

Therapeutics

Paroxetine was effective for reducing symptoms in social phobia

Baldwin D, Bobes J, Stein DJ, et al on behalf of the Paroxetine Study Group. *Paroxetine in social phobia/social anxiety disorder. Randomised, double-blind, placebo-controlled study. Br J Psychiatry* 1999 Aug;175:120–6.

QUESTION: In patients with social phobia, is paroxetine effective for reducing symptoms?

Design

Randomised (allocation concealed*)†, blinded (clinicians, patients, outcome assessors, statisticians)*†, placebo controlled trial with 12 weeks of follow up.

Setting

39 centres in Belgium, France, Germany, Ireland, South Africa, Spain, and the UK.

Patients

290 patients who were ≥18 years of age (mean age 36 y, 54% women) and had a primary diagnosis of social phobia according to the *DSM-IV* criteria. Exclusion criteria included any other Axis I disorder in the previous 6 months, serious medical disorders, or recent treatment with psychotropic drugs or psychotherapy. 73% of patients completed the study, and 97% were included in the analysis.

Intervention

Patients were allocated to paroxetine, 20 mg/day initially and increased by 10 mg/day as needed to a maximum of 50 mg/day (mean dose 34.7 mg/day) (n = 139), or to placebo (n = 151) for 12 weeks.

Main outcome measures

Mean change in scores on the Liebowitz Social Anxiety Scale (LSAS, maximum score 144 points) and the proportion of responders on the Clinical Global Impression (CGI) scale (maximum score 7 points). Secondary outcomes included the Social Avoidance and Distress Scale (maximum score 28 points).

Main results

More patients in the paroxetine group than in the placebo group were treatment responders ($p < 0.001$) (table). Paroxetine led to greater improvement from baseline than did placebo in scores on the LSAS (difference in mean change from baseline 13.8, 95% CI 6.1 to 21.5)‡ the Social Avoidance and Distress Scale (difference in mean change from baseline 3.3, 1.4 to 5.3)‡ and the CGI (difference in mean change from baseline 0.7, CI 0.4 to 1.0)‡.

Paroxetine v placebo for social phobia at 12 weeks¶

Outcome	Paroxetine	Placebo	RBI (95% CI)	NNT (CI)
Treatment response	66%	32%	103% (57 to 166)	4 (3 to 5)

¶Abbreviations defined in glossary; RBI, NNT, and CI calculated from data in article.

Conclusion

In patients with social phobia, paroxetine was effective for reducing symptoms.

*See glossary.

†Information provided by author.

‡Difference in mean change and CI calculated from data in article.

COMMENTARY

Social phobia is a situationally linked, intense, irrational, and persistent fear of being scrutinised or negatively evaluated by others¹ and is associated with fear of humiliation or embarrassment.² Thus, socially demanding situations become disabling. Patients are cognitively aware of the irrationality of their fear.^{1–3} Prevalence rates are about 13% for lifetime³ and 7% at 1 year.^{1,3} The presence of social phobia increases the risk for mental, drug, and alcohol comorbid illnesses.¹ Untreated, the condition can become chronic and unremitting, leading to education and employment difficulties.^{1,3,4}

Cognitive behaviour therapy with or without antidepressants is the most effective treatment.¹ Properly administered therapy, however, is not available, affordable, or obtainable for most people with social phobia. Current drug options are selective serotonin reuptake inhibitors (SSRIs), monoamine oxidase inhibitors, and benzodiazepines. Little evidence exists for the effectiveness of tricyclic antidepressants.¹

The study by Baldwin *et al* and the current deluge of consumer education and marketing illuminate this hidden, underdiagnosed anxiety disorder. A crossover design would yield more information; the effects after 12 weeks of treatment or discontinuation are unknown. Of note, the abnormal ejaculation rate was 10 times higher in the paroxetine group than in the placebo group. As is often the case, the sample was selected: patients had pure social phobia, no comorbid conditions, and no history of failed SSRI therapy for any illness. Excluding previous non-responders biases the results toward SSRI efficacy. This luxury does not exist in the office where initial treatment occurs. The overall results of this study, however, support using paroxetine to treat social phobia initially; other data also support using other SSRIs and treatments.¹ The main message is the importance of recognising and diagnosing this under-recognised, debilitating illness because of the tremendous implications for quality of life and wellness.

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- 2 American Psychiatric Association. Task Force on DSM-IV. *Diagnostic and statistical manual of mental disorders: DSM-IV* 4th edition. Washington, DC: American Psychiatric Association, 1994.
- 3 MCP Hahnemann University Social Anxiety Treatment Program. <http://www.mcphu.edu/shp/fear/#3>.
- 4 Davidson JR. Pharmacotherapy of social anxiety disorder. *J Clin Psychiatry* 1998;59 Suppl 17:47–53.

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