The correct application of biostatistics as a key element in clinical nutrition research

La correcta aplicación de la bioestadística como elemento clave en la investigación en nutrición clínica

A aplicação correcta da bioestatística como elemento-chave na investigação em nutrição clínica

Úrsula Medina[1,2], Antonio Gordillo-Moscoso[2,3], Rafael Almendra-Pegueros[4,5*].

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The European Society for Clinical Nutrition and Metabolism (ESPEN) defines *clinical nutrition* as the discipline responsible for the prevention, diagnosis, and treatment (nutritional care) of metabolic and nutritional changes related to acute and chronic diseases, as well as those caused by deficient or excessive intake of energy and nutrients[(1)]. Within this discipline, the current archetype of work is the prevention and treatment of malnutrition due to deficiency in caloric and protein intake, currently defined as *disease-related malnutrition.* Although the interrelation of diverse etiological factors is recognized, the decrease in energy and nutrient intake has been positioned as *the predominant factor*, reason why the first line of treatment within nutritional care is the replacement of these dietary components, whether orally or by artificial nutritional support, in those patients who require it[(2)].

This current work paradigm has been rooted in the results of key research for the construction of the concept of *clinical nutrition* as a discipline, which demonstrates that nutritional replacement therapy in sufficient form, quantity and quality is associated with better health outcomes in hospitalized populations[(3-5)]. Despite these advances, the current understanding of disease-related malnutrition and its correct management have not been enough, and this model needs to be broadened. Cárdenas and Ochoa[(2)] describe this modification as: "a paradigm shift in clinical nutrition …", a change that must go hand-in-hand with nutrition research from a translational and implementation perspective[(6,7)].

Research in nutrition and in every discipline of the health sciences is based on the correct application of the scientific method, and is on that basis that we can describe research as the systematic, organized, and objective process to answer a question. The question may originate from aspects such as: experience, specialized bibliography (which when read, casts doubts), the emergence of new technologies, skepticism and observation, and other external sources[(8,9)]. Identifying a good research question is just the first step and, in order to answer it, it is necessary to build a research protocol, which is the systematized recipe of what should be done to solve the question that originated the study.

The first step, starting with the question, is to define the main objective, select the appropriate study design and, with this, develop the methodological process of the research: define the criteria for selecting the sample unit based on the population within our reach, the variables to be measured, their scale, and an adequate measurement technique. The statistical analysis should be in accordance with the design and measurement scales of our variables. This set will give rise to the research results which, when interpreted in the light of current knowledge, will answer our question[(8)].

[1] Department of Pharmacology, Faculty of Medicine, Autonomous University of San Luis Potosí (UASLP). San Luis Potosí, Mexico.
[2] Translational Research Laboratory in Pharmacology, Faculty of Medicine, Autonomous University of San Luis Potosí (UASLP). San Luis Potosí, Mexico.
[3] Masters in Clinical Research, Faculty of Medicine, Autonomous University of San Luis Potosí UASLP). San Luis Potosí, Mexico.
[4] Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau. Barcelona, Spain.
[5] Institut d'Investigació Biomèdica Sant Pau (IIB SANT PAU). Barcelona, Spain.

***Correspondence**: Rafael Almendra-Pegueros.
ralmendra@santpau.cat

It is precisely the development of the methodological process of the research: the selection of the type of study design, the choice of variables and the appropriate statistical analysis, which could represent important challenges for the researcher in health sciences and clinical nutrition. Although these elements are intertwined and the possible errors made in one of them will affect the other, we could say the selection of the most adequate statistical treatment for the data obtained and the study design performed suggests the area of greatest challenges/opportunities for the researchers.

It has been described that up to 60%-80% of articles published in scientific journals of health sciences may contain errors in the statistical analysis performed or in the interpretation of their results. This situation may be explained by the little interest of taste in scientific methodology and biostatistics on the part of researchers, as well as the lack of frequent updating in the knowledge of these specific areas among the participants of the editorial process: authors, reviewers and editors[10].

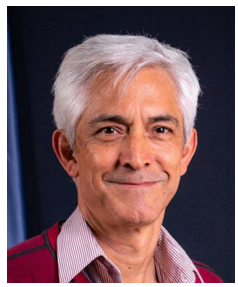
In addition to the foregoing, a survey performed to biostatisticians in the U.S.A. informed that health sciences researchers frequently request statistical analyses to be performed by third parties, so that the reporting of results is often inappropriate and not in agreement with the study design and the variables recorded. Among the main requests, the following were identified: data removal or alteration (which may include scientific fraud), lack of reporting of missing values, performing unjustified *post-hoc* analyses or considering the results of the analysis as *a priori* outcomes, modifications of the measurement scales of some variables to obtain the expected results, interpretation of findings based on expectations and not on the actual results, ignoring the violation of necessary assumptions in some statistical tests, and interchanging secondary variables for primary variables to obtain statistically significant results[11].

In addition to these violations to scientific ethics, the most common problems encountered in health sciences research have been specifically described: lack of sample size calculation, failure in the adequate randomization process of the different study groups, inadequate reporting of the summary measures of the study variables, lack of adequate selection of graphs for the presentation, and poor interpretation of the results. The most frequent errors in the application of statistical tests comprise the inappropriate use of parametric tests (Student's t-test or ANOVA) on non-normal data or vice-versa, failures in the analysis of repeated measures and violation of assumptions for the multiple comparisons analysis[12]. In the case of nutrition research, this analysis has not been performed in depth. Some journals in the discipline have reported that only 21.2% of the published studies and that required a sample size calculation presented it; 88.3% of the statistical analyses were correctly applied, and that in 11.4% of the studies, the *p* value between >0.05 and 0.10 was reported as statistically significant or as "*trend*"[13].

The combination of all these errors in the statistical analysis and interpretation of the results not only diminish the reliability and validity of the findings reported in the research, but also the credibility of the journals that publish them. This fact affects the practice of medicine or, in this case, evidence-based clinical nutrition, which biases health decision-making[14] and significantly influences the development of new areas of research with possibilities of translation and implementation in clinical nutrition.

That is why from the *Journal of Clinical Nutrition and Metabolism* (RNCM) we encourage our authors, readers, reviewers, editors, and all professionals involved in the development of clinical nutrition to work to ensure basic competences in biostatistics, to integrate experts in data analysis in our research groups and to participate in continuing education for the proper selection of our data analysis and the correct implementation of results[10,15,16].

Úrsula Medina, MD, PhD
Faculty of Medicine, Autonomous University of San Luis Potosí (UASLP). San Luis Potosí, Mexico.



Antonio Gordillo-Moscoso, MD, PhD
Faculty of Medicine, Autonomous University of San Luis Potosí (UASLP). San Luis Potosí, Mexico.

Rafael Almendra-Pegueros, ND, MSc
Associate Editor, Journal of Clinical Nutrition and Metabolism (RNCM). Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau. Institut d'Investigació Biomédica Sant Pau (IIB SANT PAU). Barcelona, Spain.

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