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REVIEW ON BIOSTATISTICS IN PHARMACOLOGY AND MEDICAL RESEARCH

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Abstract:

statistics is a major tool in pharmacological research that is used to sum up experimental data in terms of central tendency like mean or median and variance like standard deviation, standard error of the mean, confidence interval or range but more importantly it authorize us to managing hypothesis testing. It is the science that helps in control medical uncertains. It is consist of different steps like generation of hypothesis, collection of data and importance of statistical analysis in medical reasearches and experimental pharmacology.

Key words: Test of significance, student's t-test, chi square test, ANOVA, non-parametric test, kruskal walis H-test, wilcoxon's signed rank test, null hypothesis.

Introduction:

Statistical analysis is use to determine the results of experiment are significant or not. Statistics is the scientific study of numerical data based on natural circumstances. Biostatistics deals with the collecting, organizing, interpeting and reporting the data. It is important to apply statistics in the calculating of the experimental protocols at the origination of the study. To study the statistical analysis first we have to build an null hypothesis. It is accept that there is no difference between controll group and the treatment group. Statistics have to do with mathematical facts and data related to biological events and it covers implimentation and offering not only for health, medicines, nutrition but also use in fields such as genetics, biology, epidemiology, and many others. Scientific reasearches or any science needs accuracy for its growth. Accuracy is all the more dominant when it comes to health sciences. For accuracy; facts, observation or quantification have to expressed in figures. The activity of transforming data into information needs a special perspective called statistics. It is the science which compact with the evolution and appeal of the most aprropriate methods for the: collection of data, demonsrtation of the collected data, analysis and elucidation of the results, making conclusions on the basis of such analysis.

History:

Origin and development of statistics in medical research: Sir francis galton is the father of biostatistics. He was the first to used the statistical methods to the study of human differences and inheritence of intelligence, and introduced the use of test and assessment for collecting data on human communities, which he needed for ancestry and biographical works and for his sociodemogrphic studies.

In 1929, Dunn published huge paper on application of statistics in physiology journal.

In 1937, Austin Bradford Hill published 15 articles on statistical methods in the form of book

In 1948, a RCT of streptomycin for pulmonary tb., was published in which Bradford Hill has a key influence.

Then the development of statistics in medicine from 1952 was a 8 fold increase by 1982.

Biostatistics in pharmacology:

Pharmacology generally use statistics to help summarize data and, more importanlty, to test hypothesis. It is a quite simple matter when one is only involved in testing the null hypothesis that two sample means are equal. though, this kind of experimental design and hence analysis does have a number of control. For example , one never simply investigate the effect of one dose of drug in vivo, and in addition, it would not be realistic to have a control group for every drug dose group. Economic consideration notwithstanding, it is unethical to use large number of animals if a more relevant experimental design can be implemented. In fact, one can potentially reduce the number of animals used in an experiment by utilize a better experimental design that, while a little more complex (for instance using factorial designs) has the advantage of answering more than one scientific question.

With the help of tools of statistics, biostatisticians help to find the answers related to the research questions in medicine, biology and public health, such as whether a new drug works, what causes of diseases, and how long a person with a certain illness is likely to survive. Biostatistics has an important role in both designing a pharmacuetical experiment and evaluating its results. Randomization techniques are needed in plotting experiment. The aim of randomization is transforming organized errors into random errors and confirming comparability between experimental groups. Randomization also give rationale for applying statistical test. collaborating randomization techniques with blinding and local control enables us to build a scientifically reliable and effective experiment. A proper statistical analysis depends on the methods of randomization. For the successful pharmacological study it is importnat to consider statistical aspects in the designing stage.

In medicine, it is called Medical statistics. In this we can study about the defect, injuary, disease, efficacy of drug, serum and line of treatment, etc. For decades, biostatistics played an essential role in modern medicine in everything from analyzing data to determining if a treatment will work to developing clinical trials. Role of biostatistics in health planning and evaluation is to carry out a valid and reliable health situation analysis, including in proper summerization and interpretation of data. To asses the efficay of sera and vaccines in the feild. In epidemological studies – the role of contributing factros is statistically tested. Biostatistics use to test whether the difference betweem two population is real or a chance occurrence.

Hypothesis testing:

The Aim of doing a study is to examine whether the data agree with certain predictions. These predictions are called as hypothesis. Hypothesis make an appearance from the theory that derives the research. Significance test – it is a way of statistically testing a hypothesis by compairing the data values. It contains two hypothesis – null (H0) and alternative hypothesis (H1). Null hypothesis is generally a declaration that the parameter has value corresponding to, in some sense, no effect. Alternative hypothesis is a deny null hypothesis. Hypothesis are already put togehter before collecting the data. Significance test inspect the strength of sample evidence against the null hypothesis. The test is conducted to investigate whether the data contradicts the null hypothesis, suggesting different hypothesis is true. P-value – it is the probability of obtaining results at least as greatest as the observed results of a statistical hypothesis test, accepting that the null hypothesis is correct. A smaller the p-value means that there is stronger confirmation in favor of the alternative hypothesis.

Branches of biostatistics:

Descriptive biostatistics- in this we can organizing and summerizing information. It concludes graph, chart, tables and calculations of averages, percentiles. Inferential biostatistics- it has methods for drawing and measuring the reliability of conclusions about population based on information obtained. It includes point estimation, interval estimation, hypothesis testing.

Test of significance:

There are two types of tests in use for the interpretation of the results.

1. **Parametric tests :**
   - i) Student’s t-test,
   - ii) Chi square test,
   - iii) Analysis of variance.

2. **Non parametric test :**
   - i) Kruskal – wallis H-test,
   - ii) Wilcoxon’s signed rank test.

1. **Parametric tests:** In this tests data follows the normal distribution. Sample size is sufficient for central limit theoram to lead normality of averages. In this tests data is not normal but it can be change.

i) **Student's t-test:** In 1908 W.S. Gosset discovered the student t-distribution for small samples and it was then improved by R.A. Fisher in 1926. The t-test is the most common statistical procedure used in biostatistics. This test is applied to evaluate the statistical significance of difference between two independently drawn sample means (unpaired means) obtained from the two series of data with an presumption that the two means are from normally distributed populations, with no significant variations.

ii) **Paired t-test :** This test is used for the analysis of paired data. In this test no. of population in both groups are same. In the paired t test experiments are designed that the animals or tissues are carefully matched or the same animals or tissues are exposed to both the treatments. In this subject is acting as self control. The observed difference in both is calculated.

iii) **Analysis of variance test (ANOVA):** When compairing more than two samples the analysis of variance test is applied. T-test- difference between 2 means. So when there are >2 means to be compared we use ANOVA. Types – one way study- study effects of one factor, Two way study- study effects of multiple factors. Assumptions of ANOVA : Normality, Linearity, normal distribution, independent sample, random population. The significance of the difference of means of the two samples can be conclude through either Z- test or t-test. This technique is used when multiple samples cases are involved. This test minimizing the type1 error. This have variance of each and their means and variance of the group and all group means. It determines so many differences between seperate means.disturb the total variance of large sample and makes it two groups.

iv) **Tukey's Test:** it is also called as Tukey's Honest significant difference test. This test is carry out to find out difference between particular group mean by comparision. It is accept that observations are independent within and between groups, for which mean in the test are normally distributed. Within-group variance across the groups associated with each mean in the test is equal.

Method to performed Tukey's test: First performed the ANOVA test. Then select the two means from ANOVA table for comparison. Calculate the HSD using formula. Then scored is obtained from tukeys critical value table and compared with to check significnat difference in two means.

v) **Chi square test:** This test generally applied for the analysis of quantal or all or none responses. This test analysis the categorical data. In this test sanple should be indpendent and size of sample should be large. Expected cell frequency should not be <5. Yate's correction is applly if expected cell frequency is <5. Other tests like fisher exact test, McNemar's test are used. Fisher exact probability test is used when sample size is small. McNemar's test is used if there are two connected samples or repeated measurements.

2. **Non parametric test:** It is also known as distribution free tests. It is conducted when data does not follow normal distribution. In this the average is better constituted by the median. It is required small sample size and it is simple to conduct. In case of non- parametric test the assumptions are less strict than parametric test. It is eassy in computations. It is based on the series of the observations instead of the observations themselves. They are avialable for nominal, ordinal, interval or ratoi sacles. It is also called as distribution-free statistics.

i) **Kruskal-wallis H test:** This is one of the popular test used in non-parametric test to compare the groups. The test does not assume that the populations arenormally distributed.

ii) **Wilcoxon's signed Rank test:** It is applicable when the measurements are continuous and having the strength of only the ordinal scale.

Application of biostatistics in pharmacology and medicine:

i) To find the action of drug – when drug is given to the animal or human beings to see the changes produced due to drug or by chance.

ii) Biostatics in pharmacology used to compare the action of two drugs or two consecutive dosages of the same drug.

iii) It use to find the potency of a new drug with standard drug.

iv) To compare the efficacy of particular drug, operation or line of treatment

v) It is use to find an relationship between two characteristics such as cancer and smoking.

vi) To identify signes and symptomes of a disease or syndrome

vii) It is use to trial on sera and vaccines in the field – ratio of assault or death between the vaccinated subjects is compared between the unvaccinated subjects to find out observed difference is statistically significant.

viii) In the epidemological studies the role of causative elements is statistically tested.

ix) In clinical medicine biostatistics use for documentation of medical history of diseases. design and control clinical studies. Evaluating the quality of different procedures.

x) In preventive medicine it is use to provide the dimensions of any health problem in the community. It is use to discover basic factors underlying the ill-health. To asses the health programs which was introduced in the community. To introduce and promote health legislation.

xi) It is helpful in pharmacuetical industry to overcome matters related to the medicines, issues of designing experiments, to analysis of drug trials, issues related to the commercialization of medicines.

xii) It is use to asses the activity of drug. To find out analysis and the interpretation of results. Recognize risk factors for diseases. Design, monitor, analyze, interpret and report the results of clinical studies.

xiii) Identify and expand treatments for diseases and approximate their effects. Develop statistical methodologies to address questions arising from medical data.

Conclusion:

Biostatistical techniques can insure that the results found in the equivalent study are not only because of chance. In medical reasearches statitstics plays a important role for superior and accurate results.

A elegant and accurately conducted study is a basic requirement to achieve valid conclusion. Some methods and good practice in biostatistics must be learnt to understand their use and application in diagnosis.

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