Designs and methods for impact evaluation of interventions. Response

Diseños y metodologías para evaluar el impacto de las intervenciones. Respuesta

To the Editor,

We would like to thank Antonio Sarria-Santamera for the interest shown in our article.[1] In his letter, he raises 2 different issues.

First, he mentions limitations in interpreting the hazard ratio. However, these limitations are inherent in the estimator and do not depend on whether the study is experimental or not and, consequently, would not be mitigated by a different study design.[2]

Second, he mentions the causal relationship between implementation of the PROGALIAM program and the decrease in mortality. The ideal context for this kind of inference is a clinical trial, but conducting a trial would not have been ethical in view of the nature of the study. As he points out, the alternative is to find a comparable group around the same timeframe. In the case of the IPHENAMIC program, this was not possible because the PROGALIAM network was established simultaneously throughout the geographical area, which precluded application of some of the methods proposed. Other alternatives, such as propensity score matching, are not desirable because they start with the effect that the intervention could influence the profile of patients arriving at the hospital alive, and this effect should not be cancelled out. The plausibility of causal effects between PROGALIAM implementation and reduced mortality is supported by the survival analysis and by observations such as the fact that 30-day gross mortality before PROGALIAM was almost unchanged and began to decline after implementation, as shown in figure 2 of our article.[1] Likewise, figure 1 of the additional material shows that 30-day mortality in the total population and in each of the areas dropped significantly, particularly in areas where access improved to a greater extent. Although not impossible, it is highly unlikely that there are any variables not included in our study that coincided with PROGALIAM implementation and had sufficient impact on mortality to explain these findings.

Despite the limitations of observational studies, we believe that they are essential in certain settings and, as expressed by the European Union and by the author himself in his references, are very useful for collecting real-world information, identifying outcomes, and ensuring responsible use of public funds.[3,4]

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116? How much should LDL-C be lowered in the «low risk» population?

¿116? ¿Hasta cuánto hay que bajar el cLDL de la población catalogada como en «bajo riesgo»?

To the Editor,

Although the target values for plasma lipid concentrations have been revised and reduced, there is no consensus as to whether or not low density lipoprotein cholesterol (LDL-C) levels should be treated according to target values.[1,2]

The American Heart Association/American College of Cardiology guidelines published in 2014[3] recommended a "shoot and forget" strategy in which the strength of the statin selected was more in line with the patients' cardiovascular risk (CVR) than with their final target.

In the European Society of Cardiology guidelines published on 31 August 2019, the recommended LDL-C level for the low-risk population (score, <1%) is < 116 mg/dL.[4] This recommendation was already present in the previous guidelines of 2016,[5] but with a huge difference: At that time, the recommendation specified "lifestyle recommendations" (no intervention on lipids) when LDL-C concentration was 155 to 190 mg/dL and the CVR was < 1%, whereas now it indicates "Lifestyle intervention, consider adding drug if uncontrolled" when LDL-C is between 116 and 190 mg/dL at the same CVR (see table 5 in both guidelines).[4,5]

Then I wondered, how many of my patients, regardless of their CVR, had LDL-C values < 116 mg/dL without receiving treatment, and how many had those values with treatment? I reviewed the analysis requests for the past week and found that more than 70%