Fundamentals in Biostatistics for Research in Pediatric Dentistry: Part I – Basic Concepts

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The purpose of this report was to provide the reader with some basic concepts in order to better understand the significance and reliability of the results of any article on Pediatric Dentistry. Currently, Pediatric Dentists need the best evidence available in the literature on which to base their diagnoses and treatment decisions for the children's oral care. Basic understanding of Biostatistics plays an important role during the entire Evidence-Based Dentistry (EBD) process. This report describes Biostatistics fundamentals in order to introduce the basic concepts used in statistics, such as summary measures, estimation, hypothesis testing, effect size, level of significance, p value, confidence intervals, etc., which are available to Pediatric Dentists interested in reading or designing original clinical or epidemiological studies.

Keywords: *Evidence-based Dentistry, Biostatistics, Pediatric Dentistry, Dental Investigation.*

INTRODUCTION

As health science professionals, many Pediatric Dentists are interested in how and why facts or phenomena occur along our daily clinical or academic activities. New and relevant scientific information arise every day, and clinicians who wish to remain updated should understand, and effectively and safely apply this information during the care of their pediatric dental patients. In the practice of Evidence-Based Dentistry (EBD), Pediatric Dentists require access to original investigation reports and perform a critical appraisal of the best published articles, including their design, conduct, and analysis of each study, and subsequent interpretation of the results about specific oral interventions, supported by clinically relevant scientific evidence.[1–4] In addition, Pediatric Dentists must possess basic knowledge of investigation techniques, and those interested in reading valid literature must learn matters related to statistical methods, in order to appraise those data collected from studies, whose findings are supposed to be based on sufficiently large samples of similar subjects.[5,6] Biostatistics (BS), when employed cautiously, aids Pediatric Dentists in improving their clinical decision-making process.[7–9]

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This report describes the BS fundamentals in order to introduce the basic concepts used in statistical analysis, such as 'summary measures', 'estimation', 'hypothesis testing', 'effect size', 'level of significance', '*p* value', or 'confidence intervals', and make them available to those Pediatric Dentists who are interested in improving their clinical practice, through the implementation of EBD. This learning philosophy consists in applying on their patients the most validated clinical evidence collected, taking also in account the own Dentist's clinical experience, and considering the patient's opinion and expectations.[2,3]

According to Kim and Dailey, Statistics is defined as the field of mathematical sciences that deals with data. Besides, "*Biostatistics is a branch of statistics that emphasizes the statistical applications in the biomedical and health sciences (including Dentistry). It is concerned with making decisions under uncertainties that occur when the data are subjected to variation*".[10] Human beings vary among them in a lot of aspects, as physiology, biochemistry, anatomy, environment, lifestyle, pathogenesis, and thus, to the responses to different dental and medical therapeutic procedures. So, BS collects, analyzes and helps interpret collected data, under variable conditions, to assess the results and findings of the newer published clinical evidence.[10] As you can realize, an essential knowledge of BS is a necessary component during the practice of EBD.

Descriptive analysis: Variables and data summary

Statistical analysis determines, mathematically and with high probability, whether an observed outcome occurred because of a real factor (an intervention or an exposure to risk) or simply by chance. The results of any study are usually documented with numbers or with categorical values recorded for each sample, which address the behavior of that sample; because this behavior may vary from sample to sample, it is called a *variable*.[11,12] Thus, a variable is

a quantity that describes an attribute and acquires different values, denominated *data*.[13] Before choosing any statistical analysis, it is necessary to know that data obtained during the experiment can be better understood when the variables are classified correctly, and that the type of variable being studied primarily determines the appropriate analytical method to carry out. First, variables are classified as *independent*, or *predictor*, which is a possible cause of variation of the *outcome-of-interest* in an investigation. A *dependent* variable, or *effect*, is defined as the outcome or *response-of-interest*; the dependent variable varies as a function of the independent variable. Normally, statistical analysis depends on the scale of the dependent variable; in this regard, the latter are classified as follows:[14–17]

- *Quantitative or numerical:* Expressed by numerical values. For example, the number of missing or extracted primary teeth in each patient, or the length in millimeters of a root canal. They should be summarized or reduced to a single datum, representing the whole sample, to yield some sort of average value, such as the arithmetic mean, or a middle value (named *median*). Among these, *continuous* variables, obtained by measurement of any characteristic, can take any value within a given range (e.g., child age in months or years, or pediatric weight in kilograms) and may have decimal points, while *discrete* variables, obtained by count of units or events, have values equal to integers without decimal points (e.g., the number of primary decayed teeth, or the number of topical fluoride applications per year).
- *Qualitative or categorical:* Data is simply assigned as "names/nouns", instead of values, based on the presence or absence of a specific characteristic (gender, disease, health status, and race). This type of variable is classified as *nominal* or *ordinal*. *Nominal* variables are characterized in no specific order (e.g., hair color: black, reddish, blonde, etc.); they can have only two outcomes (yes or no), called dichotomous or binary variables, or three or more outcomes (multiple variables). *Ordinal* variables are arranged according to a natural, intrinsic order (e.g., pain: mild, moderate, severe; or Frankl's scale of child's behavior: Definitely negative, negative, positive, definitely positive).

Instead of analyzing individual data, biostatistical analysis deal with data condensed into *summary measures*, or a value representing the set of all individuals.[9,13] The first step in a statistical analysis is to describe the different characteristics of the sample studied through the summary measures; this step is named *descriptive statistics*. For qualitative data, frequencies, or number of units belonging to a specific category, and proportions (percentages) comprise frequently employed measures. For quantitative data (discrete or continuous), measures of *central tendency* ('average value') and *dispersion* or variability are applied; both play a key role in BS. *Mean* and *median* are the most common measures of central tendency.[1,5,7,9] Mean (or average) takes into account all individual values of the data; therefore it is sensitive to extreme values; we add up the observed values and divide them by the number of the latter. The median is calculated by obtaining middle values of a set of data ordered from lowest to highest: thus, 50% of the values are smaller than, and 50% of these are larger than the median; it is less sensitive and a better central measure when one or more observations are widely separated from the mean, and may also be used with ordinal data.[16,17] The formula for calculating the median, regardless whether there is an even or odd number of data, is:

$$\text{Median} = (n + 1) / 2$$

where n is the number of data. In case of an even number, an average is obtained from the two central values. For example, odd number of data: 2.1, 4.2, 5.9, 6.3, 8.7; median = (5 + 1) / 2 = 3, the third value in the series, namely 5.9. Even number of data: 2.1, 4.2, 5.9, 6.3, 8.7, 9.4; median = (6 + 1) / 2 = 3.5, the average between the third and fourth values, (5.9 + 6.3)/2 = 6.1.

All biological data have certain natural or random fluctuation. After calculating the mean, it is necessary to know how the observations are scattered around it, and an important measure of variability, in this case, is the *Standard Deviation (SD)*, extensively employed with dental and health numerical data; these two measures are expressed as 'mean ± SD'. In case of using the median, the dispersion measures employed are the *interquartile range* and the *amplitude* (both will be detailed below, in the part of 'normal and non-normal distribution of quantitative data').[17,18]

Populations and samples

One of the main aims of research in Pediatric Dentistry is to infer or generalize the observations obtained from a sample to a larger population (all subjects meeting certain characteristics-of-interest). A population commonly contains too many individuals to study conveniently, so that an investigation is often restricted to one well-chosen and representative sample drawn from the population, and from which data are gathered to allow valid and reliable inferences.[12,17] So, first, a specific population must entail clearly defined features such as age range, gender, race, and health status (*selection criteria*), and then, a subset of this population or sample is randomly or non-randomly (e. g., the *convenience or quota sampling* , made up of patients who are easy to gather, for example, at public hospitals, university dental clinics or local malls) selected and subsequently studied.[16] On employing a sample, we save time, costs, and manpower, and efficacy is increased.[8] Sample size (expressed as '*n*'), or the minimal number of required units to achieve satisfactory precision and statistical power, is employed to accurately test our study hypothesis;[7,19] in addition to being ethical, sufficient sample size is very important in biomedical investigation and should be previously and carefully determined. Calculating the appropriate sample size is the most important determinant of the reliability of results of a study;[20] several factors should be taken on account during this process, mainly: the research question, the principal outcome (numerical or categorical), type of design and analysis, the smallest treatment effect or benefit we would like to be detected (in proportion or mean values) or *delta*, number of treatments, variability (for numerical outcomes), and the maximum risk of obtaining false negative or positive results (*significance level* and *power*);[21,22] some of these factors should be determined by the investigators, and some of them are collected from previous similar studies or by carrying out a pilot study.[20,22] Various methodologies for determining sample sizes could be employed, mainly through mathematical formulas (in which the mentioned factors are included), nomograms (like Altman's), or by employing user-friendly online calculators available on the internet.[21,22] We recommend to read the paper of Pandis

et al. (pages e142 to e144), which provides some common formulas for calculating the sample size, frequently employed in dental clinical trials, together with several illustrative examples with simulated data.[21] Furthermore, three useful real examples about sample size calculation can be consulted: in Huang *et al.* (pages 33 and 34), who compared the effectiveness of two treatments for white spot lesions, in 120 adolescents (12-20 years old);[23] in Aminabadi *et al.* (page 343), in a trial investigating the association between parenting style and child anxiety/behavior during dental procedures in 288 four-to-six-year-old patients;[24] and in Arrow (page 327), who compared in a child trial two local anesthetics (articaine and lignocaine) in block and infiltration techniques, among 57 Australian patients.[25]

Regardless the type of clinical study planned, the following statement should be taken into account: *"The larger the sample size, the less the variability within it, and the more accurate and precise your results"*.[13,26–28] However, too large samples may amplify the detection of minor differences between the study groups, that, though statistical significant, are not clinically relevant (which is called *type I error*). Besides, by using an excessive number of participants can also involve more financial and human resources than necessary, to obtain the desired response; ethical constraints can also be considered, because more individuals will be exposed to the proposed procedures, increasing unnecessarily the general risk of adverse effects occurrence.[20]

Normal and non-normal distribution of quantitative data

There are many possible distributions of quantitative data. If data are symmetrically distributed on both sides around the mean and form a smooth, bell-shaped curve with a central 'hump' with two equal 'tails' at either side, the distribution of data is called *normal* or Gaussian (Figure 1); in other words, the greatest amount of data values is symmetrically clustered in the center, around the mean, and the smaller data values, on the right and left tails.[29] Normal distribution is defined by only two measures: the mean (the top of the 'hump' in the curve), and the standard deviation (SD); both should be supplied to provide a sense of the overall distribution. This is considered a probability distribution, and the area under the bell curve is equal to 1 (or 100%), and because it is symmetrical: one half of the area is on the left (0.5 or 50%) and the other on the right (0.5 or 50%), both around a centerline, which corresponds to the mean. If the observations follow a normal distribution, the values lying between the points corresponding to one SD above the mean and one SD below it (mean ± 1 SD), include about 68% of all values, and the mean ± 2 SD (exactly 1.96 SD), approximately 95% of values about the mean, excluding 2.5% above and 2.5% below these 2 SD.[29,30] Therefore, if we know the mean and SD of a set of observations, we can estimate the range of values that we would expect to find according to the number of SD around the mean. In an ideal distribution, mean and median are equal within samples under study. When quantitative data are normally distributed statistical methods called *parametric tests* are indicated.[16,26]

When one tail of the distribution is longer, or positively or negatively skewed (in a normal distribution, the skew is zero), the data are non-normal distributed, due to the presence of outliers or extreme values (Figure 2). Therefore, median and interquartile range or the amplitude should be used, rather than mean and SD. *Quartiles* divide the ordered data set into four equal parts. The values that divide each part are called the first, second, and third quartiles; they are denoted by *Q1*, *Q2*, and *Q3*, respectively. Thus, Q1 (or 25th percentile) is the "middle" value in the lowest half of the rank-ordered data set; Q2 is the median value in the set; and Q3 (or 75th percentile) is the "middle" value in the second half of the rank-ordered data set. The interquartile range is equal to Q3 minus Q1, and includes 50% of the total values, which are positioned around the median. For example, this is a series of ordered data: 1.5, 2.2, 5.5, 6.1, 6.2, 8.4, 9.3, 13.6, and 15.7. The median (Q2) is 6.1; Q1 is the middle value of the lowest half of values (1.5. 2.2, 5.5, 6.1, 6.2), or 5.5; Q3 is the middle value of highest half of values (6.2, 8.4, 9.3, 13.6, 15.7), or 9.3. The amplitude (highest value minus lowest value) is also commonly used, as dispersion measure together the median.[11,30,31]

When the distribution is skewed, then an appropriate transformation of all raw data, prior to the statistical analysis, may be employed, such as logarithmic (log), reciprocal (1/x) or square root (√) transformation, in order to decrease the mean and variability (SD) of data, and to fit the distribution more closely to the normal one. For example, let see these data: 1, 2, 2, 3, 4, 5, 5, 19, and 22; the mean and SD are 7 ± 7.81, which indicates a non-normal or skewed distribution (note that SD is higher than mean) due to 19 and 22 values. When the same data are log transformed: 0, .69, .69, 1.09, 1.38, 1.61, 1.61, 2.94, 3.09, then the mean and SD are equal to 1.45 ± 1.02; this transformed distribution shows less variability and is closer to normal. The measures resulting from these transformed data should be retro-transformed to their original scales (*antilog*) once finished the statistical analysis.

However, on occasion it is not possible to utilize this approach; thus, alternative tests, known as *non-parametric* tests, can be applied, depending on nature of the data, although the statistical power is decreased.[32,33] These methods, rank the sample values (from lowest to highest) and each datum receives a value, according to the order; for example: 3, 4, 8, 9, 15, 18, 26; these values are now, the first one, 3, is 1, the next one, 4, is 2, and so forth (26 is 7).[18] (Non-Parametric methods are described in more detail in the part two of this paper series). More practical pediatric dentistry examples about parametric and non-parametric statistical approaches can be reviewed in Yassen*et al.*[34], Doğan*et al.*[35], and Tulsani*et al.*[36].

Inferential analysis: Estimation, hypothesis tests, and confidence intervals

By means of statistical methods, dental investigators can make generalizations or *inferences* of the results obtained from the sample to its respective population. Any statistical measure in a specific population that has been extracted from a sample is called *parameter* (in other words, the measure obtained from the sample is generalized to the population, and this measure becomes a parameter).[32] For example, to know the population mean of a particular characteristic, such as the mean number of decayed and restored primary molars in a specific ethnic child population – supposing that it is an unknown measure –, we can calculate the mean of an adequate random sample drawn from that population and use the sample mean to closely determine (or *estimate*) the population (parameter) mean. In other words, we have a high security or precision (the appropriate statistical term is *confidence*) that the sample mean (or a proportion, in case of categorical data) is approximately equal to the population mean (or proportion). Remember: the larger the sample size, the

Figure 1. An example of normal distribution: Birth weight in kilogram in a sample of Mexican children (n = 200). The distribution curve is symmetric; its hump represents the mean value (4).

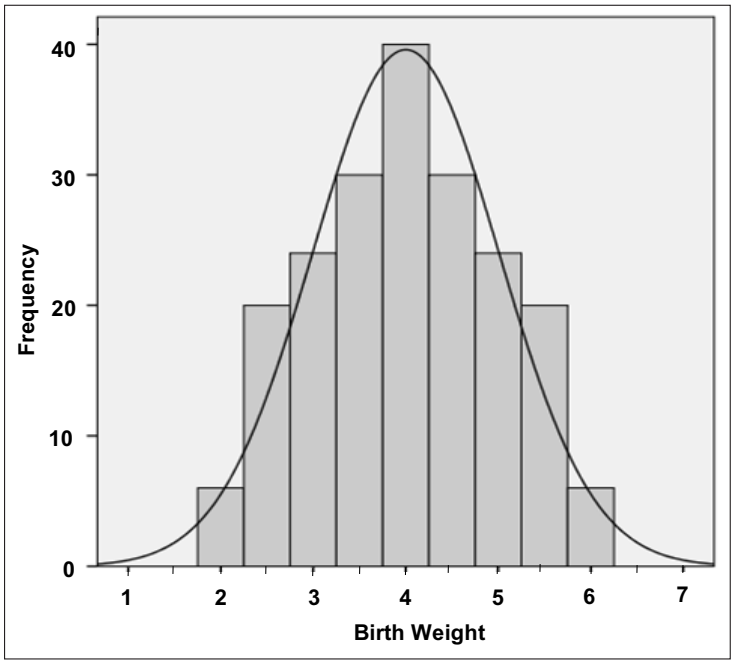
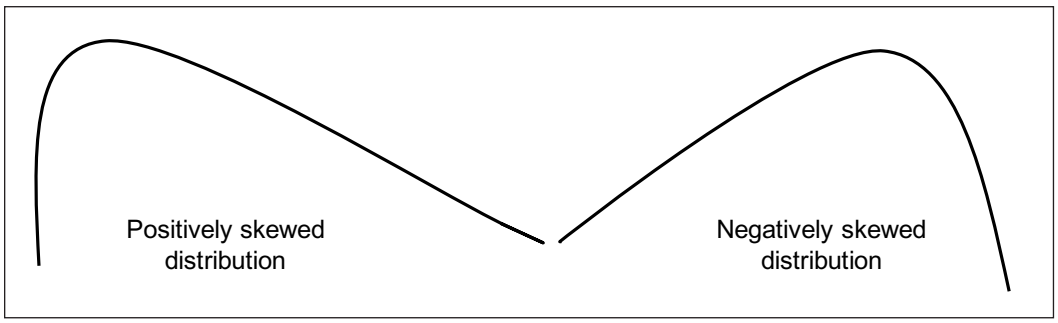


Figure 2. Non-normal distributions. In these cases, both distribution curves are not symmetric (tails are skewed). More extreme data on the side opposed to the tail, are present.



'better' the precision about the population parameter.[13] Therefore, for a correct inference of population parameters, the investigator should choose an adequate sample, with two needed properties: a sufficient number and representativeness; this former means that the sample must be as similar as possible in many biological or demographic characteristics, to the population which was extracted.[16]

Estimation

Parameters, like the prevalence of early childhood caries (ECC) in a preschool population living in a specific city or region, are typically unknown, and sample statistics are used to generate *estimates* of these parameters. This process is called '*estimation*'. An estimation is the very close, single-valued estimate (also known as *point estimate*) of the population parameter (mean or proportion) and always possesses some degree of variability. For example, to obtain the prevalence as the proportion of ECC in young children, an investigator can randomly gather a sample of sufficient number of preschool children (say, 100) from a total population of 5,000 preschool children, in a Mexican city; then, he or she calculates the sample statistic, the percentage of children with the disease (or prevalence), and this single value is now considered an estimation of the unknown population parameter, or the point estimate of the ECC prevalence of the *total* population, although the total population was not studied. However, the point estimate alone is usually insufficient in an estimation problem, due to that a sample selected at random always will be different from a second sample or many other possible samples, although the samples are extracted from the same population; consequently, the respective point estimates are also different from sample to sample.[33] For this reason, we employ interval estimates or *95% Confidence intervals* (*95% CI*) instead of point estimates. Confidence intervals define an upper limit and a lower limit – or confidence limits –, or the interval values between which the true population parameter being estimated is contained, with 95% confidence or precision (or, how close estimates from different samples are to each other), if determined in similar experiments with different random samples. The wider the interval, the less precise the result is. Confidence intervals can be established for any population parameter (e.g., mean or proportion).[16,13,33] Returning to the previous example, let us suppose that the investigator found in the studied sample a ECC prevalence equal to 6%, with a 95% CI of

4.5–7.5; it means that the true population ECC prevalence is found between this value range, with a 95% of security. But if an IC with less confidence (e.g. 90%) would be used, then a wider value range would be obtained, say, 4-8, which is logically less precise.

In order to determine the 95% confidence limits for quantitative variables, it is necessary to calculate the *standard error of the mean* (*SE*). As noted previously, if different samples are drawn from a specific population, their means will vary from one to another. Variation may be estimated through the SE (instead of the SD), which indicates how far the sample mean falls from the true unknown population mean, and is calculated by dividing the SD of the sample by the square root of the sample size or (*n)*, or:[13,28]

$$SE = \frac{SD}{\sqrt{n}}$$

We previously mentioned that, in normal sample distribution, 95% of the area under the distribution curve is contained between –1.96 and +1.96 SD around the mean. This statement is employed to derive the equation for determining 95% CI limits; thus, by multiplying the SE by 1.96 a value named *margin of error* is obtained, and finally, the margin of error is added and subtracted from the point estimate – in this case, the mean.[7,12,30] Thus, the general form of a CI is: point estimate ± margin of error. For clarification, SD is part of descriptive statistics (for individual values) and SE is a part of inferential statistics.[18] For example, you want to estimate the mean time of effect onset in seconds of a new local anesthetic drug, in a sample of 40 children (3-6 yr), before comparing it against the one most accepted; the obtained mean and SD were 150 ± 28 seconds, then the SE is equal to $28/\sqrt{40} = 4.43$. SE is multiplied by 1.96 = 8.62, the margin of error, and this is in turn summed and rested to 150 (the point estimate), thus giving a 95% CI of 141.38–158.62. The investigator concludes, with a high security, that the true population mean in seconds is located between 141 and 153 seconds.

In cases of qualitative variables, the SE associated with a proportion must be calculated to obtain the CI around the proportion. For example, when a dichotomous variable is being analyzed, one proportion represents subjects with the characteristic-of-interest (*p*) and the other proportion does not (*1-p* or *q*). The formula for calculating the SE is:

$$\sqrt{\frac{p(q)}{n}}$$

where *n* is the sample size; then, the SE is multiplied by 1.96 to form the error margin, and finally, as in the case of the mean, the error margin is added and subtracted from the proportion with either the characteristic (*p*) of interest or without it (*q*) to create the CI.[11,33]

Hypothesis testing

A hypothesis is concerned with answering a simple question on comparing the therapeutic effect of two drugs, or on the difference between the effects, in a sample drawn from a population. Likewise, an investigator may be interested in finding a likely association or correlation between two or more population variables.[16,18] Association refers to the extent to which two or more qualitative variables tend to occur together, for example, a cause-effect relationship; common association measures are the *relative risk* or the *risk difference*, for cross-sectional or prospective studies (or *cohorts*), and the *odds-ratios* for retrospective or *case-control* studies.[14] Correlation denotes the interdependence or the degree to which a quantitative variable increases or decreases as another, one or more, quantitative variable also changes.[32] For example, is correlated the monthly amount of ingested carbohydrates with the DMF index values in young children? Two statistical tests are appropriate for answering this type of epidemiological questions: The Pearson's correlation coefficient, for normal data, and the Spearman's test, for non-normal data.[32] Therefore, a typical investigative question may be expressed in terms of there being some differences between groups or an association among different variables (possible causality), for example: "*Is group A different from group B?*", "*Are factors 1 and 2 associated with or are they the cause of a disease?*", "*Does a new treatment have an effect on a population?*" and "*Is this new treatment better than the standardized treatment or than a placebo?*".[19,27] Excellent explanations and examples about association measures and correlation can be seen in Hackshaw *et al.* pages 44-50, and D'Agostino *et al*. pages 466-476, respectively.[2,18]

Proportions, in the case of qualitative variables, and means and medians, when quantitative variables are used, are all outcome measures employed in BS. In hypothesis testing, these measures must be compared between groups of subjects to obtain what is called *effect size*, or an assessment of the magnitude of the difference or association between these groups.[16,32]

When a study is planned, an explicit statement or hypothesis is generated with regard to an effect of an intervention, or variable association, and the primary aim of statistical analysis is to find out whether the effect size is real and not due to chance. Thus, hypothesis testing helps determine the likelihood that the result would occur even if the study were repeated over and over. Statistical analysis can never prove the truth of a hypothesis, but can provide the evidence to support or refute it.[5,11,27] To do this, the question should be stated in terms of equality, no difference, or no association between groups, which is known as the *null hypothesis*, an assumption that there is no existing significant difference or association between groups or variables-of-interest. Examples of null hypothesis for the next research questions could be: *Is group A different from group B?* (Null hypothesis: Group A is NOT different from group B); a*re factors 1 and 2 associated with, or are they the cause of a disease?* (Null hypothesis: Factor 1 and factor 2 are NOT associated, and are NOT cause of a disease either); and, *is this new treatment better than the standardized treatment or than a placebo?* (Null hypothesis: The new treatment is NOT better than the standardized treatment, and not better than the placebo either). In hypothesis testing, we prove how likely it is that any observed difference or association is explained by chance alone, or statistically not significant, if the null hypothesis is true. When the null hypothesis is rejected, then the alternative hypothesis – one that sets a true difference or association between groups and is contrary to the null hypothesis – is accepted, it means that the results are statistically significant, perhaps clinically meaningful, and not explained by chance.[17] Obviously, the majority of investigators favors rejecting the null hypothesis; thus, the analysis usually assigns a test of the level of statistical significance.

Several statistical tests are available, according to any type of investigation. The final result of a biostatistical test is the level of significance of the event or outcome. For this purpose, we can use the *p value.*[28,29] This value is always related to hypothesis testing and indicates the probability of obtaining the result that was observed by chance only (or non-significant). The *p* value is calculated after the test has been performed; if *p* is less than the conventional *level of significance* value (or α) of 0.05, the null hypothesis is rejected. In other words, our results would be wrong in 5% of cases if the study were repeated many times.[11,28,29]

Confidence intervals

Confidence intervals (CI) are also used in hypothesis testing. There is a close relationship between confidence intervals and significance tests. In general, if the value of a difference or association is significantly different from zero at the 0.05 level, then the 95% CI will not contain zero, and the null hypothesis can be rejected. As stated previously, all values within the CI are plausible values for the parameter, whereas values outside of the CI are ruled out as plausible values for the parameter.[33]

The majority of authors recommends the regular reporting of CI because simply mentioning the *p* value[31,32] by itself is not sufficient, as it does not provide information on the size of the effect. CI provide more meaningful evidence on the magnitude of the effect because they do not only contain information from *p* values, but additionally demonstrate the direction of the treatment effect, the size of the effect estimate, and its degree of precision. Therefore, both *p* and CI should be reported.[13,27,30] Here a real example. In 2015, Chi *et al*. investigated a possible positive association between added sugar intake (g/day, measured from hair samples) and tooth decay, measured as the mean proportion of carious tooth surfaces, in a sample of 51 Alaska Native children (6-17 yr.), through a cross-sectional pilot study; their results indicate that the added sugar intake was associated with an increase of absolute risk of dental caries: absolute risk = 6.4%, 95% CI = 1.2%–11.6% (p = 0.02). As you can see, both approaches, the 95% CI and the hypothesis testing, are strongly related and confirm the null hypothesis rejection: the CI range of values around the mean do not include zero and the p value is less than 0.05. In this same study, the authors also tested an association between a parent self-reported survey on sugar-sweetened food and beverage with tooth decay. Now there was no statistical association between the two variables; but, although values are not mentioned, we can guess that the 95% IC does includes zero (the lowest limit is a negative number), and the p value is > 0.05.[37]

CONCLUSIONS

Statistical analysis is necessary to obtain valid conclusions from data and results collected during clinical Pediatric Dentistry studies. When reading an original investigation published paper on Pediatric Dentistry, an important part that must of necessity be clearly understood is the results section, where the statistical conclusions should be described and explained. So, a clinician interested on making critical evaluations of published papers must understand, among other aspects proper to the EBD, the basic concepts on descriptive and inferential BS, as those mentioned here. Also, other important and more advanced issues, like the main statistical methods applied in health sciences, will be reviewed in the next part of this series.

REFERENCES

1. Windish DM, Huot SJ, Green ML. Medicine resident's understanding of the Biostatistics and results in the medical literature. J Am Med Assoc; 298: 1010–1022, 2007.
2. Hackshaw A, Paul E, Davenport E. Evidence-Based Dentistry. An Introduction. Blackwell Munksgaard, Oxford, UK; 1–9, 44–50, 2007.
3. Sathorn C, Parashos P. Questions and answers in evidence-based patient care. Br Dent J; 203: 309–315, 2007.
4. Maia LC, Antonio AG. Systematic reviews in dental research. A guideline. J Clin Pediatr Dent; 37: 117–1124, 2012.
5. Jacobson BC, Rowland DY. A simpler approach to Biostatistics. Gastrointest Endosc; 73: 570–574; 2011.
6. Martin-Kerry JM, Lamont TJ, Keightley A, Calache H, Martin R, Floate R, Princi K, de Silva AM. Practical considerations for conducting dental clinical trials in primary care. Br Dent J; 218: 629–634, 2015.
7. Gupta U, Lal H, Sibal P, Sibal A. Biostatistics – A tool for improving clinical decisions. Apollo Med; 2: 158–161, 2005.
8. Baccaglini L, Shuster JJ, Cheng J, Theriaque DW, Schoenbach VJ, Tomar SL, Poole C. Design and statistical analysis of oral medicine studies: common pitfalls. Oral Dis; 16: 233–341, 2010.
9. Tu Yu-Kang, Gilthorpe MS. Key statistical and analytical issues for evaluating treatment effects in periodontal research. Periodontology 2000; 59: 75–88, 2012.
10. Kim JS, Railey RJ. Biostatistics for Oral Healthcare. Ed. Blackwell Munksgaard, Oxford, UK; 1, 2008.
11. Pezullo JC. Biostatistics for dummies. 1st ed, pp 31–38. Hoboken: John Wiley & Sons, Inc., 2013.
12. Dakhale GN, Hiware SK, Shinde AT, Mahatme MS. Basic Biostatistics for post-graduate students. Indian J Pharmacol; 44: 435–442, 2012.
13. Petrie A, Bulman JS, Osborn JF. Further statistics in dentistry. Part 1: Research designs 1. Br Dent J; 193: 377–380, 2002.
14. Mandrekar JN, Mandreaker SJ. Biostatistics: a toolkit for exploration, validation and interpretation of clinical data. J Thorac Oncol; 4: 1447–1449, 2009.
15. Hannigan A, Lynch CD. Statistical methodology in oral and dental research: pitfalls and recommendations. J Dent; 41: 385–392, 2013.
16. Dawson B, Trapp R. Basic and Clinical Biostatistics. 2nd ed, pp 82–97. New York: McGraw-Hill, 2004.
17. Cohen ME. Analysis of ordinal dental data: Evaluation of conflicting recommendations. J Dent Res; 80: 309–313, 2001.
18. D'Agostino RB Sr, Sullivan LM, Beiser AS. Introductory Applied Biostatistics. 1st ed, pp 157–162. Belmont: Thomson Brooks/Cole, 2005.
19. Krithikadatta J, Valarmathi S. Research methodology in dentistry: Part II – The relevance of statistics in research. J Conserv Dent; 15: 206–213, 2012.
20. Faber J, Fonseca LM. How sample size influence research outcomes. Dental Press J Orthod; 19: 27–29, 2014.
21. Pandis N, Polychronopoulou A, Ellades T. Sample size estimation: an overview with applications to orthodontics clinical trial designs. Am J Ortho Dentofacial Orthop; 140: e141–e146, 2011.
22. Wang D, Bakhal A, Del Buono A, Mafflulli N. Sample size determination for clinical research. Muscles Ligaments Tendons; 3: 116–117, 2013.
23. Huang GJ, Roloff-Chiang B, Mills BE, Shalchi S, Spiekerman C, Korpak AM, Starret JL, Greenlee GM, Drangsholt RJ, Matunas JC. Effectiveness of MI Paste Plus and PreviDent fluoride varnish for treatment of white spot lesions: a randomized controlled trial. Am J Orthod Dentofacial Orthop; 143: 31–41, 2013.
24. Aminabadi NA, Deljavan AS, Jamali Z, Azar FP, Oskouei SG. The influence of parenting style and child temperament on child-parent-dentist interactions. Pediatr Dent; 37: 342–344, 2015.
25. Arrow P. A comparison of articaine 4% and lignocaine 2% in block and infiltration analgesia in children. Aust Dent J; 57: 325–333, 2012.
26. Kyrgidis A, Triardis A. Methods and Biostatistics: a concise guide for peer reviewers. Hippokratia; 14(Suppl 1): 13–22, 2010.
27. Morton JP. Reviewing scientific manuscripts: how much statistical knowledge should a reviewer really know? Adv Physiol Educ; 33: 7–9, 2009.
28. Shulz KF, Grimes DA. Sample size calculations in randomized clinical trials: Mandatory and mystical. Lancet; 365: 1348–1353, 2005.
29. Lew MJ. Bad statistical practice in pharmacology (and other basic biomedical disciplines): You probably don't know P. Brit J Pharmacol; 166: 1559–1567, 2012.
30. Williams AC, Bower EJ, Newton JT. Research in primary dental care. Part 6: Data analysis. Br Dent J; 197: 67–73, 2004.
31. Sainani KL. Putting P values in perspective. P M R; 1: 873–877, 2009.
32. Krzywinski M, Altman N. Significance, p values and t-tests. Nat Methods; 10: 809–810, 2013.
33. Gardner MJ, Altman DG. Statistics with Confidence. 1st ed, pp 6–19. London: British Medical Journal, 1998.
34. Yassen GH. Evaluation of mandibular infiltration versus mandibular block anaesthesia in treating primary canines in children. Int J Paediatr Dent; 20: 43–49, 2010.
35. Doğan S, Durutürk L, Orhan AI, Batmaz I. Determining treatability of primary teeth with pulpal exposure. J Clin Pediatr Dent; 37: 345–350, 2013.
36. Tulsani SG, Chikkanarasaiah N, Bethur S. An *in vivo* comparison of antimicrobial efficacy of sodium hypochlorite and Biopure MTAD™ against *Enterococus faecalis* in primary teeth: A qPCR study. J Clin Pediatr Dent; 39: 30–34, 2014.
37. Chi DL, Hopkins S, O'Brien D, Manci L, Orr E, Lenaker D. Association between added sugar intake and dental caries in Yup'ik children using a novel hair biomarker. BMC Oral Health; 15: 121–128, 2015.

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