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BIOSTATISTICS FOR CLINICAL PRACTICE IN HEALTHCARE: A NARRATIVE REVIEW IN CLIPPINGS FROM BRAZILIAN PUBLICATIONS

BIOESTATÍSTICA PARA A PRÁTICA CLÍNICA EM SAÚDE: UMA REVISÃO NARRATIVA EM RECORTES DE PUBLICAÇÕES BRASILEIRAS

Julia Cortes - cortesjuju1@gmail.com
Biomedical engineer - PUC - SP.
Beatriz Miranda- beatrizsmiranda97@gmail.com
Physiotherapy Graduate - UFBA.
Sarah Souza Pontes - sarahpontes@gmail.com
PhD in Medicine and Health - UFBA.

Abstract: Biostatistics in healthcare plays a crucial role in data collection and analysis, medical research, health care delivery, and health policy development. Statistical inference is used to generalize results from samples to larger populations, with special application in epidemiology. Biostatistics involves selecting samples, analyzing sample variation, carrying out hypothesis tests and evaluating statistical significance. The distinction between target population and study population is essential. The choice of sampling methods, such as random sampling, is critical, with an emphasis on adequate documentation. Data organization and analysis include measures of central tendency, measures of dispersion, assessment of normality and standardization of distributions. Furthermore, binomial and Poisson distributions are mentioned. These aspects are essential for research and data analysis in healthcare. Therefore, the objective of this study is to review the uses of biostatistics in clinical practice in the literature. Method: The bibliographic search took place online, carried out between September and October 2023, using the descriptors indexed in the Health Science Descriptors (DECS) and the Medical Subject Headings (MESH): “Bioestatística” or "Biostatistics " in the database The Scientific Electronic Library Online (Scielo). The descriptors indexed in the Health Science Descriptors (DECS) and the Medical Subject Headings (MESH) were used: “Biostatística” or “Biostatistics”. Results: 49 titles found, 27 articles and Brazilian works were considered, resulting in 26 studies included in the review after excluding one that did not deal with biostatistics. Conclusion: Understanding biostatistics is crucial to advance in the medical field, directly influencing the improvement of healthcare and the quality of research.

Keywords: Health Sector; Biostatistics; Epidemiology; Sampling Methods.

INTRODUCTION

Biostatistics plays a crucial role in evidence-based health by providing statistical methods and tools to analyze clinical and epidemiological data. Having a fundamental role in the health area because it is a crucial tool for professionals, researchers and managers. It is used to objectively evaluate medical interventions, identify risk factors and possible associations between exposures and health outcomes. [7]

The concept of expanded health favors that health administrators can allocate resources effectively and policymakers to develop strategies based on solid evidence for the dimensions of primary, secondary and tertiary health through the data obtained by biostatistics. [7]

For this, statistical methods are used, such as means, medians and standard deviations, contributing to the extraction of useful information. [7] Other statistical techniques are employed for data analysis such as parametric tests, t-test and analysis of variance, as well as non-parametric tests, such as the chi-square test, the Mann-Whitney test and the Spearman correlation, among other statistical approache.[5]

The general stages of health research involve the definition of the study theme, the selection of the target population and the planning of the sampling, followed by the collection, entry and processing of data, analysis and interpretation of the results, critical evaluation of the study and, finally, the editing and dissemination of the findings. Statistics play a critical role in all these stages, especially in sample selection, data analysis and critical evaluation of the research. [7]

It is essential to highlight the importance of the appropriate choice of the study population in health research. The population represents the set of individuals who share at least one common characteristic and is the focus of inferences based on the results of the study.

The interest in understanding inequalities in human illness dates back to the end of the 18th century and the beginning of the 19th century, a period marked by the Enlightenment movement. In this context, the first efforts emerged to investigate the socio-natural "laws" of illness, aiming to understand and control, in a rational way, the health and life conditions of the populations. Throughout the second half of the 19th century, Epidemiology began to develop systematic methods to study the relationship between the environment and pathophysiological events, as perceived by the medical sciences of the time. These historical transformations are essential to understand how the concept of epidemiological risk has become central in contemporary health practices [1].

Causal analysis in research is fundamental to understand the relationships between variables and their effects. Controlled experiments provide a robust structure to identify causes and

effects, allowing you to isolate variables and control interventions. Graphs offer a visual representation of the causal relationships between variables, elucidating the direction of the influences. Observational data can be useful for investigating causality in contexts where controlled experiments are impractical, while natural experiments offer unique opportunities to observe natural events such as experiments. Techniques such as differences in differences, discontinuous regression and instrumental variable are used to mitigate bias in observational studies, identifying more accurate causal relationships [14]

The validity in epidemiological studies consists of a thorough analysis of the sources of systematic and random errors to avoid biases. Epidemiology is not limited to causation or determination studies, but also covers "analytical" studies, in which all stages are affected by issues of validity, especially in observational studies. Identifies four aspects of validity (comparion, follow-up, measurement and specification of the analysis model). Thus, it is necessary to understand the types of validity: comparison, follow-up, measurement, specification of the analysis model, conceptual, operational and domain validity [13].

The validity in epidemiological studies covers several crucial aspects to ensure the reliability and relevance of the conclusions obtained. It includes conceptual validity, which ensures the coherence between the theoretical concepts and their practical application, guiding the formulation of hypotheses and the interpretation of the results. Operational validity refers to the appropriate choice of measures and indicators to represent the theoretical concepts in the empirical context, ensuring that these measures faithfully capture the phenomena studied. The domain validity considers the scope and scope of the results, taking into account the characteristics of the population studied and the specific conditions of the study to ensure the generalization of the results. In addition, the validity of comparison ensures impartiality in the comparison between exposure groups, while the validity of follow-up ensures the accuracy and completeness of the follow-up of the participants over time. The measurement validity refers to the reliability and accuracy of the measurements used, while the specification validity of the analysis model refers to the adequacy and robustness of the statistical model used to analyze the data. Together, these aspects contribute to the construction of robust and reliable epidemiological studies, capable of providing valuable insights into the determinants and patterns of health and disease in human populations.[13].

The p-value, widely used in epidemiological research, is often misunderstood and used arbitrarily in clinical research, focusing on a value of <0.05 as a threshold for significance. This results in biases in the biomedical literature and can lead to waste of resources in fruitless research and inadequate therapeutic policies [6].

The practice of testing the null hypothesis using the p-value has been predominant in statistical inference, where the level of significance is established based on the acceptable alpha error

when rejecting the absence of association between the variables of interest. However, the variation of the p-value due to the sample size and the magnitude of the association, combined with the generalized application of the same level of significance, can result in divergent conclusions, especially in studies with limited samples or weaker associations. Alternatives such as the use of lower significance levels and the calculation of post-test probability have been proposed to address the lack of replication of affirmed associations. Despite this, a recent article in the journal Nature instigated the scientific community to abandon the concept of "statistical importance" in scientific publications, a proposal that received broad support. However, the feasibility of this recommendation and its implementation in scientific practice remain under debate, especially considering the increasing use of the term "statistically significant" in the biomedical literature. To explore this issue, a research was conducted with the signatories of the article, aiming to evaluate the willingness to no longer use this term and validate the support for the recommendation to abolish statistical significance [(4)].

Therefore, a precise definition of the population is essential, because it will determine the applicability of the study results to specific groups of interest. However, to obtain valid and reliable results, it is indicated that the samples are selected in a representative and impartial way, which is achieved through random selection methods. [(5)]

It is essential to recognize that sample variation is not the only factor that can contribute to the differences between the samples. Systematic errors, known as bias, can arise if sampling is not carried out in an appropriate and representative way. This means that the selection of the sample may not adequately reflect the composition of the population, leading to distorted and non-representative results.

Therefore, randomization is often used to ensure that all individuals in the population have the same probability of being selected for the sample, minimizing bias. In addition, when planning the research, it is crucial to clearly define the sample unit. Thus, this study aims to carry out a review of the Brazilian literature regarding the study of the use of biostatistics during the professional exercise of the health team regarding clinical practice.

METHODOLOGY

This is a narrative review of the literature, and the steps of its elaboration and organization derive from other studies [(12)]. This was operationalized according to the following steps: identification of the theme, bibliographic survey, selection of texts, preliminary structuring and logical structuring of the study.

The bibliographic search took place online, carried out in the period between September

and October 2023, using the descriptors indexed in the Descriptors in Health Science (DECS) and Medical Subject Headings (MESH): "Biostatistics" or "Biostatistics" in the database The Scientific Electronic Library Online (Scielo).

Table 1 - Bibliographic search strategy in databases.

Database	Keywords MESH/DECS
Scielo	Bioestatistic OR Biostatistics

Sowrce: Author's own.

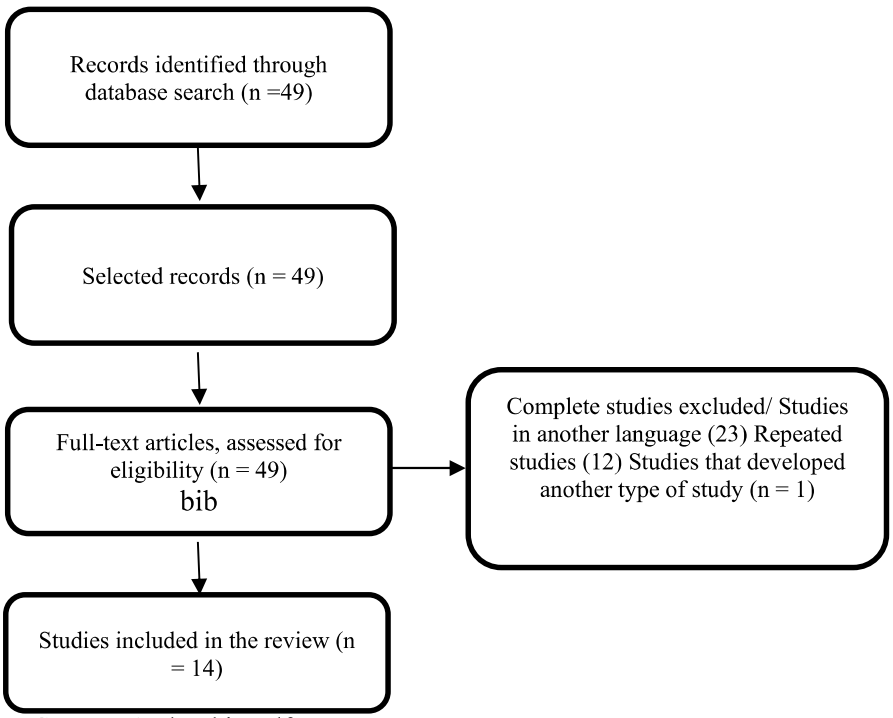
National scientific articles in Portuguese were sought, published between September and October 2023, in which the bibliographic search was carried out by two independent researchers. Titles of interest related to Biostatistics were included in the professional exercise of the health team in which the outcome observed the diversity of ways for the use of this knowledge directed to clinical practice.

Duplicate studies, dissertations, theses, articles in duplicity, and studies that did not emphasize the use of Biostatistics directed to clinical practice and that were not publications of Brazilian authors and non-Brazilian research were excluded.

For the selection of studies, the titles and abstracts of each article were evaluated at first. In a second moment, the articles were analyzed in full, with the objective of confirming the relationship with the theme of Biostatistics directed to professional practice in health.

After the initial search, a total of 49 titles were found in Scielo. However, only 27 were Brazilian articles and/or works. Of these, 1 was excluded for not addressing biostatistics and 12 for being studies in another language. With this, the number of studies included in this review was 14.

Figure 1 - Flowchart of the systematic literature review.



Source: Author himself.

RESULTS AND DISCUSSION

Biostatistics plays a key role in the health area, improving clinical practice, diagnosis and the cycle of rehabilitation, treatment, prevention and health promotion. It focuses on data collection, analysis and interpretation, providing a solid basis for informed medical decisions.

By applying statistical techniques, biostatistics helps identify patterns, evaluate the effectiveness of medical interventions, and provides support for evidence-based decision-making. Therefore, this article sought to review the state of the art of the use of biostatistics in the Brazilian literature scenario [2,5,8,11,15].

Table 2 - Description of the included studies that are related to the theme of Biostatistics and Clinical Practice in Health. São Paulo, SP, 2023

TITLE	TYPES OF STUDY	RESULT
Biostatistics: Essential Concepts for the Clinician	Literature review	Biostatistics plays an essential role in data analysis in the areas of health and biology. It deals with information from samples that represent larger populations and involves classifying variables as categorical or continuous, based on their

TITLE	TYPES OF STUDY	RESULT
		measurements. The normal distribution plays an important role, being fundamental for the application of inferential statistical tests, which allow comparing samples and making predictions. Concepts such as significance levels, type I and II errors, study power and confidence intervals are crucial in this context. Biostatistics encompasses different types of studies, such as analytical observations, randomized clinical trials and systematic reviews, each with its specific methodologies. Avoiding common errors in statistical methodology, such as the inappropriate use of graphs or parametric tests in non-normal situations, is vital to obtain reliable results and support decisions in the area of health and biology.
Visual Data: A New Tool to Improve the Presentation of Clinical Trial Results	Literature review	Visual data is a valuable tool in business, providing visual representations that simplify the identification of problems in processes. For example, a large circle may be used to represent the main outcome, with smaller circles for secondary outcomes, using colors (green, yellow, red, gray) to show the impact of the intervention. In a study with 80 participants divided into experimental groups and control, the results are clearly interpreted, demonstrating that the majority of participants in the experimental group had an improvement in the main outcome compared to the control group. The use of visual data surpasses traditional graphs, offering a

TITLE	TYPES OF STUDY	RESULT
		complete view of the effects of the intervention on primary and secondary outcomes for each participant. The categorization of variables (improvement, maintenance, worsening) makes the results clinically relevant and understandable.
Optimal size of samples and fruits and seeds for determining polyembryony in Citrus	Experimental Study	The study analyzed data on citrus fruits and seeds collected between 2009 and 2012, taking into account the rootstock. From 6 to 100 fruits were collected, depending on the presence of developed seeds. The seeds were washed and stored for evaluation in the laboratory, including the number of embryos per seed and the polyembryony rate, which underwent statistical analysis. Citrus genotypes were classified based on the number of seeds per fruit and the polyembryony rate, resulting in five classes of genotypes, divided into monoembryonic and polyembryonic. Genotypes with lower polyembryony rates showed greater variation due to a higher frequency of seeds with monoembryony. It was determined that the optimal fruit sample size varied by genotype, with four, five, and eight fruits being suitable for three specific genotypes. . For the polyembryony rate attribute, samples of 156 seeds were considered appropriate for analysis. On average, about 10 seeds were sufficient to estimate the average number of embryos per seed, although varieties with a high polyembryony rate required smaller samples, while varieties with a low rate required larger samples

TITLE	TYPES OF STUDY	RESULT
		than expected.
Biostatistics: fundamental concepts and practical applications	Literature Review	Statistical tests in ophthalmological studies, emphasizing the importance of formulating hypotheses, selecting representative samples and considering the distribution of samples, as well as their dependence or independence. It also highlights the use of normality tests and the choice between parametric and non-parametric tests based on sample characteristics, along with the relevance of the cut-off point in diagnostic tests. Explores concepts such as sensitivity, specificity, ROC curve (Receiver Operating Characteristic) and area under the curve to evaluate the performance of diagnostic tests in ophthalmology. It also addresses the difference between statistical and clinical significance, and the usefulness of confidence intervals. Furthermore, it mentions the combination of variables to improve diagnostic accuracy and the increasing application of artificial intelligence methods in ophthalmology.
Analysis of the use of sample calculation and method error in scientific research published in national and international orthodontic literature Objective: to	Literature Review	The results revealed that sample calculation was mentioned in only around 4% of articles in one journal and a little more than 21% in the other. Regarding the analysis of method error, most studies included it, with 61% in the first magazine and 77% in the second. This suggests that researchers were more concerned with addressing method error than with properly calculating sample size.

TITLE	TYPES OF STUDY	RESULT
evaluate, quantitatively, how often researchers in orthodontic science have used sample calculation and method error analysis in research published in Brazil and the United States		
Hypsometric relationship modeling using data collected from tree scaling and inventory plots.	Observational	The study evaluated the performance of eight hypsometric models that relate tree height and diameter. The data came from scaling 118 trees and 25 forest inventory plots. Several statistical criteria were used to evaluate the accuracy of the models. Results indicated that the "prodan" model was the most accurate when height and diameter data from 10 trees per plot were combined with scaling data in even-aged forests. Furthermore, the study highlighted the importance of using data from both sources (scaling and inventory) in estimating hypsometric equations, and emphasized the relevance of considering diameter classes in this process.
Choosing a statistical test - a tutorial in the form of a PowerPoint	Experimental	The guide in PowerPoint presentation format aims to assist in the choice and application of statistical methods in Orthodontics. It offers step-by-step guidance and practical examples specific

TITLE	TYPES OF STUDY	RESULT
presentation		to the area, making it easier to understand and use statistical concepts. It is useful for students, researchers and reviewers of academic articles, promoting a better application of Biostatistics in Orthodontics and, consequently, high quality research and effective data analysis.
The Role of Research Methodology in the Rational Use of Technology in Monitoring and Preventing Communication Disorders	Literature Review	It highlights the importance of methodological research in the area of communication disorders, highlighting the need to understand the needs of different groups of patients to provide comprehensive assistance and effectively utilize financial and human resources. Furthermore, it emphasizes the fundamental role of epidemiology, biostatistics and social sciences in obtaining specific information to improve communication sciences and their participation in the international scientific scenario related to health. However, the article does not present details of a specific study, providing an overview of the importance of research methodology in this context.
What not to do in medical statistics	Literature Review	It is advisable to avoid using hypothesis tests on baseline variables of randomized trials, as randomization ensures that any imbalance is due to chance. Instead, assess the imbalance by considering the size of the difference and its relationship to the outcome. Do not conclude that an intervention does not work just because a study did not find a statistically significant effect ($p > 0.05$); take effect size and confidence intervals into

TITLE	TYPES OF STUDY	RESULT
		account. Be aware of regression to the mean when analyzing changes from baseline and consider Analysis of Covariance (ANCOVA) to adjust for correlations. In meta-analyses, use appropriate weighting based on standard error and recognize unexplained variation between studies by accounting for random effects. Additionally, consider confounding factors in the analysis and adjust for them to avoid misleading results.
Essential items in biostatistics	Literature Review	The author addresses essential concepts in biostatistics, starting with the importance of the "p value" (descriptive level) in scientific research. The "p-value" is associated with hypothesis testing and is used to determine whether a result is statistically significant. The author explains the concepts of null and alternative hypotheses and the relationship between the significance level (α) and the p-value. The main advantage of using the p-value is the ability to quantify significance. Furthermore, the author addresses the importance of confidence intervals in biostatistics, highlighting how they provide information about the variability of estimates. Confidence intervals help assess the precision of estimates and the reliability of results.
Teaching Biostatistics in Undergraduate Studies: an Experience	Transversal	The majority of students achieved A or B grades, demonstrating satisfactory understanding of statistical tests. Students with grade D had the opportunity to recover and were

TITLE	TYPES OF STUDY	RESULT
		approved. A survey of the most consulted journals showed that with knowledge only of descriptive statistics, students could understand around 38.2% of the articles. However, with knowledge of the T and Chi-Square tests, this percentage would increase to 73.9%. The author concludes that the teaching of biostatistics at postgraduate level must include the active participation of students in the selection of topics, focusing on understanding the choice of statistical tests and the interpretation of results. The use of software in teaching was well received by students and should be maintained.
Quantitative-Qualitative: Opposition or Complementarity ?	Literary Review	The comprehensive view in social sciences, highlighting its emphasis on the deep understanding of human and social phenomena. It also mentions the historical debate between quantitative and qualitative methods, with reference to figures such as Comte and Durkheim favoring the statistical approach. On the other hand, thinkers such as Weber and Dilthey defend the qualitative approach, which focuses on subjectivity and understanding the meanings behind human actions. Qualitative research is described as dialectical, analyzing meanings, structures and contradictions in social contexts, with an emphasis on critical understanding. Scientificity in the qualitative approach is based on a regulatory idea of high abstraction, considering all stages of the research process as part of the object of study.

TITLE	TYPES OF STUDY	RESULT
The paths of statistics and their forays into epidemiology	Literature Review	The development of Statistics, ranging from its probabilistic origins to contemporary models of dependence in time and space. It also explores the evolution of the quantitative method in epidemiology and addresses the limitations of traditional statistical techniques, emphasizing their theoretical assumptions and their applicability in data analysis. The author highlights the importance of developing procedures that overcome methodological challenges in causal inference studies in epidemiology. Furthermore, the text mentions the increasing prominence of sampling in statistical research, thanks to the work of W. G. Cochran in the systematization of sampling techniques. Statistical research addresses diverse questions of inference, such as hypothesis testing for means, variances, and proportions, and explores the evolution of nonparametric methods, which do not rely on rigid theoretical assumptions.
Health as the absence of disease: criticism of Christopher Boorse's functionalist theory	Literature review	The essay presents Christopher Boorse's Biostatistical Theory of Health (TBS) from the 1970s, highlighting his naturalistic approach to defining health and disease without value judgments. Boorse distinguishes illness from illness, defining health as the absence of disease. Criticisms focus on the negative definition of health and the lack of consideration of social factors. The essay highlights the need to articulate biological and social approaches in the study of health and disease.

Quantitative and qualitative approaches in the social sciences are central to academic research. The text "Quantitative-Qualitative: Opposition or Complementarity?" Explores this debate, highlighting the understanding current as a pioneer of qualitative approaches, emphasizing the deep understanding of phenomena. In contrast, positivism, represented by thinkers such as Comte and Durkheim, values objective observation and seeks regularities, avoiding subjective explorations [9].

The historical debate on the preference between quantitative and qualitative methods, highlighting the research of Samuel Stouffer, who favored the statistical approach due to its speed and comprehensiveness. Max Weber and Wilhelm Dilthey are cited as defenders of the importance of the qualitative approach in the human sciences, emphasizing the understanding of the meanings and singularities of social phenomena.

There are different approaches and debates in the social sciences. The qualitative approach, characterizing it as focused on subjectivity and symbolism, with emphasis on understanding underlying meanings and a dialectical perspective. The scientificity of the qualitative approach does not depend on rigid models, promoting the importance of qualitative research at all stages of the process [9].

The development of statistics and its growing relevance in epidemiology, addressing the evolution of statistical methods and the importance of sampling. It also highlights methodological challenges in studies of causal inference. The third text presents Boorse's Biostatistics Theory of Health, with criticism of the negative definition of health and the lack of consideration of social factors, emphasizing the need to integrate biological and social approaches in the study of health and disease. These texts show the diversity of approaches in the social sciences and the importance of considering multiple perspectives in scientific research (ALMEIDA; JUCÁ,2002).

The use of the calculation of the sample size reveals a stability in this practice over the years. However, a significant contrast was observed between the health and sports sub-areas, where the health sub-area demonstrated greater adoption, possibly due to its proximity to the medical literature, which emphasizes the importance of appropriate sample sizes.

On the other hand, the negligence of this practice in the sports sub-area indicates a possible undervaluation of the methodology. Although the calculation of the sample size is relevant, the overall quality of the methodology, including the choice of appropriate statistical tests, accuracy in data collection and interpretation of results, is equally crucial for the validity and reliability of the research. Thus, the results encourage researchers to consider the importance of a solid and accurate methodology in their studies [3, 10].

CONCLUSION

The understanding of biostatistics is essential to advance in the medical area, after all it impacts on the improvement of health care. Quantitative and qualitative approaches, highlighting the understanding current and positivism. As for the use of the calculation of the sample size, stability is demonstrated, with the health sub-area more attentive, while those directed to sports there is negligence. In this way, it is noted that methodological quality is important, including the choice of tests and interpretation of results.

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