of one year. Cases occurred throughout the year, though there was a significant decline every year from May to July.

The age profile of our subjects is similar to that from the epidemic reported from Thiruvananthapuram in South Kerala(l). The male preponderance can be explained by the fact that complications due to mumps occur more frequently in boys(2).

The data presented highlights the fact that mumps contributes significantly to morbidity in children. MMR vaccine is not included in the routine immunization schedule in Kerala and so majority of children do not receive MMR vaccine. The IAP has recommended inclusion of MMR vaccine in the immunization schedule(3). Our data suggests that this needs to be complied with urgently.

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Indomethacin Prophylaxis for Intraventricular Hemorrhage in Very Low Birth Weight Babies

The article on indomethacin prophylaxis for intraventricular hemorrhage by Nair, *et al.* in the June 2004 issue of Indian Pediatrics has some serious statistical and methodological errors that need clarification(1).

The calculated sample size with the assumptions of the authors (15% to 5% reduction, alpha error 5% and beta error 85%) using Epi Info 6 yields a requirement of 180 subjects per limb, rather than 154 as stated.

The authors' calculation of post hoc power of the study after the interim analysis is also erroneous. The authors have to explain how they arrived, post hoc, at a figure of "70% power". Epi Info 6 program shows that to detect a 15% to 5% reduction in the key outcome, the interim sample size (n = 115) had a power of only 30%. To detect the difference in major IVH that was actually present in the study (10.7% vs 6.7%), as being significant with a 5% error, the interim sample size had a power as low as 6%. For the sub-group analyses where p value was <0.05, post hoc power calculation was anyway meaningless.

The relative risk calculation of IVH grade III and IV in the birth weight category of 750-999 g is faulty. Since RR is defined as the incidence among exposed divided by incidence among the unexposed, it works out to be 6/24 divided by 1/26 (*Table II*). This

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% C10.98-7.5)(*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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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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