Evaluation of the impact of pharmacist-led tobacco cessation classes on abstinence rates in patients of a Patient-Centered Medical Home (PCMH) practice

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Abstract

Background:
Even with the resulting decline in cigarette smoking from 42% in 1965 to 18% in 2012 following the initial US Surgeon General’s Advisory Committee report on smoking and health, over 42 million Americans still smoke. Guidelines explicitly advocate for the combined use of counseling and medication(s) as the most effective means to improve cessation rates. This study evaluated abstinence rates of patients that attended pharmacist-led group tobacco cessation classes in
conjunction with tobacco cessation medications compared to those who utilized medications alone.

**Methods:**

Patients with a documented active smoking status in the electronic medical record (EMR) of a patient-centered medical home (PCMH) beginning July 2013 through October 2015 were invited to attend a pharmacist-led tobacco cessation class titled “The Courage to Quit.” Study inclusion criteria for the intervention group included the use of nicotine replacement treatment (NRT), bupropion, or varenicline and attendance in at least 3 of the 4 the classes. An EMR report was used to identify patients for the control group who utilized NRT, bupropion, or varenicline during the same timeframe but did not attend the class. Tobacco abstinence rates in both the control and intervention groups were assessed telephonically at 2, 4, 12, and 24 weeks following treatment.

**Results:**

Of the 80 patients who had previously taken “The Courage to Quit” classes, 30 patients met the inclusion criteria and consented to involvement in the study. The control group of 30 patients was determined based on smoking cessation treatments utilized in the intervention group and by consent to study participation. The primary endpoint, cessation at 24 weeks, was identical between intervention and control groups (26.7%).

**Conclusion:**
While overall cessation success rates did not differ between groups, patients who attended “The Courage to Quit” classes were equipped with additional knowledge and resources to support future attempts to quit.

**Background**

Over 50 years have passed since the landmark release of the 1964 report of the Surgeon General’s Advisory Committee on smoking and health. While the information in this report contributed to a decline in cigarette smoking of 42% in 1965 to 18% in 2012, more than 42 million Americans still smoke.\(^1\) Unfortunately, despite this overall decline in smoking prevalence, the burden of smoking-attributable mortality is expected to remain high for decades to come.\(^1\) Recognizing the importance of tobacco cessation on health, three of the Healthy People 2020 objectives address tobacco use in adults. Specifically, these objectives aim to: (1) reduce cigarette smoking in adults from 18.1% to 12%, (2) increase smoking cessation attempts from 48.3% to 80%, and (3) increase smoking cessation success from 6.0% to 8.0%.\(^2\)

Even with the abundant evidence in support of the deleterious effects of tobacco, its use continues to be the greatest cause of preventable death in the world. Tobacco kills over half of its users, equating to approximately 6 million people annually.\(^3\) While most tobacco related deaths are due to its direct use, over 600,000 of the deaths are caused by second-hand smoke (SHS) exposure.\(^3\) Tobacco dependence is a chronic condition that often requires repeated interventions for tobacco-free success. As reported by the Centers for Disease Control and Prevention (CDC) Morbidity and Mortality Weekly Report (MMWR) on smoking cessation among adults, 68.8% of cigarette smokers expressed a desire to quit, with 52.4% reporting recent quit attempts for
greater than one day\textsuperscript{4}. However, the overall presence of maintained cessation was only 6.2\%.\textsuperscript{5} Maintenance of smoking cessation is frequently interrupted by withdrawal symptoms and stress, often requiring multiple attempts for permanent cessation. Several evidence-based strategies to promote and facilitate tobacco cessation exist such as motivational interviewing and pharmacologic treatment options. The United States Public Health Service (USPHS) Clinical Practice Guidelines on Treating Tobacco Use recommends the dual approach of counseling in combination with medication to treat nicotine dependence.\textsuperscript{6}

There are seven first-line pharmacologic treatments for smoking cessation. These include five forms of nicotine replacement therapy (patch, gum, lozenge, inhaler, and nasal spray), bupropion, and varenicline. While each of the seven FDA approved treatments is not recommended as more effective than the others, the guidelines explicitly advocate for the combined use of counseling and medications as the most effective means to improve tobacco cessation success.\textsuperscript{6} A meta-analysis of 18 studies found the effectiveness of medication alone for abstinence rates to be 21.7\%, while combined use of medication and counseling demonstrated estimated abstinence rates of 27.6\% (95\% CI: 25.0-30.3).\textsuperscript{6}

Multiple randomized controlled trials provide evidence in support of behavioral counseling combined with pharmacotherapy.\textsuperscript{7} One single group prospective study of 21 patients using cessation medications and pharmacist-led group counseling found significant quit rates at 3 and 6 months following the class, with 47.5\% and 52.4\% of patients reporting cessation respectively.\textsuperscript{8} The combination of counseling and pharmacotherapy for smoking cessation was evaluated in another observational study involving a cohort of 6,824 smokers, which showed 6 month
reported abstinence rates of 28.1% (95% CI: 27.7-30.1). This study involved consultation and design of a customized behavioral and medication treatment plan and workbook from a tobacco treatment specialist (TTS).

A tobacco treatment specialist is a health care professional trained to aid patients in tobacco cessation attempts. Professionals completing this training are equipped with the knowledge and skills to provide education with regards to the mechanism behind nicotine addiction, the symptoms of withdrawal, and tools to help patients overcome the challenges associated with tobacco cessation. Tobacco treatment specialists are adequately prepared to convey accurate information to patients, design customized treatment plans, recommend effective treatment options to aid in quit attempts, and to provide the follow-up necessary to promote success. All pharmacists involved in orchestrating the tobacco cessation classes described in this study were tobacco treatment specialists to allow for development of effective smoking cessation plans in addition to medication education and behavioral change counseling to patients participating in the classes.

The objective of this study was to evaluate the impact of pharmacist-led tobacco cessation classes in combination with any of the seven FDA approved cessation medications on abstinence rates versus use of medication alone in patients of a PCMH model.

Methods

Study Setting
The practice site for this study was an independently-owned physician group consisting of over
twenty offices located throughout the Pittsburgh region. As part of an academic partner agreement, a pharmacist faculty member and pharmacist resident from a nearby school of pharmacy have an established practice with this group as part of a patient-centered medical home (PCMH) model. This practice identified a population of adult smokers that could benefit from additional cessation support including individuals with high-risk comorbid conditions such as asthma, chronic obstructive pulmonary disease, diabetes, hypertension, and/or coronary heart disease.

**Procedures**

To help meet this need, the pharmacist who was a clinical faculty member from a nearby school of pharmacy who practiced at this site created a tobacco cessation support group/educational class entitled “The Courage to Quit.” “The Courage to Quit” program is a pharmacist-developed and led group tobacco cessation class consisting of four face-to-face meetings for patients of the practice group in the Pittsburgh region. Class meetings occurred once weekly for four consecutive weeks. During each meeting, the pharmacist facilitator covered various topics related to tobacco cessation, including but not limited to the health risks of tobacco use, the benefits of tobacco cessation, the medication options available, and nonpharmacologic strategies for successful cessation attempts. Patients are provided handouts each week with prompts to explore their personal motivators, barriers, and support systems for their individualized quit attempts. While the pharmacist leads the class, open discussion and sharing of personal experiences is strongly encouraged. If patients attending the smoking cessation classes desire medications, the pharmacist was able to collaborate with physicians of the practice to ensure selection of optimal cessation therapy. At the end of each class session, participants are asked to complete an
anonymous feedback form. This form asks the participant to rate the helpfulness of each topic covered in that particular week on a Likert scale, as well as leaves space to write in any additional comments. These forms are used by the facilitator to address any additional questions and for quality improvement of the course as a whole.

“The Courage to Quit” classes are held periodically throughout the year, based on pharmacist availability and patient/prescriber demand. At a minimum, classes occur at least quarterly. Classes were typically held in the evening hours (5:30pm-6:30pm); however, periodically an afternoon class would also be added (3:00pm-4:00pm) to accommodate patient schedules. As peer support is a huge component of this class, patients were encouraged to attend their class for which they registered. If a patient missed a class session and the facilitator was not notified, they were contacted via telephone to determine the reason for their absence and confirm attendance the next week. The facilitator then brought the material the next week that the participant had missed and stayed after class to review if the participant was interested or able.

Follow-up for “The Courage to Quit” class was completed telephonically by the pharmacist class facilitator 2, 4, and 12 weeks from the date of the final live class session. During each of these calls the pharmacist assessed whether or not the patient was using tobacco products and/or cessation medications. The pharmacist also discussed any barriers the patients may have experienced and provided counseling and support as needed or appropriate.

Patients of the practice site offices were identified through an electronic medical record (EMR)
A report run by the practice’s informational technology (IT) department that identified patients with nicotine addiction or abuse based on diagnoses codes in patient problem lists. An invitation letter was mailed to patients at least one month prior to the initial class. The program was started in July 2013 and has served over 80 patients to date.

The study was designed as a retrospective, controlled trial with a prospective follow-up component. The study was IRB approved under expedited review.

Inclusion criteria for the intervention group were as follows: participation in at least 3 of the 4 classes occurring from July 2013 through October 2015 and use of at least one of the seven FDA approved cessation medications. Patients in the intervention group were called as part of normal follow-up procedures for “The Courage to Quit” class at 2, 4, 12, and 24 weeks after the class concluded.

Patients of the same designated primary care practices who were prescribed nicotine replacement therapy (NRT), bupropion, or varenicline for tobacco cessation between the dates of July 2013 through October 2015 were eligible for inclusion in the control group. Patients were excluded from the control group if they participated in “The Courage to Quit” class, did not have documented use of one of the aforementioned smoking cessation medications in the EMR, or if use of smoking cessation medications occurred prior to July 2013. Control group patients were identified via a report generated from the EMR which included patients prescribed NRT, varenicline or bupropion, with a sample size determined by the final response rate from the intervention group. Patients were excluded from the control group if they participated in “The Courage to Quit” class, did not have documented use of one of the aforementioned smoking
cessation medications in the EMR or used these medications prior to July 2013, or did not respond to calls to participate in the study. Patients were included in the control group from the EMR list based on response and willingness to participate in the study. As the final response rate from the intervention group was 30, the control group identified was matched by medication utilized to 30 patients.

Tobacco abstinence rates were assessed telephonically by a pharmacist or student pharmacist (under pharmacist supervision). Three attempts were made to contact each patient, with exclusion of patients in both the intervention and control groups if contact was not made. Patients of both the intervention and control groups were asked to self-report their smoking status at each phone call. A standardized script for both control and intervention groups was approved by the physician practice and utilized by pharmacists and student pharmacists for the standard of care phone calls. Verbal consent to participate in the study was obtained from patients in the intervention and control groups. For patients of the intervention group, follow-up calls at 2, 4, and 12 weeks had previously been conducted as a part of the class structure with documentation of data obtained at time of contact. These patients were all contacted an additional time to assess for study consent and 24 week cessation. Both groups were also offered counseling in regards to their quit attempts as appropriate and were invited to attend future “The Courage to Quit” classes if interested. Additional data collected during these follow-up calls included baseline demographics, nicotine product of choice, duration of nicotine use, quantity of nicotine used per day, and reason for relapse if present or known.
Statistical Analysis

Data was analyzed using descriptive statistics with measures of central tendency as appropriate. The Mann-Whitney U test was utilized to evaluate differences between the groups. The primary endpoint evaluated was smoking cessation status at 24 weeks following quit attempts. Cessation at 24 weeks required complete abstinence from all forms of nicotine, including electronic cigarettes.

Results

Of the 80 patients who had previously taken “The Courage to Quit” classes, 30 patients met the inclusion criteria and consented to involvement in the study. The control group was determined based on smoking cessation treatments utilized in the intervention group and by first response and consent to study participation to a final number of 30 patients.

Baseline demographics are detailed in Table 1. Baseline demographics were comparable in both groups in regards to gender and cigarettes per day prior to quit attempt. All patients reported cigarettes to be their primary nicotine product utilized. The median age was higher in the intervention group than in the control group, at 59 years (39 - 73) and 47.5 years (29 – 73) respectively. Nearly all patients in both intervention and control groups were Caucasian, with the exception of two patients in the control group that identified as “other.” Duration of cigarette use, defined by number of years, was greater in the intervention group, as was the prevalence of significant comorbidities.
Cessation medications utilized during quit attempts are summarized in Figure 1. As control group patients were matched to the intervention group by cessation treatments utilized, treatments used were comparable between groups with the most frequently used cessation treatment option as the nicotine patch.

Patient reported cessation at 2, 4, 12, and 24 weeks is detailed in Figure 2. The primary endpoint, cessation at 24 weeks, was identical between intervention and control groups (26.7%). Reasons for relapse amongst both control and intervention groups are summarized in Figure 3, with “stress” identified as the most prevalent reason.

**Discussion**

The prevalence in 24 week cessation maintenance was equal in both intervention and control groups at 26.7%. This is comparable to similar studies involving the combination of counseling and medications, as well as medications alone.⁷⁻⁹ Findings from the VA Normative Aging Study suggests 60 to 90% of smokers relapse within the first year of quitting, with 15% of those reaching one year of smoking cessation relapsing by the second year.¹⁰ Once previous smokers are abstinent for two or more years, the risk of relapse becomes 2 to 4%, with a less than 1% risk after 10 years of maintained smoking cessation.¹⁰ This data supports the risk for relapse being higher in the first year of cessation, with a reduction in risk for relapse after one and two years of abstinence. As our study evaluated cessation status within the first year of quitting, our findings are consistent with data reported in similar studies. While the majority of patients in our study had previous quit attempts, most could not recall a specific number. With an average of six to
nine quit attempts per smoker for maintenance of permanent cessation, patients in this study may require additional quit attempts for success.

While “stress” was the most commonly provided reason for relapse amongst both groups, a significant portion of patients in both the control and intervention group reported reason for relapse to be “lack of desire to quit” (Figure 3), which may have contributed substantially to the high rates of relapse amongst both groups.

In addition, 95% of patients in the study had commercial or Medicare insurance, which may have made the use of medications more likely. In an assessment of smoking among U.S. adults from 2001-2010, smokers with private health plans were more likely to have quit smoking than those with Medicaid or without insurance coverage. One possible explanation for this is that those patients with private health plans have more access to resources in terms of cessation medication coverage and counseling support. The same report indicated that quit attempts decrease with increasing age, with 62.4% of those aged 18-24 years reporting a quit attempt, compared with 43.5% of those aged ≥65 years. Baseline demographics differed between intervention and control groups, specifically in terms of age and comorbid conditions, with the intervention group patient population being significantly older than the control group patients. Patients in the intervention group also had a higher prevalence of significant comorbidities. The difference in age between the intervention and control group may be attributable to times the classes were held. While the majority of the classes were held in the evening hours (5:30-6:30pm), some were held during the afternoon to accommodate those with varying schedules (3:00pm-4:00pm).
Despite the different class time offerings, there may have been a great potential attraction for retired patients versus those that may have had to work during class times.

The data evaluated was also primarily self-reported, especially in regards to nicotine use history, previous cessation attempts, and current smoking status. However, the necessity of reliance of self-reported data for nicotine use is unavoidable and common amongst similar studies. Smoking history and cessation status was evaluated through chart review to verify information obtained from patients of both intervention and control groups.

The results of this study and feedback from previous class attendees have allowed for refinement of “The Courage to Quit” classes to better meet the needs of patients pursuing smoking cessation attempts. While patients overall reported enjoying the classes, many stated they would have benefited from an extension of the classes. To address this need, classes occurring in the year 2016 onward will include six classes, each of which will be one hour long in an attempt to provide additional support throughout patients’ quit attempts. This additional time will allow for more in-depth discussion on certain topics, as well as incorporation of additional active learning activities for the participants. Additional phone follow-up attempts may also be added between week 12 and 24 to identify and resolve potential contributors to relapse. As camaraderie often develops amongst patients participating in the classes, an annual reunion for all past participants will also be arranged to allow for continued support. These changes are being made in hopes of improving long term cessation success rates and to provide enhanced support to patients during their quit attempts.
This study was not without limitations. While “The Courage to Quit” classes have served 80 patients, only 30 patients responded and consented to phone follow-up and study involvement. The small sample size did not meet the minimum number to achieve adequate study power, thus limiting the ability to determine a statistically significant difference between groups. This resulted in a relatively small patient population, with nearly all Caucasian patients, which limits extrapolation of the data to all populations. Due to the non-randomized nature of the study, there was a potential for selection bias, which may have contributed to the differences in baseline demographics between the groups.

**Conclusion**

While overall cessation success rates did not differ between groups, patients with a history of attendance in “The Courage to Quit” classes may be better equipped with the knowledge and resources necessary to pursue and be successful with future quit attempts. There are many factors that can affect a patient’s success with smoking cessation such as personal desire, motivation, co-morbid conditions, support, and resources to facilitate quitting. It is the authors’ and physician practices’ belief that “The Courage to Quit” classes provide patients with some of these necessary resources to aid in their journey to becoming smoke free. Future research is warranted to determine what changes, if any, are necessary to the program structure to further improve smoking cessation rates.
References


