

gives an RR of 6.5 (95% CI of 0.8 to 50.1). This is quite different from what the authors have calculated: RR 2.05 (95% CI 1.29-3.26). In fact, there are many more errors in the relative risk calculations. For instance, among the 750-999 gms group, the authors claim that the RR for chronic lung disease is 1.84 (95% CI 1.08-3.11). But, the actual RR is 10/24 divided by 4/26, which is 2.7 (95% CI 1.09-7.5)(Table III). Next instance: in the 1000-1250 g group, the authors claim that the RR for chronic lung disease is 1.91 (95% CI 1.26-2.9). But, the actual RR is 6/32 divided by 1/33, which is 6.2 (95% CI 0.8-48.5). These are all gross deviations and there is no way that one could explain them away as being close approximations.

An important drawback in design was that the study was unblinded. Thus, a measurement bias on the part of the person doing the ultrasounds cannot be excluded. This would be a major source of error.

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REFERENCE

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Reply

The sample size was actually calculated using a beta error of 80% instead of 85%, this is a typographical error and needs correction. The power calculation we understand is more complex than how Dr. Dutta arrived at his values. Posthoc power calculation requires raw data and knowledge of delta values; it cannot be done on processed data. We agree that posthoc power calculation is meaningless. Overall, even if one was to look at our results as per the values of relative risks suggested by his calculation, one can see that our conclusions still hold good.

Regarding his observation on the study being unblinded we have no comments to make. We agree that this is a limitation of the study. The last paragraph of the article in fact mentions that there are limitations in this study and that we would like to see more data from well controlled and designed studies in the specific subgroup of patients of this particular ethnic origin.

We would like to point out that this was a prospective controlled trial of long enough duration and despite the limitations mentioned, we hope that the essential message that indomethacin is a potentially dangerous drug is not lost in the argument.

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