The importance of a proper design and the robustness of conclusions

To the Director

I have read with interest the recently published article entitled "Wall thickness and fibrosis patterns in hypertrophic cardiomyopathy assessed with cardiac magnetic resonance" by Deviggiano et al. (1) The work is methodologically presented as an observational study and it is inferred that it would be a cross-sectional design based on the objectives of the work (it postulates objectives such as "to characterize the regional distribution of myocardial wall thickness and its relation with the presence of myocardial fibrosis, determine the different patterns of LGE and quantify the percentage of myocardial fibrosis in patients with HCM evaluated with CMRI"). It is not postulated as a diagnostic study design due to the lack of a gold standard to diagnose hypertrophic cardiomyopathy (HCM). However, it is later mentioned that a control was performed with a "control group" without establishing whether it was in a 1:1 ratio or with more controls; furthermore, the control inclusion criteria are not consistent with those of cases. (2) Then, in Results, statistical conclusions are drawn comparing both groups, showing fewer controls than cases. Finally, in the Discussion certain differences between patients with HCM and controls are mentioned.

The authors adequately mention in the study limitations that the control was performed against a not very well defined group. I think this does not take away the importance and seriousness of the work, but, in terms of the robustness of knowledge, use of appropriate designs reinforces the conclusions of the work. For example, in this publication, the single description of findings is already an interesting contribution, or else having employed the design of diagnostic test studies (3) using transthoracic echocardiography as the recommended method for screening (4) in individuals at risk for developing HCM with a level of evidence Class I B, selecting them according to risk (relatives of patients with HCM or history of sudden death) by performing both studies and determining sensitivity, specificity, and predictive values.

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REFERENCES

1. Deviggiano A, Carrascosa P, De Zan M, Capuñay C, Deschle H, Rodríguez Granillo GA. Wall Thickness and Patterns of Fibrosis in Hypertrophic Cardiomyopathy Assessed by Cardiac Magnetic Resonance Imaging. Rev Argent Cardiol 2016;84:208-14. http://dx.doi.org/10.7775/rac.es.v84.i3.7168
2. Schulz KF, Grimes DA. Case-control studies: research in reverse. Lancet 2002:359:431-4.
3. Irwig L, Bossuyt P, Glasziou P, Gatsonis C, Lijmer J. Designing studies to ensure that estimates of test accuracy are transferable. BMJ 2002,324:669-71.
4. Fraiche, A. & Wang, A. Curr Cardiol Rep 2016;18:70. doi:10.1007/s11886-016-0751-8.

Authors´reply

We appreciate Prof. Pablo A. Olavegogeascoechea's kind opinion regarding the above mentioned work. First we wish to emphasize that the purpose of this work was not to establish the diagnostic accuracy of magnetic resonance imaging (MRI) compared to a reference standard, but to describe morphological characteristics and distribution of late gadolinium enhancement in patients with hypertrophic cardiomyopathy.

We understand that his main objection lies in the selection of the control group. We want to mention that this group consisted of non-diabetic patients with preserved wall thickness, dimensions and systolic function, without evidence of late gadolinium enhancement, valvulopathies, pericardial disease or congenital heart disease. Thus, structural disease was discarded, and detailed selection criteria were provided in Methods. We believed that the addition of the control group would improve the work and that is why within the limitations we mentioned that "the results of the comparison of HCM patients with a control group should be considered in the context that it was not a study designed for this purpose".

Finally, we wish to mention that a myocardial wall thickness >15 mm by echocardiography is the most widely used criterion in HCM studies, while family or sudden death history are risk factors unrelated to the diagnosis, but related to sudden death risk. (1)

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REFERENCES

1. Maron BJ, Maron MS, Wigle ED, Braunwald E. The 50-year history, controversy, and clinical implications of left ventricular outflow tract obstruction in hypertrophic cardiomyopathy: from idiopathic hypertrophic subaortic stenosis to hypertrophic cardiomyopathy. J Am Coll Cardiol 2009;54:191-200.