DOI: 10.7860/JCDR/2017/28385.10414

Letter to Editor

Paediatrics Section

Correspondence: Hordeum Vulgare in Neonatal Jaundice

ANIRBAN MANDAL[1], AMITABH SINGH[2], PUNEET KAUR SAHI[3]

Keywords: Neonatal jaundice, Hordeum vulgare

Dear Editor,

We read with great interest, the article by Panahandeh G et al., in the March 2017 issue of your journal [1]. We would like to commend the authors for their endeavor in finding newer adjunct to phototherapy in management of Neonatal Hyperbilirubinemia (NNH). In addition we have the following comments to offer:

1. The aim is appropriately stated but the objective(s) are not clear and it does not reflect whether it was a superiority, non-inferiority or equivalence study. Further, the basis of the sample size of 70 is also not clear. This is important as the power of the study would depend on the sample size [2].
2. The study is stated to be "double-blind, randomized controlled trial". Though the patient/participant may be blinded to the intervention here, it is not clear how the investigator was blinded as only the intervention group received application of Hordeum vulgare powder and no similar placebo was applied to the controlled group.
3. It is mentioned that the infants were "term, healthy, and over three-day-old, having total serum bilirubin level in between 12 mg/dl to 18 mg/dl, weighing 2500-4000 gm" without any risk factors. First, the criteria for starting and stopping phototherapy used in the study are not mentioned. According to the AAP (American Academy of Paediatrics) guideline [3], which is the most widely used guidelines for management of NNH in neonates; the serum bilirubin cut off for staring phototherapy in such newborns would be 16-18 mg/dl (depending on the presence/absence of Rh isoimmunization, ABO incompatibility or G6PD deficiency). So, it makes us wonder, whether many of these newborns actually required any intervention for NNH. Second, in the absence of standard criteria for stopping phototherapy, it would not be possible to assess the duration of hospital stay in these neonates.
4. The methodology mentions that "The infants were randomly and alternately divided into two groups (n=34 and 36) by random number table". This makes one wonder regarding method of allocation used, whether it was 'alternate allocation' or 'randomisation' with the help of random number table. We also wonder the utility of the exclusion criteria of "allergic reaction to Hordeum vulgare flour" in neonates.
5. The amount of blood drawn from the newborn infants and the details of the method employed for estimation of serum bilirubin (the principle outcome measure) is not clearly stated. This is of immense importance as the serum bilirubin values are known to defer depending on the method of estimation and the also among the different laboratories [4].
6. This being an interventional study, the authors needed to describe the intervention (Hordeum vulgare powder application) in a more detailed manner, such as the time taken for application, the time over which it was left on the body, etc., and also any adverse effects of such application. There is also no mention about the adverse effects of the phototherapy observed in the studied population as it was one of the co-intervention.

REFERENCES

[1] Panahandeh G, Khoshdel A, Sedehi M, Aliakbari A. Phytotherapy with HordeumVulgare: A Randomized Controlled Trial on Infants with Jaundice. J Clin Diagn Res. 2017;11:SC16-SC19.
[2] Jones SR, Carley S, Harrison M. An introduction to power and sample size estimation. Emerg Med J. 2003;20:453-58.
[3] American Academy of Pediatrics Subcommittee on Hyperbilirubinemia. Management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation. Pediatrics. 2004;114:297-316.
[4] van Imhoff DE, Dijk PH, Weykamp CW, Cobbaert CM, Hulzebos CV, BAR Trial Study Group. Measurements of neonatal bilirubin and albumin concentrations: a need for improvement and quality control. Eur J Pediatr. 2011;170:977-82.

AUTHOR'S REPLY

The point-wise replies to the reader's query are as follows:

1. Use of Hordeum vulgare as an adjuvant therapy to treat indirect bilirubin is effective, representing the main purpose of the study. Other data including hospital stay, weight, and measures of indirect and direct bilirubin at baseline and after discharge are considered the secondary objectives of the study.
2. Double blind means that the patients and person who tested bilirubin were blinded.
3. We considered the criteria of exchange transfusion according to AAP. However, a lower value of bilirubin was considered to be the criteria for conventional phototherapy, in the light of cultural factors, the region's ruggedness, and problems with the patients' re-examinations. Besides that, the families provided consent to perform the phototherapy after they were given satisfactory and relevant explanations.
4. We apologize for this typological error. Selection of the samples was conducted randomly.
5. Clotted blood samples (2-cc) were taken from the patients and measurements were conducted using spectrophotometer or calorimeter at 550-nm wavelength [using an autoanalyser (BT-3000)].
6. Since the beginning of the study, Hordeum. vulgare flour was applied to exposed areas of infants in the case group, except for areas around the eyes and genital area, on a daily basis. As already mentioned in the article, this application caused no side effects.

PARTICULARS OF CONTRIBUTORS:
1. Attending Consultant, Department of Paediatrics, Sitaram Bhartia Institute of Science and Research, Delhi, India.
2. Assistant Professor, Department of Paediatrics, Vardhman Mahavir Medical College and Safdurjung Hospital, New Delhi, India.
3. Senior Resident, Department of Paediatrics, Lady Hardinge Medical College, Delhi, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Amitabh Singh,
4614 Sector b Pocket 5 and 6, Vasant Kunj, Delhi-110070, India.
E-mail: dramit_amy@yahoo.co.in

FINANCIAL OR OTHER COMPETING INTERESTS: None.

Date of Submission: **Mar 15,2017**
Date of Peer Review: **May 30,2017**
Date of Acceptance: **May 30,2017**
Date of Publishing: **Aug 01, 2017**