Correspondence: Modulation of Lung Function by Increased Nitric Oxide Production

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Dear Editor,

We have read with much interest the article by Islam MN et al., published in the June, 2017 issue of your journal [1]. First of all, we would like to commend the authors for their novel endeavor in trying to find a simple measure for improving lung function in chronic smokers but at the same time we would also like to make the following comments, clarification to which would benefit the general readers of Journal of Clinical and Diagnostic Research.

- 1. The 'Materials and Methods' mention the study as a "cross-sectional comparative study". But actually it was an interventional study where a group of participants were given 'garlic' daily for three months (the intervention) and was re-examined for its effects on different lung function parameters [2].
- The aim of the present study was stated, "To investigate the effect of dietary supplementation of Nitric Oxide (NO) producing garlic on pulmonary function of smokers". In this context, the utility of recruiting the 'control group' of "healthy non-smoker males" was not well understood.
- 3. In the present study it was mention that "the participants were randomly selected by convenient sampling technique". First of all the 'convenient sampling technique' is subjected to a high degree of 'selection bias' [3]. Furthermore, it was not cleared that, how they decided on the sample size. It is important, as the power of the study is dependent on the sample size [4]. It was also not clear why they recruited patients specifically "having lower socioeconomic status".
- Materials and Methods stated, "Unpaired Student's t-test was used for group wise comparisons", but to compare Group B (male smokers before garlic administration) and Group C (male smokers after before garlic administration) 'Paired t-test' should have been applied [5].
- 5. Being an interventional study, it is very important to know the compliance of the participants to the study intervention (here garlic administration) and any adverse effects thereafter. But neither of them was presented in the research paper.
- 6. Another very important aspect of such a nonblinded study design is the risk of co-intervention bias, wherein the participants may resort to interventions, other than the studied one, which can lead to clinical improvement [2]. Here such a co-intervention might be change in the lifestyle including decrease in smoking frequency by the participants after knowing their decreased pulmonary function status.

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AUTHOR'S REPLY

Dear Editor,

We very much appreciate the effort made by the author for writing a letter to the editor, on the basis of our published research article [1]. The author raised certain issues regarding the research methodology. Author had tried to explain the research method in different way which is inappropriate and unsuitable for the present study and has no suitable rationale. Response for the comments are as follows:

- 1. A cross-sequential design is a research method that combines both a longitudinal design and a cross-sectional design. It aims to correct for some of the problems inherent in the cross-sectional and longitudinal designs [2]. Firstly, in the present study we had selected only a part of chronic smoker and healthy non-smoker population to observe the changes in the lung functions among smokers, if any. Secondly, without informing the smokers about their abnormal lung function due to smoking, we gave garlic as extra supplemental diet, and after that we revaluated the lung functions and compared with previous value of lung functions in smokers and non-smokers as well. Therefore, in true sense it was not an interventional study rather it's an observational study which analyses data collected from a population, or a representative subset, at a specific point in time-that is, cross-sectional data [2].
- 2. We were intended to find the differences, if any, in lung function parameters between healthy non-smokers and chronic smokers without any clinical symptoms. We had evaluated and found that NO production was reduced in smokers compared to normal healthy non-smokers, which was considered as control group in the present study. Therefore, we found it was important to keep healthy non-smokers as control group to draw the conclusion more clearly.
- 3. We have already mentioned that it was a cross sectional comparative type of study. For such type of study, usually sampling is based on convenience and random selection among population [3]. To limit the bias, we have taken specific group of population with same lifestyle and economic status. Moreover, low-socioeconomic people are found more indulged in smoking habits. Further, they were easily available for participating in the research work. Therefore, we conveniently chose those specific groups. Also, we mentioned in the 'limitations' of the present study that "the present study would have been strongly conclusive if larger numbers of samples had been included".
- 4. We had compared all the three groups to check the differences in mean, and not the mean difference. Moreover, variances

are not equal and independent in both the Groups (B and C). Therefore, we applied Unpaired t-test [4].

- 5. In the materials and methods section of the article it is clearly mentioned, "Prior to the study, all subjects were informed of the study procedure, purposes, and known risks and thereby obtained their informed written consent". Moreover, so far that amount of 'garlic' has no any adverse effects [5,6].
- Even chronic smoker's group were not aware of their reduced lung function parameters, as they were not having any respiratory problems. So, the change in the lifestyle including decrease in smoking frequency by the participants was unlikely.

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