

Author's reply

Sir,

We thank you for your critical appraisal of our study “Effectiveness and safety of levocetirizine 10 mg versus a combination of levocetirizine 5 mg and montelukast 10 mg in chronic urticaria resistant to levocetirizine 5 mg: A double-blind, randomized, controlled trial” by Sarkar *et al.*¹ We would like to clarify your doubts.

1. Levocetirizine 10 mg one tablet in one group was compared to Levocetirizine 5 mg + Montelukast 10 mg one tablet in the other group. Thus, the participants of either group were given one tablet of either drug, keeping the blinding intact
2. Clinical Trial Registry, India (CTRI) allows retrospective registration. However, ideally registration should be done prospectively. CTRI also takes some time to evaluate the proposal during registering, hence the time gap
3. Both Urticaria Activity Score and Total Severity Score have been considered primary outcome measures, as mentioned in Table 2 of the article with results discussed accordingly. For objectively measuring the nonresponders, we had to

consider Total Severity Score as it includes the count of the antihistamines used and because Urticaria Activity Score does not include the criteria of antihistamines used, since as physicians, we were concerned about the pill burden. Total Severity Score has been used previously in studies by Bajaj *et al.*² and Sil *et al.*³

4. The median price of levocetirizine 10 mg and levocetirizine 5 mg + montelukast 10 mg was compared from CIMS October–December, 2014 issue (at the time when the study was conducted). The cost of therapy was higher in levocetirizine 5 mg + montelukast 10 mg combination than levocetirizine 10 mg, as seen in Table 1 below. Also, in Table 2, when only the price of therapy of the trial medications (Levosiz 10 mg and Levosiz-M) was compared, the price of Levosiz M was 2.4 times more than Levosiz 10
5. Because the study was designed as a superiority trial, the sample size was calculated based on detecting two-unit difference in Total Severity Score. We have mentioned that both the trial arms were “comparable in effectiveness.” Because the drugs were different molecules and not “me too” drug or drugs of the “same class,” we did not plan for an “equivalence” or “non-inferiority” trial.⁴ Levocetirizine is an antihistamine whereas Montelukast is a leukotriene receptor antagonist. The article does not mention “equivalent” anywhere in the results or discussion. Moreover, the results (paragraph 3 of Results section) incorporate discussion on “between groups” analysis with the *P* values explicitly given in Table 2 of the article.

Table 1: Price of trial medications

Trial medications	Cost of 4 weeks treatment (rupees)
Levocetirizine 10 (Levosiz 10)	63
Levocetirizine 5 mg + montelukast 10 mg (Levosiz-M)	154

Table 2: Median price of levocetirizine 10 mg and levocetirizine + montelukast [references: Current Index of Medical Specialities, India (CIMS) 127 October, 2014]

Medications	Median price of 4 weeks treatment (rupees)	Interquartile range (rupees)
Levocetirizine 10 mg	274.4	112.7-287
Levocetirizine 5 mg + montelukast 10 mg	213.64	168-280
<i>P</i> value (between groups)	0.688	

P value by Student's *t*-test. CIMS: Current Index of Medical Specialities, India

We hope we have clarified your doubts and would be eager to reply to your comments. The research team would like to thank you for your keen interest in our study.

Thanking you.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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