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Predictors of cessation in smokers suspected of TB: Secondary analysis of data from a cluster randomized controlled trial

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ABSTRACT

Background: Smoking cessation services are rarely found within health services in low income countries. Given the interactions between Tuberculosis (TB) and tobacco, including cessation support within TB programs offers a promising cost-effective solution. We conducted secondary analysis of data from a cluster randomized controlled trial of smoking cessation in health centers in Pakistan to identify predictors of continuous and short-term abstinence in smokers suspected of TB using cigarettes or hookah.
Methods: Predictor variables of those continuously abstinent at 5 and 25 weeks post quit-date (continuous abstinence) and those abstinent only at 5 weeks (short-term abstinence) were compared with those who continued smoking and with each other. Self-reported abstinence at both time points was confirmed biochemically.
Results: Data obtained from 1955 trial participants were analyzed. The factors that predicted continued smoking when compared to continuous abstinence were: being older RR 0.97 (0.95 to 0.98), smoking higher quantities of tobacco RR 0.975 (0.97 to 0.98) and sharing a workplace with other smokers RR 0.88 (0.77 to 0.99). Those with a confirmed TB diagnosis were more likely to remain continuously abstinent than those without RR 1.27 (1.10–1.47).
Conclusions: Those diagnosed with TB are more likely to be abstinent than those diagnosed with other respiratory conditions. Beyond this, predictors of continued smoking in Pakistan are similar to those in high income contexts. Taking advantage of the 'teachable moment' that a TB diagnosis provides is an efficient means for resource-poor TB programs in low income settings to increase tobacco cessation and improve health outcomes.

1. Introduction

Taking advantage of 'teachable moments' to support smokers to quit is a well-recognized approach to cessation (McBride et al., 2003; NICE, 2013) These 'teachable moments' appear when naturally occurring health events motivate individuals to spontaneously adopt risk-reducing health behaviors (McBride et al., 2003). Care pathways for those with tobacco-associated respiratory conditions provide opportunities for such 'teachable moments' to support smoking cessation. In the resource-poor contexts of low- and middle-income countries (LMICs), smoking cessation services are rare. If scarce resources for cessation are to be used effectively then taking advantage of these 'teachable moments' becomes a necessity. Targeting cessation activities at those suspected of TB is one such strategy.

The majority (80%) of the 8.6 million new TB cases globally (2012) are found in 22 LMICs, collectively named, high-burden countries (WHO, 2013b). With the help of a broad coalition, known as the STOP TB Partnership, these countries have developed an extensive system to diagnose and treat TB patients (WHO, 2010). However, only a minority of patients suspected of TB are diagnosed with the condition and the rest are found to have a variety of other respiratory illnesses.

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In South and South-East Asia, all high burden countries also have high rates of tobacco use, with 20% or more men currently smoking (2012; WHO, 2013a). Pakistan is one such country with a high burden of TB and tobacco use. The latest estimates place TB prevalence at 376 (181 to 641) per 100,000 population and smoking prevalence at 32.4% among men and 5.7% among women (WHO, 2013a). The high rate of male smoking is particularly important as TB commonly affects more men than women (WHO, 2013b).

There is an inter-relationship between respiratory disease and tobacco that can be seen both in morbidity and mortality. For TB, this association is found at every stage from initial infection (Bates et al., 2007; Yach, 2001) conversion (Slama et al., 2007) and development of disease (Bates et al., 2007) to outcomes; as smokers are less likely to adhere to TB treatment, more likely to relapse after completing treatment or need re-treatment (Chiang et al., 2007) and have a higher chance of dying due to their tobacco use (Slama et al., 2007). In South East Asia, deaths attributed to tobacco accounted for 8% of all TB deaths (WHO, 2012b).

While tobacco is the leading cause for a number of respiratory illnesses, such as chronic obstructive pulmonary disease (COPD) and lung cancer, its continued use in the presence of respiratory illnesses worsens outcomes. For example, 32% of COPD deaths among women and 47% among men in LMICs (WHO, 2009) and 90% of lung cancer deaths in men and 80% in women are attributable to smoking (WHO, 2012a). Morbidity outcomes are also affected, asthma is one example where, compared to non-smokers with asthma, smokers have more severe symptoms and accelerated decline in lung function (Hedman et al., 2011; Jindal and Gupta, 2004; Lange et al., 1998) and a reduced response to corticosteroid therapy (Tomlinson et al., 2005).

There has been extensive integration of TB diagnosis and treatment within the health systems of high burden countries using the Directly Observed Treatment Short-course (DOTS) process (WHO, 2010). This offers opportunities for teachable moments to provide cessation to patients suspected of TB who also smoke (Ng et al., 2008). For example, DOTS facilitators can be trained to provide advice and counseling to patients with suspected TB (Awaisu et al., 2011; El-Sony et al., 2007).

This paper analyses data from the ASSIST trial (Siddiqi et al., 2013, 2010), which tested a behavioral support session with (BSS+) and without bupropion (BSS), delivered by DOTS facilitators to provide smoking cessation support to patients with suspected TB. Both treatment conditions led to an eight- to nine-fold increase in continued smoking abstinence compared to the usual care; more details can be found in the published protocol and findings of this trial (Siddiqi et al., 2013, 2010). While the ASSIST trial shows the effectiveness of both these interventions, understanding which factors are likely to predict smoking cessation in patients suspected of TB will aid the tailoring of such cessation interventions in future.

2. Methods

We conducted secondary analysis of data from the ASSIST trial (Siddiqi et al., 2013) to identify predictors of continuous and short-term abstinence, and continued smoking.

2.1. ASSIST trial methods

The ASSIST trial was a balanced, pragmatic, cluster randomized trial with 3 groups. We estimated that a sample size of 1320 participants would be required to provide 80% power (2-sided $p < 0.05$) to detect a difference of at least 10% in continuous abstinence, assuming a 10% continued smoking abstinence rate among control participants (Hughes et al., 2007; Lancaster and Stead, 2005) and adjusting for cluster effect using an intra-class correlation coefficient of 0.036 (Parker et al., 2005). With 33 clusters (11 in each group) and assuming a 20% attrition rate, we needed 50 participants per cluster. We set a non-inferiority margin of difference of 5% between the intervention groups, which was based on a smoking cessation non-inferiority trial and has also been recognized as an acceptable effect size for any new smoking cessation intervention (Lindson et al., 2009; Walker et al., 2011; West, 2007). Analyses were done in general accordance with the CONSORT (Consolidated Standards of Reporting Trials) statement and its extension to cluster and pragmatic trials (Campbell et al., 2004; Zwarenstein et al., 2008).

Thirty-eight primary and secondary health care centers registered as diagnostic centers by the TB program in Jhang and Sargodha districts of Pakistan were invited to participate in the ASSIST trial between 2010 and 2011; 33 centers agreed to participate. We randomly allocated health centers by using a simple stratified randomization procedure to achieve a balance of urban and rural health centers across trial groups. A researcher who was blinded to center identity used computer generated random-number lists to generate the allocation sequence.

The study enrolled 1955 patients aged 18 years or older with suspected pulmonary TB (cough for >3 weeks without any other cause as diagnosed by a physician) who were also regular tobacco smokers (>1 cigarette/hookah session a day). TB was diagnosed by physicians as per Pakistan's National TB Program guidelines (NTP, 2015). Current guidelines recommend all adult patients suspected of having pulmonary TB to have at least two sputum specimens examined for Acid Fast Bacilli (AFB) smear microscopy. Based on the microscopy results, pulmonary TB cases are classified as Sputum smear positive TB patient (Bacteriological positive, B+ive) and Sputum smear negative TB patient (clinical diagnosed). Smear-positivity and grade indicates relative bacterial burden and correlates with disease presentation. Clinical diagnosis of active TB is made by a clinician or other medical practitioner on the basis of X-ray abnormalities or suggestive histology and extra-pulmonary cases without laboratory confirmation (NTP, 2015).

Patients eligible for the trial were referred by the physicians to the DOTS facilitators who are paramedics responsible for registering new patients, providing education, and supervising their treatment, at the health center. The DOTS facilitators' followed up enrolled patients in the BSS+ and BSS groups at 1, 5, and 25 weeks after first contact and control patients at 5 and 25 weeks. The primary outcome was continuous smoking abstinence, defined as an expired carbon monoxide (CO) measurement (piCO_Smokerlyzer, Bedfont Scientific, Maidstone, United Kingdom) of 9 ppm or less (Russell standard) (West et al., 2005) at the 5- and 25-weeks follow-up visits.

A questionnaire was developed for collecting patient information at baseline (including demographic details, tobacco use pattern, past quit history, assessment of nicotine dependence, assessment of willingness to quit and assistance with quitting) and recording details of quit date, bupropion dispensing and CO measurements and at 1 week follow-up in case of intervention groups, where further assistance with quitting was provided in the form of behavioral support for withdrawal symptoms, recording adverse effects of bupropion (if encountered) and its additional doses. The questionnaire was originally developed in English, using standard questions like Fagerstrom Test for Nicotine Dependence and then translated to Urdu language and pilot tested.

2.2. The ASSIST smoking cessation intervention

Those who consented to participate were randomized to three groups: patients in one group received two brief behavioral support sessions (BSS group), patients in the second group received two brief BSS plus 7 weeks of bupropion therapy (BSS+ group), and