out of the study [$\chi^2(2, n = 485) = 13.94$, $P < .001$], and intensive treatment (compared to the standard care) [$\chi^2(4, n = 485) = 14.96$, $P = .005$] were associated with greater adherence to TN. Furthermore, patch adherence was associated with quit status at 6 months (OR = 2.47, CI = 1.56–3.91, $P < .001$) and 12 months (OR = 2.12, CI = 1.34–3.37, $P = .001$). Complete and partial patch adherence (compared to minimal/no adherence) were associated with a greater number of telephone intervention contacts completed (OR = 2.621, CI = 1.421–4.832, $P = .002$). Noteworthy however, was the lack of association between level of income and patch adherence. These findings suggest characteristics of those more and less likely to adhere to TN in research and clinical settings.

Keywords: Tobacco; Tobacco use cessation; Smoking

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1. Introduction

Smoking is the number one preventable cause of morbidity and mortality in the United States (McGinnis & Foege, 1993). Despite a growing body of literature that aims to reduce smoking prevalence, the overall percentage of adult smokers has not markedly decreased in recent years (25.5% in 1990 vs. 22.9% in 1998), especially compared to the noticeable decreasing trend in the 1980s (33.2% in 1980 vs. 25.5% in 1990; CDC, 2001; Giovino et al., 1994). In fact, smoking prevalence rates have *increased* in certain groups, notably lower income individuals (28.7% in 1995 vs. 29.4% in 1998; CDC, 2001; Giovino et al., 1994), and the gender gap that once existed has narrowed tremendously, resulting in a female smoking prevalence rate of 22% (US DHHS, 2001).

As a result, the refinement of smoking cessation interventions remains a public health priority. One such pharmacologic intervention is transdermal nicotine (TN), which multiple studies have confirmed produces significantly higher cessation rates relative to placebo (Fiore et al., 2000; Fiore, Smith, Jorenby, & Baker, 1994). One important factor associated with poor cessation success is poor adherence or nonadherence with TN (Alterman, Gariti, Cook, & Cnaan, 1999; Cummings, Hyland, Ockene, Hymowitz, & Manley, 1997; Jolicoeur et al., 2000; Kenford et al., 1994; Orleans et al., 1994; Stapleton et al., 1995).

Earlier studies of TN found high rates of adherence with the nicotine patch (Trandermal Nicotine Study Group, 1991); however, more recently, it has become evident that studies have failed to define, measure, or report adherence with TN (Alterman et al., 1998; Fiore et al., 1994). Among studies that have addressed TN adherence, results suggest nontrivial rates of nonadherence (Alterman et al., 1999; Cummings, Biernbaum, Zevon, Deloughry, & Jaen, 1994; Orleans et al., 1994; Stapleton et al., 1995). For example, in a large sample of elderly low-income individuals, Orleans et al. (1994) noted that adherence with TN was "far from ideal." Results indicated that approximately 44% of the respondents reported continuous patch use for under 30 days, including 29% who reported use for less than 14 days and 18% who reported use for 7 days or less. Moreover, 47% of this sample smoked while using the patch, and fully 20% smoked daily (Orleans, 1994). In a large general practice sample, Stapleton et al. (1995) found a significant decrease in patch adherence from 92% in the first week to 61% in the 12th week. In a study of smaller sample size that focused more specifically on adherence with TN and its predictors, Alterman et al. (1999) found that 55% of the sample wore the patch as prescribed for at least 50 of 56 treatment days. Taken together, these studies suggest that TN adherence rates are lower than once observed, and attention to adherence in an effort to bolster cessation rates is needed.

Three studies have assessed factors associated with TN adherence in an effort to explore the characteristics of smokers more or less likely to adhere with patch use and increase the likelihood of ultimate smoking cessation (Alterman et al., 1999; Cummings et al., 1997; Orleans et al., 1994). Orleans et al. (1994) found an association between perceived advice from the participant's provider and patch adherence. Cummings et al. (1997) found that those who were adherent were more likely female, Caucasian, more motivated to quit smoking, heavier smokers, and of higher income. Despite the latter

finding, low-income individuals provided with the nicotine patch were significantly more likely to use it than those not provided access (Cummings et al., 1997). Results from another study of TN adherence that examined multiple potential correlates identified four predictors of patch adherence: lower nicotine dependence, more intensive adjunct treatment, greater motivation for abstinence, and smoking fewer cigarettes per day (Alterman et al., 1999). Authors of that study suggested that nonsignificant findings with sociodemographic variables might have been a result of limited sample size ($n = 101$; Alterman et al., 1999). Given these inconsistent findings and the continued need to explore methods of increasing cessation, further examination of factors associated with TN adherence is warranted.

This study assessed multiple factors potentially related to adherence with TN in a large sample of men and women in an effort to better understand the correlates of adherence and ultimately bolster cessation rates. Rates of patch adherence were assessed for demographic (e.g., gender, ethnicity, and age), income-, smoking- [e.g., baseline carbon monoxide (CO), nicotine dependence, and follow-up quit status], and treatment-related (e.g., condition and drop status) variables.

2. Methods

The current study was part of a project funded by the National Cancer Institute (CA95-013) to evaluate nicotine replacement therapy and three levels of behavioral intervention on smoking cessation in primary care settings. As a result, the design of this study is based on data from a randomized controlled trial, is correlational in nature, and assesses factors associated with three levels of adherence (complete, partial, and none) to TN.

2.1. Participants

Participants were 619 males and females, 18 years of age and older, who smoked at least 10 cigarettes per day, had been smoking for at least a year, and obtained a carbon monoxide reading of ≥ 10 ppm. Potential participants were excluded from participation in the study for uncontrolled hypertension, angina, severe cardiac arrhythmias, and hyperthyroidism. In addition, exclusionary criteria included pregnancy, women who were lactating, allergic to the nicotine patch, no telephone, and inability to understand consent procedures. Of the 619 initial participants, 489 participants attended the 7-week follow-up session and 485 participants responded to questions about patch adherence.

2.2. General procedures

All participants were recruited through primary care settings. A total of 93 healthcare practitioners in four primary care settings participated in recruitment; there were 39 Veteran's Administration providers, 16 Methodist Healthcare providers, 37 University of Tennessee Medical Group providers, and one Southwind Medical Group provider. Overall, there were

40 females, 53 males, 66 nonminority, and 27 minority providers. Most participant recruitment was provided by MDs (63%), followed by nurse practitioners (24.2%), physician's assistants (11.5%), and registered nurses (0.6%). Provider credentials were not specified for three participants recruited at the VA.

All participating primary care providers were required to complete a 1-h training session. Provider training included a detailed review of the health consequences of smoking, smoking cessation techniques, and an overview of the benefits of quitting. Furthermore, the Five As of physician intervention (Fiore et al., 2000; Glynn & Manley, 1989) were reviewed. The Five As include (1) *Asking* about tobacco use at every visit, (2) *Advising* tobacco users to quit, (3) *Assessing* willingness to make a quit attempt, (4) *Assisting* the patient in quitting by helping them prepare and setting a quit date, and (5) *Arranging* for follow-up visits. Finally, the providers were trained in study protocol and their role of covering the following topics: (1) the health benefits of quitting smoking related to the participant, (2) the benefits of using nicotine replacement, (3) the rules of patch use, and (4) the importance of the participant setting a quit date.

Following acceptance into the study and signing the consent form, participants provided demographic information and were administered study questionnaires. Participants were randomized to one of three cognitive–behavioral smoking cessation programs that varied in length and intensity. Assessments were completed at baseline, 7 weeks (postpatch use), and 6 and 12 months.

All participants, regardless of condition, received a physician-led smoking cessation message (described above) and a free 6-week supply of Nicoderm transdermal patch. Participants randomized to the *Standard Care (Condition A)* received only the nicotine patches and the physician smoking cessation intervention outlined above. Participants assigned to the *Telephone/Mail Intervention Group (Condition B)* received 12 telephone calls and six mailings from lay staff over a 1-year period. In the most intensive condition, *Health Educator Group (Condition C)*, all participants were given four face-to-face visits with a health educator. In addition, they received 12 follow-up calls and six mailings over a 1-year period. The content of the calls, visits, and mailings for participants in both the B and C conditions included support building, problem solving, preparing to quit, coping with negative cognitions, relapse prevention, and weaning from the patch.

2.3. Outcome variables

2.3.1. Demographics

Participants provided information regarding gender, age, race, level of education, employment status, marital status, and annual income at baseline.

2.3.2. Patch adherence

Based on patch use during the 6-week treatment period, participants were categorized as fully adherent (used "all of the patches"), partially adherent (used "most or some of the patches"), or nonadherent (used "a bit or none of the patches"). Participants reported this information at the 7-week follow-up visit.

2.3.3. Withdrawal from the study

Withdrawal from the study or dropout was defined as unable or unwilling to complete the study or lost to follow-up after the initial 7-week follow-up.

For purposes of the primary study, smoking history, stage of change, and biochemical markers of smoking cessation were also obtained. Smoking history included the number of cigarettes smoked per day, number of years smoked, past use of other nicotine replacement products or sustained release bupropion, and brand of cigarettes used most. The participant's history of previous smoking cessation attempts was also noted. Level of nicotine dependence was assessed using the revised Fagerstrom Test of Nicotine Dependence (FTND; Fagerstrom, 1991). With regard to stages of change, Prochaska and DiClemente's (1983) stages of change model was used to assess readiness to initiate behavioral change in the participants at the screening visit. Finally, smoking status was assessed by self-report and confirmed by biochemical analysis (CO). Alveolar CO readings were taken on all participants at follow-ups. This procedure involved having participants hold their breath for 15 s and then exhale into a disposable tube attached to a Breathco Co monitor (Model 29700), which measures CO levels parts-per-million. Abstinence was defined as reporting not smoking for the 7 days leading up to the assessment period and expiration of a CO level below 10 ppm. Participants who reported having quit and who registered a CO reading greater than 10 also submitted a saliva sample for cotinine analyses. Cotinine analysis was used as the final determinant of smoking status in these cases.

2.4. Approach to analyses

Generalized logit analysis was performed using Proc Catmod in SAS/Stat, version 8.2 (SAS Institute, 2000) to assess the effect of participant characteristics, including income level, on participants' adherence with instructions on nicotine patch use at the 7-week follow-up. In addition, the relationship between patch adherence and intervention characteristics was investigated. This analysis allows us to estimate multiple logistic regression equations simultaneously using the last outcome as the reference group.

3. Results

Participants' baseline characteristics are listed in Table 1a and b by condition. Baseline characteristics were similar across the three conditions ($N = 619$). Among the 489 participants who completed the 7-week follow-up, 4 did not answer the patch adherence question, which excluded them from analysis. Because patch adherence had three levels, two logistic equations could be estimated. Table 2 reports the ANOVA table after introducing all demographic variables and the behavioral condition group assignment.

Adding in all interactions involving treatment condition yielded an equally well-fitting model [$\chi^2(816, n = 485) = 798.50$, $P = .663$]. However, testing whether any of the interactions were significant resulted in no significant condition by demographic interactions: model improvement [$\chi^2(24, n = 485) = 10.27$, $P = .993$]. Thus, a main effect model was deemed

Table 1
Demographic distribution across conditions

(a) Entire sample, $N=619$					
		n	Condition (%)		
			A ($n=214$)	B ($n=212$)	C ($n=193$)
Gender	Female	268	42	44	44
	Male	351	58	56	56
Race[a]	Nonminority	271	44	40	47
	Minority	348	56	60	53
Age	18–30	38	7	6	5
	31–45	215	34	33	38
	46–60	286	44	46	49
	Over 60	79	15	15	8
Income	< US$20,000	324	57	54	46
	≥ US$20,000	294	43	46	54
Education	≤ High school	268	45	42	43
	> High school	350	55	58	57

(b) Subsample[b] of interest, $n=485$					
		n	Condition (%)		
			A ($n=181$)	B ($n=163$)	C ($n=141$)
Gender	Female	196	40	43	38
	Male	289	60	57	62
Race[b]	Nonminority	212	44	41	46
	Minority	273	56	59	54
Age	18–30	19	4	6	1
	31–45	167	35	29	40
	46–60	228	43	48	50
	Over 60	71	18	17	9
Income	< US$20,000	250	57	50	46
	≥ US$20,000	235	43	50	54
Education	≤ High school	210	44	42	45
	>High school	275	56	58	55

No significant differences across conditions.

[a] Nonminority refers to Caucasian participants. Minority classifies participants who described themselves as African-American, Hispanic, Native American, or other.

[b] Subsample consists of participants who completed 7-week follow-up and answered the adherence questions.

adequate. Finally, removing nonsignificant main effects resulted in a logit model with three main effects, gender [$\chi^2(2, n=485)=6.56$, $P=.038$], drop status [$\chi^2(2, n=485)=13.94$, $P=.001$], and behavioral condition group [$\chi^2(4, n=485)=14.96$, $P=.005$].

Results showed that females were less likely to be completely adherent (OR = 0.691, CI = 0.518–0.922, $P=.012$) and less likely to be mostly adherent (OR = 0.750, CI = 0.577–0.975, $P=.033$) relative to males. In addition, participants who eventually dropped out of the study were less likely to be completely adherent (OR = 0.479, CI = 0.302–0.759, $P=.002$) or mostly adherent (OR = 0.529, CI = 0.362–0.774, $P=.001$) compared to participants who

Table 2
ANOVA table for all main effects: patch adherence

Source	*df*	χ^2	$P>\chi^2$
Intercept	2	5.48	.065
Gender	2	4.70	.095
Drop	2	12.63	.002
Age	2	1.76	.414
Income	2	0.51	.776
Education level	2	2.42	.298
Race	2	1.28	.529
Condition	4	14.91	.005

Likelihood ratio (LR) = 808.77, *df* = 840, *P*=.775.

remained active in the study until completion. Furthermore, participants assigned to the patch-only condition (Condition A, $n = 181$) were less likely to be completely adherent (25.4%, OR = 0.498, CI = 0.333–0.746, $P < .001$) or mostly adherent (51.4%, OR = 0.559, CI = 0.386–0.809, *P*=.002) compared to participants receiving the most intensive intervention (Condition C, $n = 141$, 32.7% and 61%; Table 3).

No significant differences in patch adherence emerged across income levels. Among those who completed the 7-week follow-up ($n = 489$), 7% later dropped out, and drop rate differed by income level with 69% in the low-income category [$\chi^2(1, n = 489) = 5.512$, *P*=.019]. For participants with incomes below US$20,000, 29.2% reported complete patch adherence

Table 3
Results of generalized logit analysis

Effect	Contrasts[a]	Estimate	Standard error	χ^2	$P>\chi^2$	OR	95% CI
Intercept	All vs. none	0.169	0.249	0.460	.498	1.18	0.727–1.93
	All vs. partial	−0.697	0.225	9.63	.002	0.498	0.320–0.774
	Partial vs. none	0.865	0.209	17.18	<.001	2.38	1.58–3.57
Gender	All vs. none	−0.370	0.147	6.31	.012	0.691	0.518–0.922
	All vs. partial	−0.083	0.108	0.590	.443	0.921	0.745–1.137
	Partial vs. none	−0.288	0.134	4.57	.033	0.750	0.577–0.975
No Drop vs. drop	All vs. none	−0.737	0.235	9.81	.002	0.479	0.302–0.759
	All vs. partial	−0.100	0.222	0.200	.654	0.905	0.586–1.398
	Partial vs. none	−0.637	0.194	10.80	.001	0.529	0.362–0.774
Condition	All vs. none						
	A vs. C	−0.697	0.206	11.41	<.001	0.498	0.333–0.746
	B vs. C	−0.096	0.215	0.20	.656	0.908	0.596–1.385
	All vs. partial						
	A vs. C	−0.116	0.147	0.620	.432	0.891	0.668–1.188
	B vs. C	0.158	0.146	1.17	.279	1.171	0.880–1.559
	Partial vs. none						
	A vs. C	−0.582	0.189	9.53	.002	0.559	0.386–0.809
	B vs. C	−0.253	0.201	1.59	.208	0.776	0.524–1.151

OR = odds ratio.

[a] Recoding "partial" as the last category and reestimating the equation obtained the comparison "all vs. partial".

($n = 73$). Similarly, 30.6% of participants with incomes at or above US$20,000 were completely adherent ($n = 72$). Trends were similar for both income levels for partial patch adherence, as well as little or no adherence with the patch. For those participants earning less than US$20,000, 52.8% ($n = 132$) were partially adherent, and 18.0% ($n = 45$) were non-adherent. Similarly, in the US$20,000 and above income level, the partial adherence and nonadherence rates were 54.9% ($n = 129$) and 14.5% ($n = 34$), respectively.

Moreover, no significant differences were detected in adherence rates (1) across income level within condition, (2) across all age groups, or (3) between higher and lower income of participants 60 years or older. Table 4 illustrates the percentage of patch adherence by significant variables as well as income variables.

A separate proportional odds analysis was performed to assess the relationship of several baseline measures (CO level, Fagerstrom dependence score, and number of years smoking) and several program measures (number of completed phone/visit contacts, and quit status at 7 weeks, and 6 and 12 months) with patch adherence. To aid in interpretation, two separate logistic regression equations were estimated (complete/moderate adherence vs. minimal/no adherence and complete adherence vs. moderate/minimal/no adherence).

When comparing complete/moderate adherence to minimal/no adherence, number of completed contacts was significantly related to patch adherence. Participants who reported greater adherence were more likely to complete eight or more contacts (OR = 3.00, CI = 1.77–5.10, $P < .001$).

Table 4
Percentage of patch adherence by variables of interest

Variable	Patches used		
	All	Most or some	Few or none
Gender			
Females ($n = 196$)	26.5	52.6	21.0
Males ($n = 289$)	32.2	54.7	13.2
Drop status			
Dropped ($n = 41$)	19.5	41.5	39.0
Did not drop ($n = 444$)	31.0	55.0	14.2
Intervention condition			
Condition A ($n = 181$)	25.4	51.4	23.2
Condition B ($n = 163$)	32.5	50.3	17.2
Condition C ($n = 141$)	32.7%	61.0	6.4
Income			
< US$20,000 ($n = 250$)	29.2	52.8	18.0
≥ US$20,000 ($n = 235$)	30.6	54.9	14.5
Income of participants over 60 years			
< US$20,000 ($n = 48$)	33.3	56.3	10.4
≥ US$20,000 ($n = 23$)	34.8	52.2	13.0

Table 5
ANOVA table for all main effects when excluding drops

Source	*df*	χ^2	$P>\chi^2$
Intercept	2	8.59	.014
Gender	2	6.63	.036
Age	2	1.76	.414
Income	2	0.67	.714
Education level	2	2.02	.364
Race	2	1.76	.415
Condition	4	13.92	.008

Likelihood ratio (LR) = 723.06, *df* = 760, *P*=.828.

For complete adherence vs. moderate/minimal/no adherence, a significant interaction between baseline CO levels and Fagerstrom dependence scores (OR = 0.395, CI = 0.175–0.890, *P*=.025) indicated that participants with higher addiction scores were more likely to be completely adherent if their baseline CO was less than 21 compared to participants with higher CO levels.

Patch adherence showed significant predictive power on smoking status at all three follow-ups: 7 weeks (OR = 1.71, CI = 1.14–2.58, *P*=.01), 6 months (OR = 2.47, CI = 1.56–3.91, *P* < .001) and 12 months (OR = 2.12, CI = 1.34–3.37, *P*=.001). Complete adherence predicted quitters at all three time points compared to moderate/minimal/no adherence.

Finally, a subanalysis excluding 41 participants who later dropped out of the study was performed. The resulting ANOVA table for the main effect model is shown in Table 5. Again, condition by demographic interactions were not significant, model improvement [χ^2(24,

Table 6
Results of generalized logit analysis when excluding drops

Effect	Contrasts[a]	Estimate	Standard error	χ^2	$P>\chi^2$	OR	95% CI
Intercept	All vs. none	0.911	0.175	27.06	< .001	2.49	1.76–3.50
	All vs. partial	− 0.588	0.110	28.38	< .001	0.555	0.447–0.690
	Partial vs. none	1.50	0.165	82.86	< .001	4.47	3.24–6.18
Gender	All vs. none	− 0.406	0.157	6.69	.010	0.666	0.490–0.906
	All vs. partial	− 0.039	0.110	0.120	.725	0.962	0.775–1.19
	Partial vs. none	− 0.368	0.145	6.39	.012	0.692	0.521–0.921
Condition	All vs. none						
	A vs. C	− 0.705	0.219	10.32	.001	0.494	0.322–0.760
	B vs. C	− 0.037	0.230	0.030	.873	0.964	0.614–1.51
	All vs. partial						
	A vs. C	− 0.115	0.152	0.570	.450	0.892	0.662–1.20
	B vs. C	0.194	0.150	1.68	.195	1.21	0.905–1.63
	Partial vs. none						
	A vs. C	− 0.590	0.202	8.51	.004	0.554	0.373–0.824
	B vs. C	− 0.231	0.218	1.12	.289	0.794	0.518–1.22

OR = odds ratio.

[a] Recoding "partial" as the last category and reestimating the equation obtained the comparison "all vs. partial".

$n = 444) = 8.47$, $P > .99$]. Removing nonsignificant main effects produced a logit model with two main effects, gender [$\chi^2(2, n = 444) = 7.54$, $P = .023$] and behavioral condition group [$\chi^2(4, n = 444) = 13.73$, $P = .008$]. Table 6 shows the findings from the generalized logit analysis are comparable to the initial results.

For the proportional odds analysis excluding drops, results were similar to the initial findings with the exception of the CO levels by Fagerstrom score interaction (OR = 0.435, CI = 0.187–1.01, $P = .054$) which was no longer significant. Participants who reported greater adherence were more likely to complete eight or more contacts (OR = 2.36, CI = 1.36–4.12, $P = .002$). Complete patch adherence again was a significant predictor of smoking status at all three follow-ups: 7 weeks (OR = 1.66, CI = 1.09–2.53, $P = .018$), 6 months (OR = 2.44, CI = 1.54–3.86, $P < .001$) and 12 months (OR = 2.12, CI = 1.34–3.37, $P = .001$).

4. Discussion

Results from this study indicate that adherence with TN was associated with abstinence from smoking at all three follow-ups: 7 weeks, and 6 and 12 months. In addition, four correlates of patch adherence were found: gender, remaining in the study, more intensive behavioral intervention, and a greater number of completed telephone contacts.

Consistent with multiple other studies, results from this study indicate that TN adherence is associated with greater abstinence at extended follow-ups of 6 and 12 months (Alterman et al., 1999; Cummings et al., 1997; Jolicoeur et al., 2000; Kenford et al., 1994; Orleans et al., 1994; Stapleton et al., 1995). Thus, not only does the literature consistently show that those who receive the patch are more likely to quit than those who do not receive the patch (Fiore et al., 1994, 2000), these results confirm that among those who obtain the patch, adherence also predicts outcome. Thus, future research should study methods of increasing patch adherence.

That female gender was associated with decreased patch adherence is of interest. Previous studies of the relationship between TN adherence and gender have suggested that there is no relationship (Alterman et al., 1999) or that greater adherence is found among females (Cummings et al., 1997). Despite these differences among studies, the current results are consistent with studies that suggest poorer cessation outcomes for females relative to males (Monso, Campbell, Tonnesen, Gustavsson, & Morera, 2001; Norregaard, Tonnesen, & Petersen, 1993; Razavi et al., 1999). Studies suggest that poor adherence leads to poor cessation outcome (Alterman et al., 1999; Cummings et al., 1997; Kenford et al., 1994; Orleans et al., 1994; Stapleton et al., 1995), and poorer female adherence with TN offers one potential explanation for the gender gap that exists for smoking cessation rates. However, other moderator variables, for example, postcessation weight concerns, greater sensitivity and tolerance to nicotine, hormonal fluctuation, depression and negative affect smoking, and need for social support (Gritz, Nielsen, & Brooks, 1996) may be more strongly related to poorer cessation outcomes for women. Further cessation studies that ensure measures of adherence and potential correlates of adherence and outcome in large gender representative samples are warranted to further explore this relationship.

The finding that dropping out of treatment is associated with poor TN adherence is consistent with the study by Alterman et al. (1999). It also supports the practice of regarding participants lost to follow up as smokers when determining cessation rates in clinical trials that use gold standard intent to treat analyses. Future research should continue to assess factors related to both dropping out of the study and not adhering to treatment protocol to develop interventions that target individuals at high risk of either behavior.

The finding that intensity of behavioral counseling and number of telephone contacts increased TN adherence is not surprising. In addition to replicating the only other treatment study of TN adherence (Alterman et al., 1999), this is consistent with studies of adherence to other medical regimens (Van Ejiken, Tsang, Wensing, DeSmet, & Grol, 2003), which suggest improvements in adherence with adjunct behavioral counseling. It is important to point out that given that treatment assignment was a randomized, and not a correlational factor, we can be more confident in asserting that intensity of behavioral interventions may lead to increased adherence. The finding is also consistent with smoking cessation outcome studies that indicate cessation rates are associated with counseling intensity and frequency (Fiore et al., 2000; Franke, Leistikow, Offord, Schmidt, & Hurt, 1995; Swartz, Ellsworth, Curry, & Boyko, 1995). Finally, adjunct behavioral counseling in most studies not only addresses cognitive and behavioral aspects of tobacco cessation but also serves to encourage participants and help them solve barriers to adherence problems. Given this finding, future studies should explore the relationship between separate components of adjunct behavioral intervention and adherence to ensure key components are included in state-of-the-art cessation programs.

Another finding of interest is that patch adherence was not associated with level of income. This result indicates that given access to TN, adherence rates are similar for both higher and lower income individuals. This finding is consistent with the conclusions of Cummings et al. (1997) that differences in usage of TN between higher and lower income groups are reduced, and in this case, eliminated, provided access to or given free TN. Moreover, these findings are consistent with studies that indicate nicotine replacement cost may represent a significant barrier to cessation, affecting participants' intentions to quit smoking (Hines, 1996), their use of NRT (Johnson, Hollis, Stevens, & Woodson, 1991; Sippel, Osborne, Bjornson, Goldberg, & Buist, 1999), and resultant cessation success (Cox & McKenna, 1990). Conversely, dropping out of the study was significantly associated with income in that lower income participants were more likely to withdraw from the study than higher income participants. Reasons for this finding are unclear; however, others have suggested moderating influences, such as increased intention to quit and low self-efficacy (Pohl, Martinelli, & Antonakos, 1998) This finding suggests the exploration of a potential barrier for low-income individuals to attend smoking cessation counseling, especially given the disproportionate attention in the literature on pharmacotherapy adherence.

Similarly, results suggest that provided aid, adherence rates with TN are similar between higher and lower income elderly individuals. Orleans et al. (1994) assessed adherence with patch use and found that approximately 44% of the elderly respondents reported continuous patch use for under 30 days, including 29% who reported use for less than 14 days and 18%

who reported use for 7 days or less. Given the fact that patch adherence was measured differently between this study and the Orleans et al. study of lower income elderly individuals, it is not possible to make comparisons between levels of adherence in the two elderly samples. However, it is important to note that in this study with the inclusion of a higher income comparison group, no differences in adherence rates emerged in this age range, indicating that less than ideal adherence in the elderly is not likely mediated by income status.

Strengths of this study included assessment of adherence with the patch within a typically recommended time frame for patch use and an adequate sample size of the general adult population, as well as assessments of adherence by multiple variables. The primary limitation of this study was its reliance on self-reported adherence to the patch. Future studies of adherence with TN should include the use of daily adherence logs or a used patch return protocol to obtain adherence rates as accurately as possible. Despite this limitation, we were unable to identify any systematic biases that would have caused the over or underreporting of patch adherence according to variables of interest (e.g., gender, intervention condition, and income).

The results of this study further confirm the impact of adherence on outcome in smoking cessation. Furthermore, it appears that gender, remaining in the study, and intensity and frequency of intervention are important factors associated with TN adherence that should be considered in future cessation studies and interventions. Continued assessment of adherence and its associated factors with both pharamacological and behavioral cessation components will likely result in the development of more efficacious smoking cessation interventions and ultimately decrease tobacco prevalence.

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