

conclusion drawn that the short course antibiotics is not harmful can not be validated adequately even by this pilot study.

**BALJEET MAINI AND VIPUL GUPTA,**  
MMIMSR, Mullana  
Ambala, Haryana, India.  
b\_maini@rediffmail.com

## REFERENCES

1. Saini SS, Dutta S, Ray P. Short course versus 7 day course of intravenous antibiotics in probable neonatal septicemia. A pilot open label randomized controlled trial. *Indian Pediatr.* 2011;48:19-24.
2. Edwards MS. Immune system (part2) –postnatal bacterial infections. *In: Martin RJ, Fanaroff AA, Walsh MC (editors). Fanaroff and Martin's Neonatal and Perinatal Medicine-Diseases of Fetus and Infant. 8<sup>th</sup> ed. Philadelphia:Elsevier Mosby; 2006.p.798.*

## Short Course Antibiotics in Neonatal Sepsis

We have a few comments on the recent article by Saini, *et al.* [1]. The attempt to investigate the shortest possible duration of antibiotics in probable neonatal sepsis is appreciable as it will lead to decreased economic burden, hospital stay, and adverse effects associated with treatment.

The Table II showing comparison of co-interventions, number of neonates receiving CPAP and number receiving conventional oxygen shows statistically significant difference in the two groups [1]. More invasive procedure can lead to more chances of introduction of fresh sepsis in otherwise culture negative non sepsis children. This could be one of the reasons behind more cases presenting with treatment failure in the group receiving antibiotics for 7 days as more number of children in this group incidentally received CPAP.

The basis of choosing fifteen days as cut off time for following up neonates after completion of antibiotics has not been explained.

**SUNNY NARANG AND VIPUL GUPTA**  
MMIMSR, Mullana, Ambala.  
narang\_sunny84@yahoo.com

## REFERENCE

1. Saini SS, Dutta S, Ray P. Short course versus 7 day course

## REPLY

The diagnosis of neonatal sepsis using a “sepsis screen” is not as simple as it sounds. Two systematic reviews have concluded that although none of the standard sepsis screen parameters (or combinations thereof) is satisfactory, CRP is the best individual parameter. It is for this reason that we opted for CRP alone. CRP is widely accepted and used and the objection about its “high cost” is an individual viewpoint. It is true that fresh cases of culture-negative sepsis may get incorrectly included as “treatment failure” and may not necessarily get evenly distributed despite randomization. This is an unavoidable risk in a pilot trial. We have not concluded that a shorter duration of antibiotics should become a standard of care. We have only suggested that on the basis of this small study, a large definitive non-inferiority trial could be planned.

**SOURABH DUTTA AND SHIV SAJAN SAINI**  
sourabhdutta@yahoo.co.in

of intravenous antibiotics in probable neonatal septicemia: A pilot open label randomized controlled trial. *Indian Pediatr.* 2011;48:19-24.

## REPLY

It may be true that more co-interventions in the 7-day arm have resulted in slightly higher treatment failure rate. However, two facts need to be considered before one prematurely draws conclusions. Firstly, the difference in failure rates between the short-course and the 7-day treatment arms was not statistically significant. This means that the “difference” was likely due to a chance phenomenon and one must not read too much into it. An appropriate sample size may well have thrown up an insignificant difference or significantly higher rates in either of the groups. Secondly, in a randomized controlled trial, all post-randomization events whose distribution is significantly different are either associated with the intervention or are chance phenomena or are biased associations. Thus, differences in co-intervention rates (*e.g.* CPAP) could be related to the duration of antibiotics *per se* or chance or related to a performance bias (this being an unblinded trial). Thus, we feel it is premature to make a direct association between a co-intervention that happened to be statistically different and an outcome that showed no significant difference.

**SOURABH DUTTA AND SHIV SAJAN SAINI**  
sourabhdutta@yahoo.co.in