

## Paroxetine reduces social anxiety in individuals with a co-occurring alcohol use disorder

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### Abstract

Patients with social anxiety disorder who are seen in clinical practice commonly have additional psychiatric comorbidity, including alcohol use disorders. The first line treatment for social anxiety disorder is selective-serotonin-reuptake-inhibitors (SSRIs), such as paroxetine. However, the efficacy of SSRIs has been determined with studies that excluded alcoholics. Forty two subjects with social anxiety and a co-occurring alcohol use disorder participated in a 16-week, double-blind, placebo-controlled clinical trial to determine the efficacy of paroxetine for social anxiety in patients with co-occurring alcohol problems. Paroxetine was superior to placebo in reducing social anxiety, as measured by the Liebowitz Social Anxiety Scale total and subscale scores and additional measures of social anxiety. This study provides the first evidence-based recommendation for the use of an SSRI to treat social anxiety in this patient population.

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### 1. Introduction

Social anxiety disorder, also known as social phobia, is characterized by an excessive or unreasonable fear of scrutiny in social situations (American Psychiatric Association, 2000). The lifetime prevalence of social anxiety disorder is 5%, and the mean age of onset is 15 years (Grant et al., 2005). Two types of social anxiety disorder have been identified. Generalized social anxiety disorder indicates that the affected individual fears multiple social situations (i.e., eating, writing,

speaking in public), whereas individuals who have only one social fear (typically public speaking fears) are considered to have the non-generalized type (Mannuzza et al., 1995). The generalized type is considered to be more severe and more debilitating (Kessler, Stein, & Berglund, 1998; Wittchen & Beloch, 1996; Wittchen & Fehm, 2001) and is the type most likely to seek treatment (Kessler et al., 1998).

One of the challenges in treating generalized social anxiety disorder is that it is often complicated by an additional Axis I disorder, most commonly other anxiety disorders, affective disorders, and/or substance use disorders (Burns & Teesson, 2002; Chartier, Walker, & Stein, 2003; Kessler et al., 1998; Magee, Eaton, Wittchen, McGonagle, & Kessler, 1996; Merikangas & Angst, 1995; Rosenbaum, 1995). These patients tend to have more severe social anxiety and greater functional

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impairment (Lecrubier, 1998). Unfortunately, little is known about how to treat social anxiety disorder in the context of a current comorbid psychiatric condition, as clinical trials typically exclude individuals with comorbid disorders (Herbert, 1995). In fact, a recent consensus paper on investigating treatments for social anxiety disorder specifically recommends excluding comorbidity because it may interfere with the measurement of efficacy (Montgomery et al., 2004). Consequently, there is a lack of evidence-based research to guide the treatment of social anxiety in individuals with comorbid conditions. A recent review of pharmacotherapy for social anxiety disorder and a recent review of treatment recommendations for persons with a co-occurring affective or anxiety and substance use disorders specifically have called for more research on comorbid samples (Stein, Ipser, & Van Balkom, 2006; Watkins, Hunter, Burnam, Pincus, & Nicholson, 2005), including alcohol use disorders (i.e., alcohol abuse or alcohol dependence), which occurs in about 20% of individuals seeking treatment for social anxiety disorder (Morris, Stewart, & Ham, 2005; Van Ameringen, Mancini, Styan, & Donison, 1991).

Given that one in five individuals who seek treatment for social anxiety disorder has an alcohol use disorder, an important question is whether a first-line treatment for social anxiety disorder, such as an SSRI, is a safe and effective treatment for social anxiety in this patient population. To our knowledge, the only study addressing this question was a pilot project conducted by our group (Randall et al., 2001). Those results, based on a small sample size and 8-week treatment period, were encouraging, but a larger scale study was warranted to confirm the pilot study results.

The present study was conducted to follow-up and extend our pilot study to include a larger sample size and a longer treatment period. We chose paroxetine as the treatment for social anxiety disorder, as its efficacy has been demonstrated with well-controlled clinical trials (Baldwin, Bobes, Stein, Scharwaechter, & Faure, 1999; Liebowitz, Gelenberg, & Munjack, 2005; Stein et al., 1998), and it was used in our pilot study. The randomized clinical trial was 16 weeks and double blind. It included individuals seeking treatment for social anxiety disorder who also met DSM-IV criteria for an alcohol use disorder. All individuals reported deliberate drinking to cope with social stress. Data on social anxiety severity and alcohol use were collected weekly using standardized and validated instruments. Research and clinical assessments of social anxiety were conducted separately to insure independent ratings of outcome variables. Data analysis used state-of-the-art statistical methods. The

effects of paroxetine treatment on drinking outcomes (e.g., quantity/frequency of drinking, drinking to cope with social anxiety) is presented in more detail in a stand-alone publication. The current paper focuses only on social anxiety outcomes. The a priori hypothesis tested was that the paroxetine-treated group would demonstrate improvements in social anxiety compared to the placebo-treated group.

## 2. Methods

### 2.1. Subject selection

Participants were recruited from the community through advertisements in the local media. Individuals were encouraged to call study personnel for a confidential telephone screening interview if they were interested in participating in a research study on the pharmacologic treatment of social anxiety; alcohol use was not mentioned in the advertisements. The screening interview included questions from the Mini-SPIN (Connor, Davidson, Sutherland, & Weisler, 1999) which helped determine whether the individual would likely meet diagnostic criteria for social anxiety disorder. Individuals were also asked questions related to their quantity and frequency of drinking. The telephone screening was used to determine whether an individual should be invited for an in-person interview.

The in-person eligibility interview was conducted on 102 individuals, who first signed an informed consent agreement approved by the university's institutional review board. All in-person interviews were conducted by clinically-trained research personnel and by the study physician (SWB). Each individual was evaluated by study personnel using the Structured Clinical Interview for DSM-IV (SCID); (First, Spitzer, Gibbon, & Williams, 2001) the results of the evaluation were used to determine eligibility. Individuals were required to meet diagnostic criteria for current social anxiety disorder, generalized type, and current alcohol use disorder (alcohol abuse or dependence). They were excluded if they had current bipolar disorder, schizophrenia, substance abuse or dependence other than alcohol, nicotine, marijuana, or presence of significant suicidality. Any SCID evaluation completed by a master-level clinician was followed up with a review by doctoral level clinicians trained and experienced in SCID administration in clinical trials.

In addition to these diagnostic criteria for inclusion, a medical examination, laboratory tests, and an assessment battery (described below) of standardized instruments were used to determine final eligibility. The study

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