Addictive Behaviors 38 (2013) 1865–1875

Contents lists available at SciVerse ScienceDirect

Addictive Behaviors

Does combination pharmacological intervention for smoking cessation prevent post-cessation weight gain? A systemic review

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HIGHLIGHTS

- Combination therapy had less post-cessation weight gain than monotherapy in short term.
- Long term weight gain was not well documented by most of the studies.
- Smoking cessation medication plus behavioral intervention is suggested for weight gain.

ARTICLE INFO

Keywords:
Systematic review
Combination pharmacological treatment
Smoking cessation intervention
Weight gain

ABSTRACT

Background: Most smokers who quit smoking gain weight. There are some interventions designed to limit weight gain following smoking cessation.
Objective: To conduct a systematic review to evaluate if combination pharmacological therapy interventions for smoking cessation are effective in reducing post-cessation weight gain.
Methods: The following databases were researched: Medline, PubMed, PsycINFO, CENTRAL and EMBASE. Detailed inclusion and exclusion criteria were specified *a priori* before conducting abstract and full text screening. Included studies were required to: (1) report data on combination pharmacotherapy including at least one FDA-approved smoking cessation medication; (2) report outcome measure of weight change from baseline to the end of follow up; (3) incorporate a minimum of 2-week follow-up; (4) recruit adult smokers. Studies were excluded if they had (1) behavioral interventions; (2) sample size of <30; (3) switching medications; or (4) they were not written in English. Abstracts and the full texts were reviewed independently by two investigators. Inclusion of studies was decided by a third independent investigator in case of disagreement between the two primary investigators.
Results: Out of 1873 studies identified, 1083 studies were included for abstract screening. Finally, 12 studies met the eligibility criteria after full text screening of 242 studies. Seven studies showed that participants in the combined therapy group had less post-cessation weight gain than those in the group of individual drugs or placebo. Four studies did not report differential weight gain measures by treatment groups. Only one study showed that post-treatment weight gain in the combined therapy group was more than the monotherapy group, although the result was not statistically significant.
Conclusions: Seven out of twelve studies indicated that combination smoking cessation medications had less post-cessation weight gain than monotherapy or placebo in short term. Long term weight gain was not well documented by most of the studies and future research is warranted.
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1. Introduction

Tobacco use remains the primary preventable cause of premature mortality and morbidity in the United States, with an estimated 443,000 deaths from diseases including cardiovascular and respiratory diseases and cancer (Centers for Disease Control, Prevention (CDC), 2012). It was estimated that smoking cost the United States $193 billion in annual health-related expenditures between 2000 and 2004, with $96 billion in direct medical costs and approximately $97 billion in lost productivity (Centers for Disease Control, Prevention (CDC), 2008). An estimated 46.5 million Americans acknowledged smoking; of these, 70% reported that they were willing to quit completely (Corelli & Hudmon, 2002). It was reported that around 52% in the United States made a serious attempt to quit; however, without receiving proper assistance in smoking cessation, more than 70% and 93% failed to quit

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http://dx.doi.org/10.1016/j.addbeh.2012.11.007

smoking at 1 month and 1 year after their initial quit date, respectively (Berg et al., 2010). Efforts to promote smoking cessation among smokers should be a routine preventive health care measure since tobacco-related disease is preventable (Corelli & Hudmon, 2002).

Cigarette smoking has had the perception of controlling body weight for many years (Audrain-McGovern & Benowitz, 2011). Female adolescents report initiating and continuing with cigarette smoking to control and lose weight (Fulkerson & French, 2003). Weight gain is one of the major reasons that hinder smoking cessation success (Meyers et al., 1997). Borrelli and Mermelstein (1998) noted that weight gain was associated with subsequent relapse of smoking behavior; Swan, Ward, Carmelli, and Jack (1993) found that "weight concerned" female smokers were more likely to reinitiate smoking than any other group; Meyers et al. (1997) concluded a lower likelihood of quitting smoking among weight-concerned smokers than any other group. One exploratory study with a sample of 113 participants reported that 40% of recruited female respondents expressed an unwillingness to gain any weight at all (Pomerleau & Kurth, 1996) post cessation, however, it is estimated that 80% of smokers who quit smoking gain weight in the United States (USDHHS, 2000). Moreover, smokers gain weight differentially after quitting smoking (Hall, McGee, Tunstall, Duffy, & Benowitz, 1989; Kawachi, Troisi, Rotnitzky, Coakley, & Colditz, 1996; Moffatt & Owens, 1991; Stamford, Matter, Fell, & Papanek, 1986; Williamson et al., 1991). Smokers gain between 7 to 19 pounds within 8 years of their successful initial quitting, whereas those who continue to smoke gain an average of 4 to 5 pounds (Lycett, Munafò, Johnstone, Murphy, & Aveyard, 2011; O'Hara et al., 1998). Williamson et al. (1991) reported that approximately 10% of smokers gained nearly 30 pounds in weight after quitting smoking. Weight gain occurs greatest in the first 1–2 months and mostly within the first 5 months, although continues to increase for 6 or more months after quitting smoking (Audrain-McGovern & Benowitz, 2011; Klesges et al., 1997).

It is therefore not surprising that a widespread concern prevails among smokers that quitting smoking is in general accompanied with weight gain; this weight gain can lessen some of the health benefits of quitting smoking (Audrain-McGovern & Benowitz, 2011). Although most health care providers would agree that the benefits of smoking cessation significantly outweigh the health risks associated with post-cessation weight gain (Audrain-McGovern & Benowitz, 2011); nonetheless, post-cessation weight gain may contribute to an increased risk of type 2 diabetes (Yeh, Duncan, Schmidt, Wang, & Brancati, 2010), hypertension (Janzon, Hedblad, Berglund, & Engström, 2004), and a reduced improvement of lung function (Chinn et al., 2005).

The US Public Health Service Clinical Practice Guidelines suggest that smoking cessation interventions should include at least one FDA-approved medication, if feasible and not medically contraindicated, in combination with tobacco dependence counseling, to increase the likelihood of smoking cessation success (Fiore et al., 2008). In some instances, combination pharmacological interventions may be appropriate (Fiore et al., 2008). Several smoking cessation pharmacotherapies have been evaluated to be effective and are available for preventing post-cessation weight gain. First-line smoking cessation medications, which are approved by the FDA, include nicotine agonists (also names as nicotine replacement therapies (NRTs)), nicotine antagonists (sustained-release bupropion hydrochloride <amfebutamone>), and nicotine partial agonists (varenicline <Chantix>). NRTs include nicotine gum, nicotine transdermal patches, nicotine nasal spray, and nicotine inhaler. Second-line medications, which are not approved by the FDA for smoking cessation but have demonstrated some effectiveness, include clonidine hydrochloride and nortriptyline hydrochloride (Table 1). The use of approved smoking cessation medications doubles the likelihood of quitting smoking (Fiore et al., 2008; West, McNeill, & Raw, 2000); and new evidence has revealed that combination pharmacological interventions are especially effective. Clinicians also should consider the use of certain combination pharmacological interventions identified as effective in this Clinical Practice Guideline (Fiore et al., 2008).

The effects of these smoking cessation medications on weight gain have been reviewed (Parsons, Shraim, Inglis, Aveyard, & Hajek, 2009). Several trials have demonstrated a lesser post cessation weight gain when using bupropion compared to varenicline or placebo (Gadde & Xiong, 2007; Parsons et al., 2009). At the end of treatment, participants taking bupropion were found to gain significantly less weight than those on varenicline (−0.51 kg (−0.09 to −0.93)) (Gonzales et al., 2006; Jorenby et al., 2006; Nides et al., 2006) and placebo (−1.11 kg (−1.47 to −076)) (Parsons et al., 2009). However, varenicline had no significant effect on post-cessation weight gain compared with placebo at the end of treatment (Gonzales et al., 2006; Jorenby et al., 2006; Nides et al., 2006; Oncken et al., 2006). The reduction in weight was less with bupropion compared to placebo at 1-year (3.8 vs. 5.6 kg) and 2-year follow-up (4.1 vs. 5.4 kg) (Jorenby et al., 1999). However, no studies reported varenicline treatment differences versus placebo or bupropion in weight gain in the longer term follow up (Parsons et al., 2009). There are evidences from randomized control trials (RCTs) and observational studies that NRT, antidepressants (i.e., bupropion) and probably varenicline for smoking cessation all reduce weight gain after smoking cessation in the short term (Parsons et al., 2009). Combination therapy has been introduced as an aid for smoking cessation with the hope of limiting gain in weight. Combining agents with different mechanisms of action such as bupropion with NRT, varenicline with NRT, NRT with NRT seems to be promising (Fagerström, 1994; Sweeney, Fant, Fagerstrom, McGovern, & Henningfield, 2001). Unfortunately, there is no gold standard for selection among the first-line medications (Fiore et al., 2008). Nevertheless, efficacy of combination pharmacotherapies for smoking cessation in reducing post-cessation weight gain is not well summarized as the corresponding monotherapies. A systematic review was conducted to examine whether combination pharmacological therapy for smoking cessation offers an effective way to reduce post-cessation weight gain.

2. Materials and methods

2.1. Data sources and systematic searches

The following databases were researched: Medline (Ovid; 1989 to September 2011; & In-Process & Other Non-Indexed Citations September 2011; searched September 21, 2011); PubMed (National Library of Medicine; searched October 6, 2011); PsycINFO (Ovid; 1987 to January 2nd week, 2012); Cochrane Central Register of Controlled Trials (CENTRAL) (searched January 13, 2012), EMBASE (Ovid Embase Classic plus Embase; 1947 to 2012 January 19; searched January 20, 2012), assisted by an experienced health sciences librarian (H.V) in developing search strategies. The core search criteria were: pharmacological/medication smoking cessation interventions, and weight gain or weight loss or weight change. An example of comprehensive search strings for Ovid Medline database can be found in Appendix A. Appropriate terms regarding FDA-approved pharmacotherapy for smoking cessation and weight gain specific to each database and keyword searching within the title and abstract fields were employed to retrieve relevant studies. Searches were limited to studies published before October 2011 with both abstract and full text written in English. Gray literature sources, unpublished conference abstracts, newspaper or magazine articles, researches in progress, or unpublished dissertations or theses were not included to retain quality of literature ensured by peer review. References from included studies were searched manually to identify relevant articles. An update search of literature databases was repeated using the same search strategy for each database with an additional limit to retrieve references published or updated between October 2011 and January 2012. The flowchart (Fig. 1) indicates the total number of references that were found through all searches.

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