Correspondence

EDITED BY MATTHEW HOTOPF

Reporting of randomised trials

Allgulander *et al* (2001) evaluated the efficacy of venlafaxine extended release (ER) in patients with generalised anxiety disorder and reported that all doses of venlafaxine ER showed significantly higher treatment response rates compared with placebo. We read this double-blind, randomised study with great interest and wish to raise concerns about the recruitment of the subjects. Randomised controlled trials are always cited as the gold standard for detecting the efficacy of results. However, they often can be flawed in design and are not immune to bias. Large-scale multi-centre trials often include hundreds of patients from a large number of centres located in different countries. The clinical relevance of such studies has been criticised on the grounds of selection bias.

Healy (2001) stated that company-sponsored randomised controlled trials invariably recruit samples of convenience, which by definition do not really sustain extrapolation to normal clinical practice. These trials also make use of restrictive inclusion criteria in order to ensure the greatest possible homogeneity of the sample studied. This creates a problem when attempting to generalise the results from available trials to more everyday patient populations.

In this context, the Consolidated Standards of Reporting Trials (CONSORT) guidelines, which state that all patients assessed for the trial should be accounted for and that the report should be accompanied by a diagram which explains what happened to all the patients involved in the trial (Begg *et al*, 1996), should be followed. Allgulander *et al* failed to follow the CONSORT guidelines. The information about recruitment of the subjects is lacking. We do not know how many subjects were initially assessed, how many were excluded and why. We also do not have any idea of the response rate or the participation rate, which have implications for generalisability and future research. Also, patients with significant depressive symptomatology were excluded, which raises concerns over whether these results are relevant to general patients.

Allgulander C., Hackett D. & Salinas, E. (2001) Venlafaxine extended release (ER) in the treatment of generalised anxiety disorder. Twenty-four-week placebo-controlled dose-ranging study. *British Journal of Psychiatry*, **179**, 15–22.

Begg, C., Cho, M. & Eastwood, S. (1996) Improving the quality of reporting of randomized controlled trials: the CONSORT statement. *JAMA*, **276**, 637–639.

Healy, D. (2001) Evidence biased psychiatry? *Psychiatric Bulletin*, **265**, 290–291.

A. K. Jainer, S. Acharya St Michael's Hospital, St Michael's Road, South Warwick Combined Trust, South Warwick CV34 5QW, UK

Authors' reply: We thank Drs Jainer and Acharya for drawing our attention to the CONSORT statement, which has in fact been updated more recently (Moher *et al*, 2001). We find that our report adopts almost all of the recommendations in the CONSORT guidelines, and are therefore left to speculate whether there has been some misinterpretation of the objectives of our study. In reporting this study, we were at pains to ensure that the nature of the studied population was transparent. We describe the total number of randomised patients, the number who met the criteria for the intent-to-treat (ITT) population for analysis of efficacy, the definition of the ITT population and the reasons for discontinuation of *every* randomised patient (not only the ITT population), and we report in detail the inclusion and exclusion criteria applied in the protocol to obtain patients for the study. We do acknowledge, however, that we did not report in the manuscript the number of patients who were assessed for eligibility for randomisation and not finally selected for the study (i.e. screen failures).

With respect to generalisability of the results, we note the limitations of this in the appropriate section of the report. However, this study was intentionally designed and executed as a well-controlled explanatory trial rather than a pragmatic study (Schwartz & Lellouch, 1967). The objective was to prove the efficacy of venlafaxine extended release in the treatment of generalised anxiety disorder. If we had included patients with 'significant depressive symptomatology', as Drs Jainer and Acharya suggest, such a trial would have confounded the aims of the study by being incapable of determining whether the efficacy observed was due to an effect on symptoms of generalised anxiety disorder rather than on symptoms of depression. Now that we know that venlafaxine is effective in generalised anxiety disorder (as well as in depression), we may start to consider its efficacy in mixed states. Indeed, one of the more pragmatic aspects of this trial, the recruitment of patients across a wide range of centres, is also subject to criticism: surely the results would be less rather than more generalisable if the patients had been recruited from only one or two centres. Some other points of criticism are difficult to understand: response rates as well as recruitment procedures are described in the paper.

We recommend to Drs Jainer and Acharya that in order to advance the generally valid points they raise with respect to the reporting of randomised trials, they do so systematically and perform a general review of such trials in this area, both psychotropic and psychotherapeutic, in order to place within context the findings of our particular study, which we stand by as a well-conducted and well-reported trial. In the treatment of generalised anxiety disorder, benzodiazepines have been widely and traditionally used. Beta-blockers and even antipsychotic treatments are also widely given to these patients in practice. We believe that the findings in our study advance the knowledge base for the rational treatment of patients with this disorder.

Declaration of interest

This study was funded by Wyeth-Ayerst Research, of which D.H. and E.O.S. are employees. C.A. is an employee of the Karolinska Instituet, Stockholm, and was an investigator for one study centre.

Moher, D., Schulz, K. F. & Altman, D. (2001) The CONSORT statement: revised recommendations for

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