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Reply to "Good! is it the best ???

Sir,

We are sincerely thankful to the readers for critically analysing our manuscript. We hereby put forth our replies to the questions that have been put up. Since, the sample size in our trial was 30, this may be considered as a pilot study and results interpreted cautiously. We have truthfully reported our findings and did not try to match it with the MARISA trial (reference 6 of our article). We are aware of the other trials mentioned i.e., ERICA, CARISA and TERISA. It needs to be appreciated that our trial is different from them on following counts:

a. Our trial was conducted in 30 Indian patients whereas the cited trials above comprised of 191, 823, 565, and 927 patients in the MARISA, CARISA, ERICA and TERISA trials respectively. Dr. Kosiborod, Cardiologist and lead author of the TERISA trial has emphasized on the importance of geographic differences in a subgroup analysis. Angina frequency between placebo and ranolazine was not different in Russia, Ukarine and Belarus, but experienced a significant reduction in other countries. The reason of such geographic differences was not clear and further exploration was recommended[1]
b. Our patients had low frequency of anginal attacks (<2/week with mean 1.8 with SD of 0.2). None of the trials cited above had patients with initial low frequency of anginal attacks. This also could be one of the reasons for the observation of zero anginal attacks at the end of eight weeks in our findings. The MARISA Trial has reported that 5% of the 191 patients had an increase in anginal attacks with ranolazine, which if translated for our study (5% of n = 30) will work to 1-2 patients who could have reported an increase in anginal attacks. However, we did not have any patient with an increase in anginal attack with ranolazine. We would be interested in knowing your sample size and it shall be an area that could be explored. We look forward to seeing your article and its reasoning for increased anginal frequency with ranolazine
c. Recently, FDA has approved ranolazine as a first line agent in the treatment of chronic stable angina, either as a primary agent or as an adjunct to ongoing β-blocker and nitrate therapy;[2] therefore, ranolazine may be considered as one of the preferred medicines in angina.

The authors have pointed out that the baseline values are perfectly matching, but the values are not perfectly matching. Please refer to Table 1 of our article.

The questions that were put forth to the patients were similar to those that were followed in the ERICA trial, i.e., patients were evaluated for average frequency of self-reported anginal episodes during the treatment phase, changes in sublingual nitroglycerine use, heart rate, blood pressure, and adverse events.[3] Most of the patients were not taking sublingual nitroglycerine by the end of the study except two patients in the ivabradine group. Publishing questionnaire used in the study is a decision of the journal. If you want and request, we are willing to share it with you in the best interest of research.

This trial was conducted in one of the few super speciality hospitals that cater to a wide chunk of the population in the Dehradun – Rishikesh – Haridwar – Saharanpur region, having average out patient attendance of 40-50 cardiac patients per day. Out of these we could recruit averagely 2-3 patients daily. Periodic telephonic reminders were given to patients for regular use of medicines; however, compliance was not measured separately by pill count or any questionnaire like Morisky instrument.

It was an observational (natural course of the treatment was studied) and not an interventional trial. We observed the effect with Food and Drug administration (FDA) approved medicines viz. ivabradine and ranolazine, which were already being taken by the patients. We did not initiate, change, modify, add or delete any medicine in this trial.

The clinical trial registry of India (CTRI) site mentions about the details of which trials should be registered as: "Studies that meet the World Health Organisation/International Committee of Medical Journal Editors (WHO/ICMJE) 2008 definition of a clinical trial should be registered. That is, any research study that prospectively assigns human participants or groups of

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human to one or more health related intervention to evaluate the effects on health outcomes. Health related interventions include any intervention used to modify a health outcome and include drugs, surgical procedures, devices, behavioural treatments, etc. Thus, all interventional clinical trials, involving drugs, devices, biologicals, vaccines, herbal compounds etc., are required to be registered. In addition, observational trials, bioavailability, and bioequivalence trials as well as post marketing surveillance trials may also be registered in the CTRI."[4]

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REFERENCES

1. American College of Cardiology's CardioSource. Drug Reduces Chest Pain in Patients with Diabetes. Beth Casteel, bcasteel@acc.org 240-328-4549. Available from: http://www.cardiosource.org/News-Media/Media-Center/News-Releases/2013/03/TERISA-Trial.aspx. [Last Updated on 2013 Apr 2].
2. Reddy BM, Weintraub HS, Schwartzbard AZ. Ranolazine: A new approach to treating an old problem. Tex Heart Inst J 2010;37:641-7.
3. Stone PH, Gratsiansky NA, Blokhin A, Huang IZ, Meng L, ERICA Investigators. Antianginal efficacy of ranolazine when added to treatment with amlodipine: The ERICA (Efficacy of Ranolazine in Chronic Angina) trial. J Am Coll Cardiol 2006;48:566-75.
4. Clinical Trial Registry-India, National Institute of Medical Statistics (Indian Council of Medical Research). Available from: http://ctri.nic.in/Clinicaltrials/faq.php. [Last Updated on 2012 May 8].

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DOI: 10.4103/0976-500X.114622

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