MAYO CLINIC

Prospective Cohort Study of the Effectiveness of Smoking Cessation Treatments Used in the "Real World"

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Abstract

Objective: To estimate the "real-world" effectiveness of commonly used aids to smoking cessation in England by using longitudinal data.

Patients and Methods: We conducted a prospective cohort study in 1560 adult smokers who participated in an English national household survey in the period from November 2006 to March 2012, responded to a 6-month follow-up survey, and made at least 1 quit attempt between the 2 measurements. The quitting method was classified as follows: (1) prescription medication (nicotine replacement therapy [NRT], bupropion, or varenicline) in combination with specialist behavioral support delivered by a National Health Service Stop Smoking Service; (2) prescription medication with brief advice; (3) NRT bought over the counter; (4) none of these. The primary outcome measure was self-reported abstinence up to the time of the 6-month follow-up survey, adjusted for key potential confounders including cigarette dependence.

Results: Compared with smokers using none of the cessation aids, the adjusted odds of remaining abstinent up to the time of the 6-month follow-up survey were 2.58 (95% CI, 1.48-4.52) times higher in users of prescription medication in combination with specialist behavioral support and 1.55 (95% CI, 1.11-2.16) times higher in users of prescription medication with brief advice. The use of NRT bought over the counter was associated with a *lower* odds of abstinence (odds ratio, 0.68; 95% CI, 0.49-0.94).

Conclusion: Prescription medication offered with specialist behavioral support and that offered with minimal behavioral support are successful methods of stopping cigarette smoking in England.

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The evidence for the efficacy of behavioral support and several medications for smoking cessation is provided by multiple randomized controlled trials.[1-7] It is important to supplement the evidence from these experimental studies with evidence from observational studies in the "real world." In a previous study, we used cross-sectional data from an English population survey to assess the effectiveness of medication for smoking cessation combined with behavioral support in comparison with unaided quitting.[8] A key issue when using nonrandomized observational data is to account for potential confounding by indication; that is, smokers who use one method of quitting may differ from smokers using another method of quitting in terms of prognostic factors. The most important confounder in this regard is cigarette dependence.

In our earlier study,[8] we used a validated measure[9] involving ratings of current urges to smoke assessed at the time of the survey to adjust for potential confounding. In smokers who were abstinent at the time of the survey, these measures were assumed to serve as a valid proxy for urges to smoke at the time of the quit attempt. This assumption holds only when different methods of stopping are not differentially linked to lower or higher levels of urges in abstinent smokers. We indeed found that urges to smoke in smokers vs quitters did not differ as a function of method.[8] Still, smokers who used medication and behavioral support reported higher levels of urges to smoke than did smokers who tried to quit unaided. After adjusting for this confounder, we found that smokers who use a combination of specialist behavioral support and medication in their quit attempts had almost 3 times the odds of success than did those who used neither medication nor behavioral support. We also found that smokers

who bought nicotine replacement therapy (NRT) over the counter with no behavioral support had similar odds of success at stopping as did those who stop without any aid.

It is important to confirm these findings with longitudinal data that are used to measure urges to smoke in current smokers at baseline, before their quit attempt. We conducted a prospective cohort study using data from the Smoking Toolkit Study to achieve this.

PATIENTS AND METHODS

The Smoking Toolkit Study is an ongoing research program designed to provide information about smoking cessation and factors that promote or inhibit it at a population level.[10,11] Each month a new sample of approximately 1800 people 16 years and older completes a face-to-face computer-assisted survey, of whom approximately 450 (25%) are smokers. The general methodology has been described in full elsewhere and has been reported to result in figures for key variables such as smoking prevalence that are nationally representative.[10] The specific methodology used for the present study and described herein was largely based on our previous study and has been described in a different article as well.[8]

Study Population

For the present study, we used aggregated data from respondents to the baseline survey in the period from November 2006 (the start of the survey) to March 2012 (the latest wave of the survey for which 6-month follow-up data were available), who smoked cigarettes (including hand-rolled) or any other combustible tobacco product (eg, pipe or cigar) daily or occasionally at the time of the survey. These respondents were asked whether they were willing to be recontacted. A follow-up questionnaire was sent to consenting respondents 6 months after baseline. Participants were given £5 ($8) remuneration, and 1 reminder letter was sent. Of the 27,219 smokers at baseline, 5757 (21.2%) were followed up 6 months later. The sample followed up differed from those not followed up by being more likely to be female, older, less motivated to stop smoking, and reporting higher strengths of urges to smoke at baseline. The differences were small but statistically significant ($P<.05$).

Respondents to the 6-month follow-up were asked "Have you made a serious attempt to stop smoking in the past 12 months? By serious attempt I mean you decided that you would try to make sure you never smoked another cigarette? Please include any attempt that you are currently making." Those respondents who answered "Yes" were then asked "How long ago did your quit attempt start?" The response options to this question were as follows: "In the last week"; "More than a week and up to a month"; "More than 1 month and up to 2 months"; "More than 2 months and up to 3 months"; "More than 3 months and up to 6 months"; "More than 6 months and up to a year"; "Can't remember." We included only those respondents who made at least 1 quit attempt about 6 months ago.

Measurement of Effect: Use of Smoking Cessation Treatments

The use of smoking cessation treatments was assessed only for the most recent quit attempt and included the following: (1) NRT on prescription, bupropion, or varenicline in combination with specialist behavioral support (ie, one-to-one or group behavioral support delivered by a National Health Service [NHS] Stop Smoking Service); (2) NRT on prescription, bupropion, or varenicline in combination with brief advice (delivered by the prescribing health care professional); (3) NRT bought over the counter without any behavioral support; (4) none of these. The behavioral support delivered by an NHS Stop Smoking Service generally involves at least 6 sessions with the client (before the quit date, on the quit date itself, and 4 weekly follow-up sessions), with a total potential contact time of at least 1.5 hours.[12]

Measurement of Outcome: Self-Reported Nonsmoking

Our primary outcome was self-reported nonsmoking up to the time of the 6-month follow-up measurement. Respondents were asked "How long did your most recent serious quit attempt last before you went back to smoking?" Those responding "I am still not smoking" were defined as nonsmokers. Previous research has found that self-reported abstinence in surveys of this kind is not subject to the kind of biases observed in clinical trials in which there is social pressure to claim abstinence.[13,14]

Measurement of Potential Confounders

We measured variables potentially associated with the use of smoking cessation treatments