

similar [1,2]. Barring the fact that meningitis is more commonly associated with late rather than early onset sepsis, the more fulminant form of disease is in fact early onset sepsis, mortality is higher in early onset sepsis. Therefore, early onset sepsis is certainly not “more benign”. In any case, these contentions are of little relevance to the core clinical issue which is that the current standard of care of probable sepsis does not distinguish between early and late onset sepsis as far as the duration of antibiotics is concerned. Our intervention (of shortening the duration) therefore was pragmatic and common to both early and late onset sepsis.

It is often easy to be wise in hindsight and say that a particular patient with probable sepsis was actually “probably not septic” and needed no antibiotics.

However, when viewed prospectively in a real-life situation, most clinicians would treat a probable sepsis (defined by us as persistence of clinical signs for at least 6 hours plus positive CRP) empirically and then try to minimize the exposure to unnecessary antibiotics, based on clinical course and culture results. This is exactly what we attempted to do in this pilot trial.

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Etiology and Clinical Spectrum of Constipation in Indian Children

I seek comments from the authors on their recent article [1] related to constipation in children.

Recommendations of the North American Society for Pediatric Gastroenterology and Nutrition for constipation [2] were updated in 2006 [3]. These guidelines and others [4], recommend testing for hypothyroidism, hypercalcemia, celiac disease and chronic lead exposure in children with constipation who respond poorly to standard treatment. Authors have not reported any case of hypothyroidism in their series of children. Is there need for testing for hypothyroidism in children with constipation who respond poorly to standard treatment in Indian set-up?

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REPLY

In pediatric practice it is important to look for hypothyroidism whenever there is some suspicion, especially in infants. As a matter of policy we look for organic causes in all infants presenting with constipation during infancy and we do thyroid profile (T3, T4, and TSH) in them. In our study population there were 11 cases of infants (up to 12 months of age) but none of them were found to have hypothyroidism [1]. Due to the newborn screening program in the West, North American Society for Pediatric Gastroenterology, Hepatology and

Nutrition (NASPGHAN) practice guideline [2] has not stressed on screening for hypothyroidism among infants with constipation. However, in India, we must investigate all infants with chronic constipation for hypothyroidism as the neonatal screening program is not in practice. Regarding older children with refractory constipation, yes if a child has other features to suggest hypothyroidism then the child should be investigated for hypothyroidism. None of our cases among non-responders/difficult responders to medical therapy had hypothyroidism.

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Advertisement of “Complan”

A claim was made by a company (Heinz India Pvt Ltd.) regarding their product “Complan” in advertisement shown in media, according to which “Complan” increases the height of children. On company website it is mentioned “Give your child the power of Complan thrice a day and see him/her grow twice as fast” [1]. A reference is also given there supporting the claim. After going through this study [2] I found some issues that need to be critically analyzed to validate this claim.

1. In the study, it is clearly mentioned that subjects who were included in the study were “school children of 7-12 years of age in Coimbatore, India” [2]. But it seems that results are generalized to all age group children in advertisement. In conclusion section authors mentioned that “Encouraging findings from the present study demonstrate the beneficial effect of health drink on growth in children of 7-12 years” so it seems that authors were very clear about the specific population of the study and generalizability of results to specific population. But in the advertisement this fact was not shown and results were generalized to all children, which is methodological wrong and unethical.
2. In the “materials and methods” section it is mentioned that children who were recruited in this study were from “middle and low income

families”. In the results section it is mentioned that “more importantly, it revealed sub-optimal food intake pattern by children in all three groups”. Therefore results of this study can not be generalized to children of high socioeconomic class families and children whose food intake is optimal. But the advertisement is generalized to all children irrespective of their socioeconomic class and nutritional status.

3. There were 58 dropouts from the study and they were not included in the final analysis. Reasons for these dropouts were not mentioned in the study. Characteristics of these subjects were not compared to the subjects who remained in the study. Intention to treat principle was not followed. This may insert bias in the observed results. Ignoring the subjects who have withdrawn from study usually introduces bias in the favor of the intervention [3].
4. Randomization process is not explained in detail. In ‘materials and methods’ section it is mentioned that “schools were randomly assigned to two treatment groups”. This statement is not sufficient to understand the randomization process.
5. This study was an open label study. No blinding was done (or not reported in the study). In an unblinded study, there are all chances of bias in the favor of treatment. This issue becomes more important as the study is financially supported by the manufacturers (Heinz India Pvt Ltd). Though authors did not report conflict of interest or source of support in the published study. The