



## Nicotine dependence, psychological distress and personality traits as possible predictors of smoking cessation. Results of a double-blind study with nicotine patch

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### ABSTRACT

**Aim:** Nicotine replacement therapy (NRT) is an effective treatment for smokers who want to quit, however, the rates of successful quitting can be improved even more. In this context, nicotine dependence (assessed via the Fagerström Tolerance Questionnaire, FTQ), psychological distress (measured via the Symptom Rating Test, SRT), and personality traits (evaluated via the Adult Eysenck Personality Inventory, AEPI) were evaluated as possible predictors of smoking cessation. **Results:** A total of 297 cigarette smokers were followed for one year as part of a NRT double-blind, parallel group, randomized trial. Baseline nicotine dependence (weeks 12 and 26:  $p < 0.05$ ), AEPI neuroticism (weeks 12 and 52:  $p < 0.05$ ), and AEPI psychoticism (weeks 12 and 52:  $p < 0.05$ ) scores significantly influenced the outcome of smoking cessation during one-year of follow-up. An increase in psychological distress during follow-up was associated with a lower probability of quitting smoking ( $p = 0.000$ ).

**Conclusions:** Nicotine dependence, neuroticism, psychoticism and, over time, psychological distress were the main factors influencing the long-term outcome (i.e., up to 12 months) of smoking cessation under NRT.

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### 1. Introduction

Cigarette smoking is the chief avoidable cause of illness and premature mortality in the world (Boyle, 1997; Mokdad, Marks, Stroup, & Gerberding, 2004). The most important strategy to reduce the rates of morbidity and mortality is to reduce the number of current smokers (Rigotti, 2002).

Nicotine dependence is widely known to influence the likelihood of smoking cessation and of maintaining abstinence. According to different studies, a high nicotine dependence score is a predictor of poor outcome (Ferguson, Patten, Schroeder, Offord, Eberman, & Hurt, 2003; Chatkin, Mariante de Abreu, Haggstram, Wagner, & Fritscher, 2004; Ong, Cheong, Prabhakaran, & Earnest, 2005). Although the treatment of nicotine dependence has improved (Hughes, Goldstein, Hurt, & Shiffman, 1999), the rates of smoking cessation are usually around 40% at the end of treatment and 25–30% after one year of follow-up (Lancaster, Stead, Silagy, & Sowden, 2000).

In an effort to increase these proportions, factors that may influence the occurrence of relapse have been increasingly studied. Pharmacotherapy (National Health Service, 1998; Rigotti, 2002; US Department of Health and Human Services, 2000), socio-

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demographic characteristics (Nides et al., 1995; Sherman, Wang, & Nguyen, 1996; O'Loughlin, Paradis, Renaud, Meshefedjian, & Barnett, 1997; Wetter, Kenford, Smith, Fiore, Jorenby, & Baker, 1999), and clinical features have become interesting issues to analyze. Although several clinical factors have been identified (e.g., years of smoking, previous attempts to quit, period of smoking abstinence) (Norregaard, Tonnesen, & Petersen, 1993; Stapleton et al., 1995; Matheny, & Weatherman, 1998), there has been growing interest in psychological and psychiatric clinical factors.

Some reports highlight that a history of any psychiatric disorder (Ferguson et al., 2003), particularly depression (Glassman et al., 1990; Hughes, 1993) or alcohol/drug problems, is linked to a reduced likelihood of smoking cessation. However, other authors have shown that a lifetime history of depressive disorder does not modify the rates of smoking cessation (John, Meyer, Rumpf, & Hapke, 2004).

The role of psychological distress is still unclear. Some authors have shown that anxious or depressive symptoms are not significantly associated with quitting rates (Catley, Ahluwalia, Resnicow, & Nazir, 2003; Raheison, Marjary, Valpromy, Prevot, Fossoux, & Tyard, 2005). Other authors have found that changes in negative affectivity and psychological distress are consistently related to the persistence of the urge to smoke (Doherty, Kinnunen, Militello, & Garvey, 1995) and to a decrease in the odds of successful abstinence (Killen, Fortmann, Kraemer, Varady, Davis, & Newman, 1996; Strasser et al., 2005).

Finally, it is widely accepted that the ability to cope with abstinence from smoking may involve inter-individual factors: self-efficacy (Bandura, 1997; Amodei, & Lamb, 2005), motivation (Dale et al., 1997; Miller, & Rollnick, 2002), readiness for change in the addictive disorder (Prochaska, & Velicer, 1997), and personality.

Relationships between personality and smoking have been addressed (Malouff, Thorsteinsson, & Schutte, 2006), yet few studies have examined personality as a factor affecting quitting. Extraversion and neuroticism were found to discriminate between abstainers and persistent smokers (Poole, Bunn, Sanson-Fisher, & German, 1982). A high trait of neuroticism (Gilbert, Crauthers, Mooney, McClernon, & Jensen, 1999) as well as great impulsiveness (Doran, Spring, McChargue, Pergadia, & Richmond, 2004) predicted higher failure rates in quitting smoking. High scores on neuroticism and low scores on agreeableness and conscientiousness were predictors of poor outcome (Hooten et al., 2005).

In this context, the purpose of the present study was to evaluate nicotine dependence, psychological distress, and personality as possible clinical predictors of smoking cessation over a one-year follow-up period in smokers who participated in a double-blind, clinical trial with nicotine patch or placebo (Paoletti et al., 1996).

## 2. Methods

### 2.1. Study design

The present study was conducted in the framework of a double-blind, randomized, parallel groups clinical trial designed to test whether more adequate nicotine replacement might improve the success rate of smoking cessation. More details are described elsewhere (Paoletti et al., 1996).

Briefly, smokers were divided into two treatment groups based on their cotinine plasma values. The low cotinine group (LC) had values equal to or below 250 ng/ml and the high cotinine group (HC) had values above 250 ng/ml. The threshold value (median value) was chosen on the basis of the frequency distribution of cotinine plasma concentrations obtained from a pre-screening representative sample of smokers ( $n=200$ ) in the city of Pisa, since no data were available on cotinine plasma values in the Italian population at the time the study was conducted. This cotinine cut-off point was similar to cut-off points used by Sachs (1995).

Smokers in the LC group were randomly assigned to placebo or to a 15-mg nicotine patch. Smokers in the HC group were randomly assigned to a 15- or 25-mg nicotine patch. Patches were worn for 16 h. Full treatment lasted for 12 weeks and was followed by a 6-week tapering period (10 mg for 3 weeks and 5 mg for 3 weeks). All participants were followed for 52 weeks.

Approval for this study was granted by the Medical Ethics Review Board of Pisa University Hospital.

### 2.2. Subjects

Four hundred smokers, aged 20–60 years, from the general population of the city of Pisa ( $\pm 100,000$  inhabitants, Tuscany, Central Italy) replied to advertisements published in local newspapers. They were screened via a telephone call by trained personnel. Study inclusion required subjects to have smoked at least 10 cigarettes per day for at least 3 years. Smokers were excluded if they met diagnostic criteria for chronic dermatological disorders and/or cardiac diseases, had a past or current history of psychiatric disorders, were currently taking daily psychiatric medications, or were pregnant or breastfeeding.

After the telephone interview, 350 smokers who fulfilled the selection criteria were invited to the University Hospital of Pisa. The first 297 subjects were enrolled in the study. One hundred twenty of them had low and 177 high baseline cotinine plasma levels. Of the LC subjects, 60 received placebo and 60 others 15 mg of nicotine. Of the HC subjects, 90 received 15 mg of nicotine and 87 others 25 mg of nicotine.

### 2.3. Baseline evaluation

At the first visit, a medical doctor performed a complete physical examination and a detailed clinical and smoking history. Expired carbon monoxide (CO) was measured. A blood sample was collected to measure nicotine and cotinine plasma values.

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