

Filtered Sunlight for Treatment of Neonatal Hyperbilirubinemia: A Rejoinder

We note the interest generated in this journal [1], on our paper [2], and wish to provide the following clarifications for the benefit of the readership. Dr. Mathew's opinion was that our study had a high risk of bias principally because: (i) specific method used for the sequence generation was unclear; (ii) the primary outcome (rate of bilirubin decline) assessors were not blinded; and (iii) 'treatment days', rather than 'number of infants enrolled' was chosen as unit of measurement.

First, Dr Matthew apparently overlooked details provided in our study protocol on the computer-generated block randomization done independently by the USA-based study statistician (provided as supplementary data to the main article [2]. The randomization method was indeed 'adequate' [3]. Second, as in most clinical settings, bilirubin levels were objectively determined by the laboratory technician using duly calibrated bilirubinometer on blood samples from the infants at stated intervals to monitor need for continuation or withdrawal of treatment by filtered sunlight or conventional phototherapy. As reported [2,4], the laboratory technician responsible for measuring serum bilirubin levels was unaware of the treatment allocation sequence prior to bilirubin determination for eligible infants. As our primary outcome was objectively measured and the risk of bias minimal, blinding of the participating parents, or the hospital personnel was considered unnecessary [2,3,5]. Third, the stated aim was to compare the rate of bilirubin decline in babies able to tolerate filtered sunlight or conventional phototherapy for at least 5 hours. As interruptions in the management of temperatures outside the acceptable range were not predetermined, treatment days were variable. Hence, the need to appropriately define the unit of measurement as a 'treatment day' rather than 'number of infants' randomized. This formed the basis of the required sample size. There was indeed no statistical or ethical justification for continuing with enrolment once the required treatment days had been achieved.

Finally, available evidence suggests that mothers and care-givers, with or without active support from health care providers will continue to expose their jaundiced infants to sunlight [6]. The duty of care, especially in populations with excessive rates of avoidable bilirubin encephalopathy [7], should compel care-providers to

explore safe and efficacious means of applying filtered sunlight where conventional phototherapy cannot be readily assured. This is the overarching message and merit of our novel study. Appropriate adaptations should follow in earnest, to optimize the benefit of this low-cost, low maintenance and readily available intervention, wherever possible.

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Author's Reply

1. The trial protocol (Contents page), in the supplementary data [1] states that the Randomization procedure is presented in Section 5.2 on page 23; however Section 5.2 described Laboratory procedures (and not Randomization). The trial protocol published in the journal 'Trials' [2] also does not describe the random sequence generation process; it only states: "A block randomization