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Does physician continuity within a clinical trial increase retention and compliance among adolescent smokers?

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Abstract

Background—Retention and compliance are hurdles in many clinical trials designed for adolescents. Factors that may improve these issues in a challenging population may lead to increased data and power in much needed adolescent substance abuse research.

Methods—Within a large-scale smoking cessation study for adolescents, physician continuity (PC) was examined to determine its effect on retention, compliance, and cessation.

Results—In an analysis of 98 participants, participants with physician continuity throughout the study were more likely to attend more treatment visits and be medication compliant. It was also found that PC had no effect on participant smoking cessation.

Conclusions—It appears that PC may be one way to increase retention and compliance within an adolescent clinical trial, without interfering with the specific aim of the research study (in this case, smoking cessation).

INTRODUCTION

Despite efforts to discourage smoking and an increase in effective treatment options, tobacco remains the number one preventable cause of death in the United States. Most smokers begin smoking during their adolescent years (Chassin, 1990). Notwithstanding the logical benefit of pursuing treatment/prevention strategies for this age group, there have been very few studies that specifically target this population. Most treatment studies have yielded small to moderate effects. For example, a meta-analysis of 48 adolescent treatment studies showed an overall treatment effect size of 2.9%, with absolute quit rates of 9.1% within active treatments vs. 6.2% for controls (Sussman, 2006). Medication studies, which typically produce greater effects, have also yielded modest abstinence results of 10.7–31.3% for active treatment vs 3.1–18% for controls (Muramoto, 2007). One potential moderating influence of any treatment outcome study is participant retention, which is a particular challenge in adolescent research. Adolescent focused psychosocial and medication intervention studies have reported high variability with retention rates ranging anywhere

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from 36–96%, with one study focusing particularly on retention strategies still only achieving a 67% retention at 6 months (Alford, 1991; Grenier, 1985; Harrison, 1989; Stinchfield, 1998; Winters et al, 2000).

Surprisingly, while retention is a recurrent problem in many adolescent treatment studies, very few researchers have examined factors that affect it (Branstetter, 2009; Meyers, 2003; Winters, 1999). One possible factor in improved retention could be continuity of care (COC). While COC is frequently cited in the medical literature and clinical practice, it lacks any general consensus on definition (Haggerty, 2003). Definitions differ among practices and disciplines (Haggerty, 2003), ranging from the relationship between a patient and a physician beyond one episode of illness (family practice), stabilization of care by an interdisciplinary team all utilizing the same treatment plan (mental health), adequate transfer of care between providers (nursing), and delivery of services by different providers in a coherent, logical, and timely fashion (disease management). Despite this heterogeneity of definitions, a review of over 260 articles showed COC improved overall patient outcomes (Cabana, 2004).

There has been some evidence supporting positive effects of COC in substance abuse treatment. In a study of 429 Veterans Administration (VA) substance abuse patients, COC was defined by a continuation of designated treatment staff between pre and post discharge treatment, providing appointments at least once per week, having an appointment scheduled before discharge, opportunity for sober housing, and provision of transportation. All of these factors improved drug abuse outcomes (Schaefer, 2008). However, another investigation of a large VA substance abuse sample (n=1576) found contrasting results. While the services provided within the substance abuse clinic showed a significant relationship between outcomes and measures, COC in this outpatient setting did not appear to related to improved outcomes (Greenberg, 2002).

Prior research on the effects of COC with adolescents is limited. A review of five studies conducted between 2002 to 2004 found COC to decrease in ER visits, lower cost, and improve overall patient and parent satisfaction (O'Malley, 2004). Other studies have found generally comparable effects of COC within adolescent populations (Apter, 2006; O'Malley & Forrest, 1996; Omar, 2008; Reid, 2005). We could find no prior study to explicitly examine continuity of care with an adolescent substance abusing population, with reported outcomes on retention or abstinence. Given the need to understand the factors that influence retention in adolescent smoking cessation studies, and given the suggestion from studies above that demonstrate the potential benefits of continuity of care, our aim was to examine the effect of the most basic definition of continuity of care (physician continuity) on an adolescent population participating in a smoking cessation study. We set out to see if increased continuity would result in better participant retention, medication compliance, and smoking cessation.

METHODS

Data for the present study were collected from a 2x2 randomized, controlled trial of bupropion SR and contingency management (CM) for adolescent smoking cessation (Gray, 2011). That study was conducted at the Medical University of South Carolina and enrolled 134 adolescent smokers for a 6-week treatment program, with follow-up at 12 weeks. Adolescents were randomized to one of 4 treatment groups (bupropion SR only, bupropion SR with CM, CM with placebo, and placebo only). During the course of a patient's participation, there were 6 physician treatment visits and 15 total visits (physician contact and otherwise). Study research personnel staffed non-physician visits. Detailed information on information on recruitment, participant demographics, and cessation data have been

published previously (Gray et al., 2011). Physician continuity was assessed only for participants completing at least three physician attended treatment visits. A total of 98 participants (57 males and 41 females) met these criteria and were assessed for continuity of physician care for the duration of the study. Four psychiatrists staffed the parent study. The study participants were offered complete flexibility of appointment scheduling. Because our physicians had numerous competing responsibilities, it was not always possible to accommodate each participant with a consistent provider. Continuity was considered achieved if the patient saw the same physician for at least 75% of his/her designated treatment visits (15–20min sessions) whom they saw during their initial treatment assessment (30–45min session). While there is no standard definition for physician continuity under these methodological circumstances (adolescent smokers participating in a cessation research study) our consensus was that, if the same physician who completed the initial assessment 3 out of every 4 visits treated a patient, this would provide a conservative level of continuity. Those who maintained this 75% or better rate of continuity were placed in the continuity group, while those who did not were in the non-continuity group.

Statistical Analysis

Descriptive statistics were used to characterize demographic and clinical variables at baseline. Differences between baseline continuous variables were assessed using a Two Sided Wilcoxon Rank Sum Test while differences in categorical variables were assessed using a Pearson Chi Square Test statistic (Fisher Exact Test was used where appropriate). To assess the effect of continuity of physician care on nicotine abstinence, the 7-day point prevalence rates for each week were compared between the two groups using a logistic regression model. Similarly, study retention was examined by looking at the differences in the percentage of participants in each group who completed all physician attended treatment visits as well as all physician attended treatment visits along with the final follow up visit. As detailed in the parent study there was no significant difference in study retention between the 4 treatment groups (Gray et al., 2011). Medication adherence was measured as the percent of the prescribed doses taken (calculated from weekly pill counts) during the period in which the participant was active in the study. To test the hypothesis that medication compliance will be associated with physician continuity, an analysis of variance (ANOVA) model was used. All reported p-values are two-sided and the type I error rate (alpha) was set to be 0.05 for each statistical comparison. No adjustments for multiple comparisons have been applied to reported p-values. All statistical analyses were done using SAS v.9.1.3 (SAS Institute, Cary, NC).

RESULTS

Baseline characteristics of participants with and without physician continuity are listed in Table 1.

Participants who experienced continuity of care were slightly older ($p = 0.003$), had more years of regular smoking ($p = 0.04$), and had a lower rate of co-morbid ADHD diagnosis ($p = 0.01$) than those who did not receive continuity of care. There were no group differences with respect to medication group (active vs. placebo) or CM group ($p > 0.35$). However, we include medication group assignment as well as contingency management status as design covariates in all subsequent analyses. Additionally, the following variables were considered as adjustment variables in all regression models: age, lifetime ADHD Status, and years of regular smoking. Age and years of regular smoking were sufficiently collinear such that age (most associated with continuity status) was chosen to represent the construct in all models. Abstinence from nicotine was determined by a combination of participant self-report and urine cotinine confirmation. Outcomes were measured on a 7-day point prevalence beginning one week following an initial two-week grace period. Abstinence rates were not

statistically different between those who received continuity of physician care and those that did not at any point during the study as depicted in Figure 1.

The hypothesis that physician continuity aids in study retention was tested by comparing the rates at which each group (continuity vs non-continuity) completed all physician treatment visits versus the rate at which they completed all study visits (6 treatment visits and 15 total study visits; see Figure 2). Of the participants receiving continuity of care, 50% completed all 6 treatment visits vs. 28.9 % among those without continuity of care ($p = 0.039$; OR = 2.51; 95% CI = 1.05 – 6.04). When assessing all six treatment visits with the addition of the follow-up visit, rates were 39.1% vs. 21.2% ($p = 0.044$; OR = 2.58; 95% CI = 1.02 – 6.45). When assessing all fourteen study visits as well as the follow-up visit (i.e., visits that did and did not include physician contact), those who had maintained physician continuity were not significantly more likely than those without continuity to complete all study visits (28.3 % vs. 19.2 %: $p = 0.336$; OR = 1.60; 95% CI = 0.61 – 4.18). The median number of total study visit (physician and otherwise, out of 15 total) was 11.0 (IQR: 6–15) in the group with continuity versus 10 (IQR: 6–14) in the group without ($p = 0.438$). Medication compliance (Bupropion SR or placebo) was greater among participants who received physician continuity (90% of all doses) as compared to those who did not (81.1% of doses; $p = 0.004$).

DISCUSSION

Continuity of care has numerous definitions in the medical literature. In our study we looked specifically at the most basic level of this definition, physician continuity. All participants placed in the “continuity of care” analysis had at least 75% of their visits provided by the same practitioner. What we observed in this analysis may give some reason to believe that physician continuity (PC) within a research protocol may be as important to compliance and retention as what the literature would suggest in clinical practice. In the group that received PC we saw significant differences in both the number of treatment visits completed for the study (increased retention), and this group also showed an increase in the total doses of medication taken as scheduled (increased compliance). These results were regardless of randomized treatment group status within the study (medication group vs. placebo, CM vs. non-CM).

As mentioned in the introduction, this population has become somewhat frustrating to many researchers to study due to their lack of retention. Within the larger smoking cessation trial of this analysis we saw a 69% discontinuation rate. Our study suggests that, by ensuring each participant has a regular physician or study practitioner throughout the course of their care, his/her ability to complete the study and comply with the treatment guidelines may be enhanced. This is very important for future research in this population. As studies continue to be limited by effect size and power, retaining more participants who are actively compliant with the protocol will ultimately lead to more valid and reliable data in a population that appears to be very different from their adult smoking counterparts.

Another important point is that it does not appear that physician continuity confounded that treatment itself. There is no indication that COC led to increased abstinence rates as an independent variable. While it did appear that for two weeks during the study the two groups did differ at a trend level (wk 3 and wk 4), the abstinence rates returned to being insignificant between the groups starting at week 6.

There were some limitations to this study. On analysis we found that the continuity group was significantly older than their counterparts by one year (18.9:17.9). We also found that they, on average, smoked more cigarettes per day (4.3/3.5). This might suggest that the continuity group was behaving more like adults who were more “chronic” smokers. It is

difficult, however, to make the case that one more cigarette a day and one more year of life would lead to one behaving more responsibly during a research study.

Another possible limitation is the difference in the percentage of ADHD diagnosed in the non-continuity group. This disorder, if untreated, may affect a patient's ability to perform, concentrate, and remember instruction. One would suspect that if the patients participating in the study were actively being treated for their ADHD, this would decrease this effect. However, studies have shown that even when treated these patients may have some difficulties when compared to their unaffected counterparts. The nature of ADHD may have also led to these patients being unable to sustain PC within the study. It could be assumed that active ADHD might lead to cancellations of appointments and appointments scheduled at various times and on various days. This would make it very difficult for a single physician to handle all of these visits. Regardless, we included ADHD status in the adjusted statistical model to account for the difference in ADHD diagnosis between groups.

Despite the study's limitations, the findings are novel and have important implications for the design and conduct of future adolescent-targeted treatment trials. It appears that attempts to increase the physician continuity within an adolescent research study may be an important way to increase both retention and compliance. It also appears to be a way to ultimately lead to studies with larger effect size and power, without adding a variable that may confound treatment results.

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FIGURE 1.

Abstinence percentages by treatment week for the physician continuity and no physician continuity groups. Strict abstinence, defined as zero cigarettes in a week on self report and confirmed by urine cotinine, was used as the variable of interest. For the third week following medication initiation, the abstinence percentage for the continuity group was 26.1 % and 15.4 % for the no continuity group ($p = 0.142$; OR = 2.24; 95% CI = 0.76–6.60). Following the fourth week, the abstinence rate fell to 19.6 % for the continuity group while rising slightly to 17.3 % for the no continuity group ($p = 0.511$; OR = 1.44; 95% CI = 0.49–4.27). After completing the fifth and sixth week of study treatment, the abstinence rate for the continuity group fell to 21.7 % and 17.4 % while the rate for the no continuity group fell to 13.5 % and 11.5 % (week 5: $p = 0.205$; OR = 2.05; 95% CI = 0.67–6.29 and week 6: $p = 0.253$; OR = 2.05; 95% CI = 0.60–6.99).

FIGURE 2.

Influence of physician continuity on physician study visit completion (treatment) and total study visit completion (study). N= number of visits. Out of the participants with physician continuity, 50 % completed all 6 treatment visits while 28.9 % of those in the no continuity group completed all treatment visits. When considering all study visits (n=15), those who experienced continuity completed 28 % complete all visits. Only 19 % of those without continuity completed all 15 study visits.

Table 1

Descriptive Statistics of Demographic Variables, Covariates, and Outcome Variables

Sample Characteristics	Overall (n=98)	Continuity (n=46)	No Continuity (n=52)
Age (Standard Deviation) **	18.3 (1.8)	18.9 (1.8)	17.9 (1.6)
Female	41.8 %	54.4 %	30.8 %
Caucasian	91.8 %	93.5 %	90.4 %
Contingency Management	49.0 %	45.7 %	51.9 %
Bupropion Group	58.2 %	63.0 %	53.9 %
Lifetime ADHD *	36.7 %	23.9 %	48.1 %
Yrs of Reg Smoking (SD) *	3.9 (2.2)	4.3 (2.2)	3.5 (2.2)
Cigarettes Per Day (SD)	10.2 (5.6)	10.1 (5.0)	10.4 (6.1)
FTND (SD)	4.0 (2.2)	3.8 (2.1)	4.2 (2.3)

Group Differences:

*
P < 0.05**
P < 0.01