CORRESPONDENCE

To the Editor:

I read with interest the well-designed study by MARQUETTE *et al.* [1], which assessed high *versus* low dose corticosteroid use in the treatment of acute, severe asthma. There are two points, however, which I would like clarified. Firstly, the data on post-treatment forced expiratory volume in one second (FEV1) presented in the text appears reversed from the same data shown in figure 1. In addition, it appears that the low dose group (if the data in figure 1 are correct) started at a lower FEV1, and though the difference in baseline FEV1 between the two groups may not have been statistically significant, I believe that the clinical importance, or lack there of, in the baseline spirometry should have been discussed.

The second point concerns the authors' discussion of sample size and power. The authors did an excellent job of presenting their initial sample size determination. They chose the 24 h post-treatment FEV1 as their outcome variable, the difference in 24 h post-treatment FEV1 between the two groups that they would like to detect (20% predicted), and provided us with their estimate of the standard deviation (obtained from a preliminary study). They determined the sample size assuming a power of 0.9, hence a 90% chance of detecting a difference in post-treatment FEV1 of 20% predicted between the two groups. They told us the difference they wished to detect, the power they wished to have, and the estimated standard deviation; the only factor essential to the sample size determination which they did not state was the alpha value, which I presume was 0.05. The difference in FEV1 that they used when calculating their sample size was quite large. If their post-treatment FEV1 was 48% predicted, as determined in their preliminary study, that means that the other group would have to have a post-treatment FEV1 of 28% predicted, or 68% predicted before a significant difference could be detected.

In the discussion section, the authors do not tell us if they performed another power calculation using the data from their study. They write "despite a power of 90% this double-blind, randomized trial could not establish a beneficial effect of high dose CS, compared with low dose CS, in treating severe, acute asthma"; this statement is meaningless. The power is not 90% but rather 0.9, which means that there is a 90% chance of detecting a difference. They do not tell us what difference they mean, although one can assume that it is the 20% predicted difference in post-treatment FEV1 mentioned in their initial sample size determination. They also fail to tell us whether they determined the actual power of the study to detect a difference based upon the data from their study, or if they are referring to their prestudy power determination. Once the data from the study has been collected, the power of the study to detect a difference should be determined from the actual study data, and I would like to have documentation that the authors did this. They should tell us, based upon the data from the study, the power of this study to detect a difference of 20% predicted in 24 h post-treatment FEV1 between the two groups, assuming a level of significance (alpha level) of 0.05.

References

1. Marquette CH, Stach B, Cardot E, *et al*. High dose and low dose systemic corticosteroids are equally efficient in acute asthma. *Eur Respir J* 1995; 8; 22–27.

E. Carter
Division of Pediatric Pulmonology, Madigan Army Medical Center, Tacoma, WA, USA 98421-5000.

REPLY

From the authors:

Dr Carter is correct in requesting classification of figure 1. As he pointed out, the data shown in figure 1 appear to be reversed from the data presented in the text. Indeed, looking at figure 1, one should read: " ■ : high dose group; and ❏: low dose group". In other words, the low dose group had higher forced expiratory volume in one second (FEV1) values than the high dose group. We are very sorry about this huge error, that we missed when correcting the galley proofs of this article.

Regarding the second point, we endorse the recommendations of Dr Carter. The proper statement should be "despite the fact that this study was designed in order to have a 90% chance of detecting a 20% difference in predicted FEV1 between the two groups at 24 h, such a difference was not detectable. Moreover, given the study design, the sample size, and the observed trend towards higher FEV1 values in the low dose group, a beneficial effect of high dose corticosteroids compared to low doses was highly improbable".

C.H. Marquette, B. Stach, E. Cardot
Dept of Pneumology, Hospital Calmette, 59037 Lille cedex, France.

CORRIGENDUM

"High-dose and low-dose systemic corticosteroids are equally efficient in acute severe asthma".
C-H. Marquette, B. Stach, E. Cardot, J.F. Bervar, F. Saulnier, J.J. Lafitte, P. Goldstein, B. Wallaert, A-B. Tonnel. Eur Respir J 1995; 8: 22–27.

The authors wish to point out that the definition of the symbols in figure 1 are unfortunately incorrect. The correct legend should read. ■ : high-dose group; and ❏ : low-dose group - a reversal of the published version.