An Overview of Research Methodology Pertaining to Prosthodontics.

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ABSTRACT

Research methodology has always been a matter of interest for epidemiologist, clinicians, biostatisticians and students for decades. Research vary in different spectrum of ways, methods and patterns for execution. Knowing the steps in study design, formulating research question and measuring the outcome forms the basis of this methodology of research. Sampling methods, types of data, measurement, sample collection, various test of significance often leads to arrival of many questions into the students and researchers mind. This article aims to provide a simple yet conclusive view on the different parameters and entities involved in performing research pertaining to prosthodontics.

Keywords: Data, Measurements, Outcome, Prosthodontics, Research.

INTRODUCTION

Research is searching the truth again and again in the light of knowledge, which requires logical thinking and reasoning. One may conduct research work retrospectively (looking backward) or prospectively (looking forward) or at present time (cross sectional studies). To find out the association of various causative factors with some disease one can perform retrospective study e.g. case control study. Case control studies are good for rare diseases, whereas to find out the effect of any treatment prospective studies are done. Cohort studies are long term or longitudinal studies to observe effect i.e. from cause to effect. We can find out the incidence of disease with cohort studies. Descriptive studies or prevalence studies are cross sectional studies. Experimental studies are done to find out the effectiveness of treatment over conventional methods. Figure 1 describes the various types of possible research studies.

The results of studies are valid only if no systemic bias is incorporated in the study. There has to be a proper randomization that is every individual included in the study has equal chance of being selected in either group – experimental or control group. This avoids systemic bias and sampling error. Secondarily, there should not be any kind of error in the study. All three types of experimental variability (observational error, instrumental error, sampling error) should be controlled. Observer error may occur if investigator alters some information or not records readings correctly.

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Instrument error occurs due to defect in the instrument. If we control experimental error (sampling as well as non-sampling) then the readings are said to be valid, accurate, reproducible and reliable. Biological variability which represents natural small difference between individual due to age, gender etc) is controlled via use of control group and including sufficient number of subjects in the study i.e. sample size. Non sampling errors are taken care by using standardized instruments, blinding (single, double or multiple) and use of control groups.

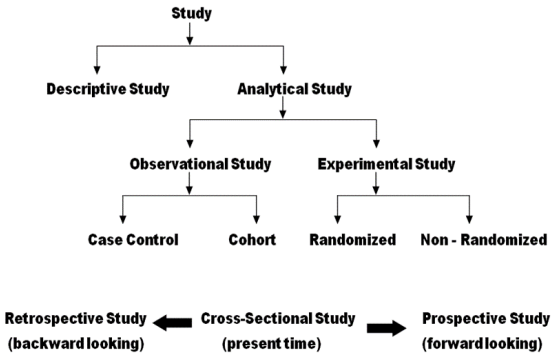

Figure 1: Basic types of research studies

STEPS IN DESIGNING A STUDY [1]

Following are the steps for quality dental research-

1) Formation of research question with its aim and objectives.
2) Hypothesis formation- e.g. null hypothesis for comparative study.
3) Decide type of Study with its outcome measures
4) Data collection - qualitative and quantitative
5) Deciding about study population with sampling method and sample size estimation
6) Randomization and blinding in comparative study.

7) Check validity and reliability of the method
8) Selection of proper statistical tests (parametric and non-parametric)

FORMULATION OF RESEARCH QUESTIONS

Formulating a research question before designing a research is of utmost importance. Based on the type of study, a research question varies as shown in Table 1.

OUTCOME MEASURES

Clinically the outcome of the research question can be in the form of different indices. Table 2 summarizes few examples of such outcome measures.

The aim of any study is to answer the research question. If the research question is fracture resistance of chamfer finish line is better than shoulder finish line in an all ceramic restoration? Our aim is to compare the fracture resistance of the chamfer finish with shoulder finish line in an all ceramic restorations. The objective will be to compare the success and failure rates of the all ceramic restorations having either chamfer or shoulder finish line. Thus by evaluating the rates we can reach a conclusion in deciding whether or not the chamfer finish line is better than shoulder line in an all ceramic restoration.

There are various types of test used to measure the data. Table 3 summarizes the various types of data and measurement used.

Table 1: Formulation of research question

STUDY TYPE	QUESTIONS
i) DESCRIPTIVE STUDY- - Case report - Case series - Cross-sectional study Measuring the prevalence of a disease	What is the prevalence of denture bearers in village population? How many people use routine dental prophylaxis? Which musculoskeletal disorders are common in the dentistry?
ii) ANALYTICAL STUDIES Analytic studies are used for testing the hypothesis **1) OBSERVATIONAL** **-Cohort** Measuring the incidence of a disease; looking at the causes of disease; determining the prognosis. **-Case-control** Looking at the causes of disease; identification of risk factors; Suitable for examining the rare disease. **2) EXPERIMENTAL STUDIES** Evaluating the effectiveness of an intervention and used to test the hypothesis.	What is the role of denture cleansers in maintaining the hygiene of dentures? Does long term edentulousness leads to temporomandibular joint disorders? What are the risk factors associated with the increased vertical height in complete denture? Which impression material is best for recording secondary impression? Are Glass ionomer and Zinc phosphate equally effective for luting permanent crown?

Table 2: Examples of Outcome Measures

Clinical Outcome Measuring Life After Receiving Dentures **Quality of Life Index (QOL):** Multidimensional coverage including five dimensions of physical wellbeing, material well-being, social wellbeing, emotional wellbeing, and development and activity. (qualitative assessment)	Measuring Temporomandibular Disorders -Fonseca's Questionnaire -Helkimo Index -RDC/TMD criteria (qualitative assessment)
Measuring Aesthetics **Implant Crown Aesthetic Index:** which measures mesio-distal dimension, convexity, colour, translucency, texture of the crown and position of the margins, colour, contour, surface of the interdental papilla and attached gingiva. (qualitative assessment)	**Measuring the parameters in Senile population** **Global Age Watch Index:** ranks countries by evaluating how well their ageing populations are faring. It is based on four domains of income, health, capability and enabling environment. (qualitative assessment)
Measuring Stability and Retention of the Denture **Modified Kapur Index:** Measures the resistance of the denture to vertical pull and rocking under pressure to evaluate the retention and stability respectively. (qualitative assessment) **Weight scales** in gms by quantification with different posterior seals using the T-device. (quantitative assessment)	**Measuring Of Oral Hygiene** **Oral Hygiene Index:** In patients with FPD. (qualitative assessment)

Measuring Diagnostic criteria **Prosthodontics Diagnostic Index (PDI):** for complete edentulous checks the bone height, ridge morphology and relations, muscle attachment, arch space, tongue anatomy etc. (qualitative assessment)	**Patient Satisfaction** **Dental visit satisfaction scale:** Measures the satisfaction level of the patient after his/her visit to the dental office. (qualitative assessment)
Measuring Colour Stability 1.**Reflectance Spectrophotometer** and CEIL ab Values (delta E) which measures colour based on photometric and colorimetric instruments and express it within 3 coordinates (L*, a*, b*). Delta E is calculated using a standard formula on a continuous scale. L*brightness a* red or green Chroma b* yellow or blue chroma (quantitative assessment)	**Measuring Chewing efficiency** 1. **Optocal Test:** the patient is asked to chew an optocal cube (3.5g) for 60 cycles without swallowing. The material is collected on sieve column, vibrated and sieved out and then weighed using digital continuous scale. (quantitative assessment) 2**. Liedberg method:** uses the two coloured chewing gum whose evaluation was done on an ordinal scale using the visual assessment and an electronic assessment was done using a scanned image of the chewed gums. (qualitative assessment)
Measuring biocompatibility H-thymidine incorporation assay measuring number of viable organisms using cell culture in Eagle' medium. Isotope incorporation of DNA and radioactivity is measured. (quantitative assessment)	**Measuring Flow Property** Checking the diameter of the mix using ZOE paste, cellophane sheet and glass plate. The diameter gives the flow of the material. (quantitative assessment)
Measuring Masseter Muscle Pain 1.**Visual Analogue Scale (VAS):** is a continuous scale measuring pain that a patient feels across a continuum from none (0mm) to an extreme amount of pain (100mm) marked on a horizontal line. (quantitative assessment) **2.Numeric Rating Scale (NRS):** whole numbers i.e. discrete scale is used to measure the pain from 0 (no pain) to 10 (worst pain imaginable) (quantitative assessment) **3.Verbal Rating Scale (VRS):** it measures pain on an ordinal scale from none to very severe (qualitative assessment)	

Table 3: Type of data and measurements used.

Type of data Collected	Scale of Measurement	Values calculated	Test used	Examples
Quantitative data	Continuous and Discrete	Mean Standard Deviation	Parametric	-Unpaired test -Paired test -ANOVA test -Pearson's correlation coefficient
Qualitative data	Nominal and Ordinal	Interval Ratio	Non parametric	-Wilcoxon rank sum test -Kruskal Wallis test -Friedmann test -Spearman's correlation coefficient

COLLECTION OF SAMPLE

The sample should be a true representation of the entire population hence it should be sufficiently large and unbiased. Then only it will give true readings which would be almost equal to the parameters of entire population. Precision is opposite of random error. Precision of study which means if study is repeated again it will almost give the similar results, depends on sample size (which ordinarily should not be less than 30). Also greater the standard deviation less will be the precision. Hence with large standard deviation the sample size should be increased. Standard random sampling method is preferred to reduce bias in sample. Sample size is determined in such a way that the study has minimum 80% power to detect a difference if there is some. Sample size is determined before starting any study. Similarly the investigator should decide how large an error due to sampling defect is allowable (allowable error) eg. 5% (0.05) or 1% (.01)

Following are formulas for deriving sample sizes [2]

Sample size for quantitative data = $4SD^2/L^2$

Sample size for qualitative data = $4pq/L^2$

SD=Standard deviation

p = proportion in the target population. If there is no reasonable estimate, use 50% (i.e. 0.5)

q = 1−p (proportion in the target population)

L = precision level or degree of accuracy required or allowable error usually set at 0.05 level (10% of p), occasionally at 2.0

For example, from a pilot study, it is reported that the complete denture wearer patients coming to

prosthodontics department have lower anterior residual ridge resorption in 28% of cases with 10% variability in the estimated 28%. How many patients are necessary to conduct this type of prevalence study?

The resulting sample size is:

Here p - 28%

q i.e. $1-p = 72\%$

L = 10% of 28% = 2.8

Sample Size = $4 \times 28 \times 72/(2.8)^2 = 987$ patients.

Table 4 shows the various types of sampling methods and there uses.

'P' VALUES AND CONFIDENCE INTERVAL [3-5]

After observations we do various tests of significance to calculate p value i.e. the probability of occurrence of any event by chance. Tests of significance allow us to know whether the difference between two samples is by chance or real. The level of significance is usually set at 5% however for critical results it is set at 1%. So if the p value is more than level of significance the difference is not statistically significant (not real) and it is by chance. However if the value is less than level of significance then the result is statistically significant (a real difference).

P value does not tell about size of effect, it simply tell us the probability of Type I error. To know whether the observed effect size (difference between two groups) is of any clinical usefulness or not we have to calculate confidence interval of the variable. Confidence interval gives us the range of possible effect sizes which would occur 95 times out of 100, if experiment is repeated. E.g. mean difference of gingival retraction after using chemical and mechanical methods of gingival retraction is 0.5 mm, if this value is statistically insignificant then 95 confidence interval (+- 2SD) is calculated. 0.3 to 0.7 mm gives us the upper and lower bound values of effect size. Thus CI helps us in drawing clinical conclusions even in non-significant results.

Normal distribution shows that 95% observations lie within mean +-2SD, probability of value more or less than this range is 5%.

The limitation of 'p' value is that it depends upon sample size and standard deviation.

If sample size is small false negative results can be obtained and if standard deviation is large false negative results can be obtained.

Table 5 and 6 describes the relationship between p value, sample size, standard deviation and between CI, precision, Range.

Table 4: Types of Sampling Methods

Type of Sampling	Uses	Example
Simple Random Sampling	-It is used for homogenous population which is readily available and accessible -It's a haphazard way of eliminating bias -Each unit has an equal chance of being selected	Number of edentulous persons in the entire hospital being selected
Stratified Random Sampling	-Used for collecting data from a large heterogeneous population and dividing it into homogeneous subgroups having similar characteristics. -The subgroups are though not equally distributed in the population.	Number of edentulous persons amongst age group 50-60 yrs, 60-70 yrs, 70-80 yrs and so on OR Number of edentulous persons amongst the high and low socioeconomic strata of population
Cluster Sampling	-It is used for a larger population having natural groups like elderly in a village, children of a school -Clusters are heterogeneous, but Different cluster are homogenous.	Number of edentulous persons in the total population of elderly in the village X or Y
Convinience Sampling	- It uses the readily available data like the first person who comes across is selected -easy to use but not recommendable	Number of edentulous person coming across when on to street to select them.
Quota	-A quota or a proportion for inclusion of a particular group is determined by some criteria, and within this group, anyone is selected.	Number of edentulous person amongst pensioners and non pensioners OR Number of edentulous person amongst Hindus, Muslims and Christians.
Snowball	-The first participant refers a friend or another person who refers another person with similar trait of interest .-Used to locate information rich key informants	

Table 5: Relationship between *p* value, sample size and standard deviation

P value	Sample Size	Standard Deviation
Significant	More	Less
Non-Significant	Less	More

Table 6: Relationship between CI, Precision and Range

CI	Precision	Range
95 CI (2SD)	More	Narrow
99 CI (1SD)	Less	Large

TEST OF SIGNIFICANCE

Test of significance is applied to know whether the difference observed is of significance or not. Test of significance can be broadly classified as [6]
1) Parametric
2) Non-parametric

Parametric (distribution dependent): Certain assumptions are made about the population.
Sample has normal distribution
Variance of sample do not differ significantly
Standard deviation is less
Data is quantitative
Non- parametric (distribution independent) – data is qualitative

Table 7: Examples of parametric and non-parametric tests

S.No	Objective	Parametric test (distribution dependent)	Non parametric test (distribution independent)
1.	To compare difference between two groups	Unpaired t test	Wilcoxon rank sum test (Mann Whitney U test)
2.	To test difference between paired observation	Paired t test	Wilcoxon signed rank test
3.	To compare difference between several groups	One way ANOVA	Kruskal Wallis test
4.	To compare group values on two variables	Two way ANOVA	Friedmann test
5.	To measure association between two variable	Pearson's correlation coefficient	Spearman's correlation coefficient

INTERPRETING RESEARCH FINDINGS[7]

The interpretation of a result depends on methodological soundness of a study. It depends on the methodological soundness that how far the study is closer to the actual value. There may be inherent weakness in study design, conduct and analysis. The treatment effect reported in the study is true if the study is valid. With transparent reporting of the study it is possible for the reader to judge how concrete the results are. Certain methodological characteristics may be associated with effect size that is why it is necessary to describe the method.[5]
While drawing conclusion from a study we must keep in mind that two types of errors: Type I (false positive) and II (false negative) may be there. Before interpreting, study bias should be assessed in the study.
Six key characteristics to assess bias are –
1. Sample size calculation
2. Random sequence generation
3. Allocation concealment
4. Reporting of withdrawals
5. Blinding of measurement assessment
6. Use of intention to treat analysis.

While interpreting results one must keep in mind the following points [8]
Statistically significant does not necessarily mean that the effect is real. One in 20 significant findings will be spurious (type I error). However, on the other hand just because we are unlikely to observe such a large difference simply by chance, this does not mean that it will not happen. One in 20 may be by chance and will mislead us.
Statistically significant does not necessarily mean clinically important. It is the size of effect that determines clinical importance and not the presence of statistical significance. A large study may identify a fairly small difference as statistically significant which may or may not be clinically significance. It is the size of effect and not just the size of significance that is important to make clinical difference.
Non-significant does not mean no effect. Small studies will often report non significance even when the difference is real & important (type II error). A non-significant confidence interval simply tells us that the observed difference is consistent with there being no difference between the two groups.

CONCLUSION

The quest for knowing more and deep has no limits. Clinical research is being carried out today on a vast scale and variety. The correct application of right research methodology is the need of hour. From the idea of framing the research question to reaching the conclusion of the study, every detail requires meticulous preparation and use of apt statistics pertaining to the research. The research conducted in a systematic manner increases the validity and reliability of the results. This improvises and provides thrust to the rational decision making process.

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