**Letters in Response to the Previously Published Articles**

# In response to "Effectiveness of topical green tea against multidrug-resistant *Staphylococcus aureus* in cases of primary pyoderma: An open controlled trial"

Sir,

I read with interest the article "Effectiveness of topical green tea against multidrug-resistant *Staphylococcus aureus* in cases of primary pyoderma: An open controlled trial" published in the March–April (2018) issue of the journal.[1] The article raises more questions in the mind of the reader than it seeks to answer. I would like the authors to clarify the following issues.

## Study Subjects

As the title suggested, the authors have compared the effectiveness of two treatment regimens against multidrug-resistant *S. aureus*, but not all study participants had multidrug-resistant *S. aureus* infection. According to the authors, 89.1% in the green tea group and 81.1% in the placebo group had multidrug-resistant *S. aureus*.

## Sample Size Calculation

The importance of sample size calculation for determining the requisite number of participants in clinical trials cannot be overemphasized. A valid conclusion about the difference between the efficacy of two (or more) treatment regimens can only be drawn if an adequate sample size is planned in advance using appropriate statistical methods. Sample size calculation for clinical trials requires consideration of predefined effect size, statistical power and the level of significance. The authors have erroneously used a formula for calculating sample size for prevalence studies rendering the whole exercise futile.

## Randomization

Randomization is an essential prerequisite of any good quality clinical trial. It ensures that the treatment groups are comparable and eliminates the source of bias in assigning trial participants to different treatment regimens. Nonrandom or pseudorandom allocation of participants to treatment groups cannot have the desirable properties of a truly randomized procedure. A computer-generated randomization schedule is currently the standard method of randomization. The authors have stated that true randomization was not done without mentioning any reason. The authors could have easily followed a randomization schedule for the participants with a 1:2 allocation ratio using a statistical software package or easily available, free online resources.

## Blinding

Blinding is another important strategy to eliminate bias in the treatment or assessment of the outcome of a controlled trial. The authors have not assigned any reason for not following at least an assessor-blinded procedure.

## Statistical Methods Used

According to the authors, their "data were analyzed by mean, standard deviation and Chi-square tests." In Table 1, figures for three variables (age, duration and sex) were tabulated, but a single *P* value is mentioned. How did the authors calculate a composite *P* value for these disparate variables? How were the means of continuous variables such as age and duration of lesions compared by Chi-square test?

## Ethical Issues

The authors studied participants belonging to the age group of 8–16 years "as the school authorities did not permit for younger children to be included in the study." The authors have also mentioned that "written informed consent was obtained before study enrollment." Who signed the informed consent? Were the school authorities legally authorized to allow the children to participate in an experimental study? In conducting research with minors (e.g. in the age group 7–17), in addition to informed consent from parents/legal guardians, assent must be obtained from the participants. Was this procedure followed by the authors?

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**Conflicts of interest**

There are no conflicts of interest.

***Debabrata Bandyopadhyay***

Department of Dermatology, Venereology and Leprosy, Medical College and Hospitals, Kolkata. West Bengal, India

**Correspondence:** Prof. Debabrata Bandyopadhyay, Department of Dermatology, Venereology and Leprosy, Medical College and Hospitals, Kolkata. 88, College Street, Kolkata - 700 073, West Bengal, India.
E-mail: dr_dban@yahoo.com

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1. Umashankar N, Pemmanda B, Gopkumar P, Hemalatha AJ, Sundar PK, Prashanth HV, *et al*. Effectiveness of topical green tea against multidrug-resistant *Staphylococcus aureus* in cases of primary pyoderma: An open controlled trial. Indian J Dermatol Venereol Leprol 2018;84:163-8.

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