



## The clinical utility of the Medication Adherence Questionnaire (MAQ) in an alcohol pharmacotherapy trial



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### ARTICLE INFO

#### Article history:

Received 16 December 2016

Received in revised form 10 March 2017

Accepted 3 April 2017

Available online xxxx

#### Keywords:

Varenicline

Alcohol pharmacotherapy

Medication adherence

Medication Adherence Questionnaire

Medical management

### ABSTRACT

**Background:** Medication nonadherence is a ubiquitous problem in pharmacology treatment for alcohol use disorders. Unintentional and purposeful nonadherence as measured by the Medication Adherence Questionnaire (MAQ) has been shown to predict problems with medication adherence; however, feedback from the MAQ has never been incorporated into a behavioral intervention to facilitate medication adherence. We assessed the integration of the MAQ into medical management (MM), a counseling approach frequently employed in conjunction with alcohol pharmacotherapy, to determine whether prior patterns of nonadherence could be addressed effectively to promote medication adherence.

**Methods:** We conducted a post-hoc analysis of data from 131 alcohol dependent smokers who participated in a double blind, placebo controlled study of varenicline for the treatment of alcohol dependence. At baseline, participants completed a single administration of the MAQ, which asks 2 questions about unintentional nonadherence (e.g., forgetting) and 2 questions about purposeful nonadherence (e.g., stopping because feeling good or feeling bad). Based on these responses, participants were divided into 1 of 3 three categories. Adherent ( $n = 60$ ), Unintentional or Purposeful Nonadherent ( $n = 50$ ) and Unintentional and Purposeful Nonadherent ( $n = 21$ ). Over the course of the 16-week treatment period, patients were expected to participate in 12 medical management (MM) sessions; a brief psychosocial treatment. Feedback based on the MAQ responses was integrated into the MM sessions to facilitate medication and treatment adherence.

**Results:** The 3 adherence groups were compared on baseline characteristics, medication adherence, treatment attendance and end-of-treatment patient ratings of treatment helpfulness. Baseline demographics and characteristics were not significantly different among the three categories. We found no statistically significant differences among the three groups with respect to pill adherence, treatment attendance, and treatment satisfaction ratings. **Conclusions:** The findings suggest that the incorporation of MAQ feedback into the MM approach could be effective in mitigating risks associated with prior patterns of nonadherence suggesting that further testing of the integrated behavioral approach is warranted.

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### 1. Introduction

Medication nonadherence is well documented as an ongoing problem in pharmacological treatment for chronic conditions. Patients receiving medications for chronic illnesses such as diabetes, asthma and heart disease have notably high rates of nonadherence ranging from 25 to 40% with similar rates reported for alcohol use disorders (AUDs) (McLellan, Lewis, O'Brien, & Kleber, 2000; DiMatteo, 2004; Weiss, 2007).

Within the past decade a substantial amount of research has demonstrated the efficacy of medications in treating alcohol use disorders. The

success of the treatment is often dependent upon patients taking the drug as prescribed. Individuals who are adherent to the medication report greater reductions in drinking as compared to those who are nonadherent (Baros, Latham, Monk, & Voronin, 2007; Chick et al., 2000; Gueorguieva, Wu, Krystal, Donovan, & O'Malley, 2013; Pettinati, 2006; Volpicelli et al., 1997; Weiss, 2004; Zweben et al., 2008). These findings highlight the need to develop innovative techniques that are effective in reducing the risk of nonadherence in alcohol pharmacological treatment.

Concerns about medication nonadherence also have implications in conducting pharmacological trials for alcohol treatment. Patient nonadherence can skew the interpretation of results by introducing bias, type II error, and reducing statistical power (Haynes & Dantes, 1987; Vander Stichele, 1991; Boudes, 1998; Kastrissios & Blaschke, 1997). Also, undetected nonadherence can lead to safety issues, e.g.,

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unanticipated side effects and overprescribing doses (Serebruany et al., 2005; Farmer, 1999). Again, this underscores the importance of addressing and improving medication adherence in pharmacological treatment.

### 1.1. Unintentional and purposeful nonadherence

There are multiple reasons for why a patient may not be adherent to the prescribed medication regimen. These reasons can be divided into two distinct categories: unintentional and purposeful. Unintentional nonadherence describes a behavior in which a patient may inadvertently not follow the regimen by being forgetful or careless with regard to taking proper doses. Some individuals lead very busy lives or have memory difficulties and are unable to manage a medical regimen, especially if the pills are taken several times a day. Most adherence interventions are designed to address this form of nonadherence (e.g., reminder systems, setting up a routine).

In contrast, a patient who is purposefully nonadherent may make the conscious decision not to follow the regimen for a specific reason. One of the circumstances in which the patient would deliberately alter or stop the medication is in response to a change in the way he or she feels since starting the therapeutic drug (Morisky, Green, & Levine, 1986). This change could be feeling worse (i.e., side effects) or feeling better (i.e., achieving treatment goal). Additionally, a patient may perceive the drug not to be working as intended and consequently decide not to adhere to the prescribed medication regime. Overall, nonadherence is multi-faceted in nature and addressing it requires a measure that will identify specific behaviors within the broad spectrum of nonadherence.

### 1.2. Medication Adherence Questionnaire (MAQ)

The Medication Adherence Questionnaire (MAQ; Morisky et al., 1986), is a widely-used device to identify distinct patterns of adherence and to predict future adherence behavior (Čulig & Leppée, 2014). The questionnaire is brief (4 items), easy to administer and to score, and can be readily applied in a wide variety of medical and social service settings.

Since the original publication, the MAQ has been used to establish validity in treatment studies of patients with various diagnoses in diverse settings. In the past decade, research has used the questionnaire (or modified versions of) in studies of hypertension (Islam, Muntner, Webber, Morisky, & Krousel-Wood, 2008; Fernandez, Chaplin, Schoenthaler, & Ogedegbe, 2008; Morisky, Alfonso, Krousel-Wood, & Ward, 2008; Van De Steeg, Sielk, Pentzek, Bakx, & Altiner, 2009; Krousel-Wood, Muntner, Islam, Morisky, & Webber, 2009; Berni et al., 2011; Lee et al., 2013), cigarette smoking (Catz et al., 2011; Toll, McKee, Martin, Jatlow, & O'Malley, 2007), psychiatric illness (Adewuya et al., 2009; Fialko et al., 2008; Kikkert et al., 2008), HIV (Cha, Erlen, Kim, Sereika, & Caruthers, 2008; Simoni et al., 2006; Sodergard et al., 2006) among others.

However, the MAQ has not been employed in the context of behavioral intervention to facilitate medication adherence. More specifically, responses to the items on the MAQ have not been linked with particular intervention strategies to forestall adherence problems and at the same time, strengthen a commitment to the medication regime. Integrating the information acquired from the MAQ into a behavioral intervention would create an opportunity, early on, to identify and address patient-specific adherence concerns and provide ongoing personalized feedback to prevent or minimize the risks associated with nonadherence to the medication.

### 1.3. Aim/objectives

The aim of the current paper is to examine the integration of the MAQ into a behavioral intervention to achieve high medication

adherence. We describe specific methods and strategies associated with using MAQ as a component of the behavioral intervention. We evaluate this model by assessing medication adherence, treatment attendance, and treatment satisfaction ratings. It is expected that our findings will inform approaches to improving medication-assisted alcohol treatment and future pharmacotherapy trials that include a behavioral platform aimed at achieving and sustaining high medication adherence rates.

## 2. Materials and methods

### 2.1. ADVANCE Study

This investigation is part of the larger study, named the ADVANCE Study, which was aimed at testing the efficacy of varenicline in treating alcohol use disorders in heavy drinking smokers (O'Malley & Zweben, 2016). Varenicline, a partial nicotinic acetylcholine agonist, has been shown to be effective for smoking cessation and considered to play a role in modifying the rewarding effects of both nicotine and alcohol (Davis & de Fiebre, 2006; Schlaepfer, Hoft, & Ehringer, 2008; Soderplam, Lof, & Ericson, 2009). In this trial, both alcohol and smoking outcomes were investigated. All protocols were reviewed and approved by the Institutional Review Boards of Columbia University and Yale University as well as a study Data and Safety Monitoring Board.

#### 2.1.1. Behavioral intervention platform

In the ADVANCE Study, medical management (MM) was utilized as the behavioral platform. MM was originally created by a cohort of experts in the alcohol treatment field for the COMBINE study (Anton et al., 2006), an NIAAA supported, multisite national study that investigated combinations of medications and behavioral interventions in 1383 patients to improve treatment outcome for alcohol dependence. In this approach, the MM practitioner orients the individual to the study medication, addresses medication adherence issues and provides ongoing support for abstinence. The MM intervention is particularly geared toward primary care settings and does not require extensive training (Pettinati & Mattson, 2010).

*2.1.1.1. Infusing the MAQ and motivational interviewing (MI) into medical management.* The original MM manual (Pettinati & Mattson, 2010) was adapted for use in the ADVANCE Study. It was decided that the original manual could be improved by incorporating feedback on the MAQ. At the same time, motivational interviewing (MI) strategies could be used to respond to issues or concerns raised in the MAQ. In a recent meta-analysis, MI was found to be significantly more effective than comparative approaches in enhancing medication adherence among adults receiving medication for chronic diseases (Zomahoun et al., 2016).

Consequently, the MM manual was modified to include MI strategies and vignettes that could be used in reducing obstacles to adherence. In line with the MI approach, greater emphasis was placed on the benefits of changing drinking behavior (i.e., improved relationships, enhanced quality of life) rather than on the risks associated with not changing the drinking behavior (i.e., elevated liver enzymes, legal issues). MI techniques such as reflective listening, normalizing, promoting optimism, focusing, and evoking change talk were incorporated into the manual to attend to obstacles related to adherence and to strengthen a patient's commitment to the medication regime (Hettema, Steele, & Miller, 2005; Miller & Rollnick, 2013; Rollnick & Miller, 1995).

To illustrate, in the initial session feedback on the MAQ was provided to help the patient develop a medication adherence plan. The plan outlines where and when to take the medication along with detailed reminders specific to the patient's lifestyle. MI strategies were used in helping to resolve situations or conditions where the patient may be ambivalent about taking the medication (see Section 2.5). These

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