



## Considering the best study designs to evaluate healthcare interventions

### Consideración de los mejores diseños de estudio para evaluar las intervenciones sanitarias

Herney Andrés García-Perdomo,<sup>1\*</sup> Carlos Andrés Pineda-Cañar.<sup>1</sup>

#### Dear Editor

Regarding the study published by Ramirez-Sevilla et al.<sup>(1)</sup> in your prestigious journal, we would like to make specific comments:

Metabolic syndrome encompasses multiple diseases, such as visceral obesity, hypertension, hyperglycemia, hypertriglyceridemia, and low high-density lipoprotein cholesterol levels (HDL-C). Multiple epidemiologic studies and meta-analyses demonstrate the association between Lower urinary tract symptoms and metabolic syndrome, according to its pathogenesis: systemic inflammation and oxidative stress.<sup>(2)</sup> In consequence, metabolic syndrome and all its components are risk factors for developing urinary tract infections, and this is a vital population for having the intention to prevent this deleterious condition. Hence, considering any new tool to prevent UTIs might improve these patients' quality of life. Furthermore, in this study, inclusion criteria are vague and imprecise, and definitions are outdated.<sup>(3)</sup> Therefore, conclusion might not be applicable nowadays.

Accordingly, assessing the effect of healthcare interventions is vital to inform and deciding. Researchers routinely use multiple study designs to evaluate the hypothesis, although a few are internationally accepted for decision-making. Randomized trials (RCT) are considered the "gold standard" of causal inference: large sample size, and randomization, among other characteristics. However, this study might be impractical and unethical in some settings. Consequently, observational studies are an alternative to RCT, ensuring a comparison group and well-documented statistical methods, mimicking the gold standard design.<sup>(4)</sup> Although Ramirez-Sevilla et al. refer to the study as being comparative, it must not be considered as it since they did not compare the vaccine against any other intervention but presenting one factor or not. In this case, they could have evaluated the effect in smokers or metabolic syndrome patients with a subgroup analysis.

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#### Corresponding author:

\*Herney García-Perdomo.  
Cll 4B # 36-00, Cali,  
Colombia. Email: herney.  
garcia@correounivalle.  
edu.co

<sup>1</sup> Universidad del Valle. Cali, Colombia.

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As it is not common to run consistent and transparent RCTs, we suggest the following ideas to improve clinical research in evaluating the effectiveness of interventions: 1) Enforce measures to register and report RCTs, 2) Invest in academia and independent clinical research, 3) Establish research priorities in all scenarios, 4) Methodological quality is the hallmark, not the “positive result,” 5) Use observational and comparative studies when RCTs are not ethical or practical.<sup>(5)</sup>

Hopefully, these ideas may help readers recognize the importance of establishing well-designed studies to assess healthcare interventions.

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