Review Article

BASIC FUNDAMENTS OF DESIGNING A QUALITY RESEARCH

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Abstract:
Introduction/ Objectives: There exists a large number of papers that are published in around 500 journals within dentistry. Most of these published papers are observational studies with fewer experimental studies. Main objective of the present article is to provide basic knowledge of the study designs, qualitative and quantitative data, framing questions for designing a research for different types of studies, sampling methods, bias that occur during conducting the research. Sources/data: We made a survey of two renowned orthodontic journals (American Journal of Orthodontics and Dentofacial Orthopedics, Angle of orthodontics) from January 2009 to October 2014 and found that most of the studies were observational (65.3%) and the rest were experimental studies (34.6%). Selection criteria: The original research articles from these journals were selected and categorized into observational and experimental studies. Case reports, clinician's corners etc. have been excluded. Conclusion: In this article, information about the step-wise approach is provided regarding research methodology relevant to our clinical research.
Key words- Research, Study design, validity, reliability, random error, systemic error, bias.

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INTRODUCTION

There are around 500 journals publishing over 43000 articles a year within dentistry alone. We conducted a survey of the journals in orthodontics *(*American Journal of Orthodontics and Dentofacial Orthopedics, Angle orthodontics) from 2009 to 2014 and found that most of the studies were observational (nearly 65.3%) and few experimental studies (≈34.6%). In a study done by AM Glenny and JE Harrison, it was found that only 15% of the research is of experimental type among three leading journals from 1994–1998 (British Journal of Orthodontics, American Journal of Orthodontics and Dentofacial Orthopedics, and the European Journal oforthodontics). The rest of the studies were observational studies. It was further stated that a large proportion of the papers showed poor quality and was of improper study design showing inappropriate statistical analysis. There were issues of validity and reliability also. Most of the research studies showed statistically significant outcomes/results which were not clinically significant. In India there is lack of scientific training of research methodology in biomedical research. When research methodology is not sound, results cannot be held conclusive. A systematic study of research methodology is essential. In this article we aim to provide relevant information regarding research methodology of high quality relevant to our clinical research.

To understand the basis of research methodology, one must understand following terminologies-

Random error- Error is the difference in true value and study value. Random error describes the role of chance. Random error creeps in because of

- Sample variability (as a subset of the population is sampled - sampling error), Subject to subject variation and measurement error leading to inconsistent value on repeating the experiment. They can be either positive or negative but average is not affected.

Random error can be reduced by taking large sample size, repeating the experiment and averaging. (Figure-1)

PRECISION- Precision is opposite of random error, if random error is less, more precise is the study. Precision is a measure of consistency and is the function of random error and confidence required. Lesser the type-I error more precise is the study.

SYSTEMIC ERROR (BIAS) - Errors are not alone the consequence of chance alone, but occur due to inappropriate patient selection method/criteria. This can be controlled by a good study design and conduct of the experiment. (Figure-2)

Validity is opposite of systemic error. Lesser the systemic error, more valid is the study. Systemic error tends to be consistently either positive or negative and thus affect the average.

VALIDITY AND RELIABILITY –

A Study should be valid i.e. it should measure what it claims to measure and reliable that is it should measure same readings even if measured on two separate occasions. A method is valid (accurate) if we are able to control systemic bias. For e.g.-

If an index is used to measure dental caries, it must only measure the caries and not enamel hypoplasia (validity). The index should give the same score if the patient is examined by two different examiners (inter-examiner reliability) or by the same examiner on two different occasions (intra-examiner reliability).

TYPE 1 ERROR (α ERROR)- Type 1 error is observing a difference when there is actually no difference (false positive results). The null hypothesis is rejected erroneously.

P VALUE-

It is the probability of committing Type – 1 error . Type -1 error is fixed in advance. The upper limit of tolerance of Type -1 error is known as the level of significance α. Usually the probability (α) is set either at 0.05(5%) or at 0.01(1%).The Lower the level, the larger is the sample size required. For critical results, the study should be more precise hence α – error is set at a lower level. If the p-value is less than 0 .05, it means that the null hypothesis is rejected. If p-value is 0.01 it means that the difference is statistically significant and there is 1% chance that the difference is by chance.

POWER(1-β) OF STUDY-

Power is probability that a test will correctly identify the difference if it is there. Usually most study accepte the power of 80% i.e. 20% chance of missing the real difference. Sometimes a larger study power is set at 90% i.e. 10% possibility of false negative results –β error. Type II or β error is missing the real difference when it is there. Power analysis should be conducted to determine the appropriate sample size.

The larger the sample size, the study will have greater power to detect the significance of difference or effect of association. Power proportionally increases as the sample size for study increases.

RANDOMIZATION- It is a statistical procedure by which participants are allocated into groups(study and control group) to receive or not to receive an intervention.It is a method for allocating subjects to different groups in an unbiased manner. (See Table-1) Each individual gets equal chance to be selected in either group. Randomization is an attempt to eliminate bias and allow for comparability.

BLINDING- It is a basic tool to prevent conscious as well subconscious bias. In single blinding study subjects do not know the type of treatment they are receiving while in double blinding subject and investigator both do not know about the type of treatment. In triple blinding subject, investigator and analyzer all are not aware of type of treatment subjects are receiving. (See Table-1)

SAMPLING

Sampling can be probability or non-probability type. In probability type every individual has an equal chance of getting selected in the study. Probability sampling methods are – simple random sampling, stratified random sampling, multistage sampling and systematic sampling. (See Table-2) While in non-probability sampling every individual is not ensured an equal chance of getting selected.

FACTOR AFFECTING SAMPLE SIZE CALCULATION- sampling size determination is one of the most essential part of any research/study. Sample size calculation provides the appropriate no. of participants to be included in the study.There are many factors which affect the sample size, some of them are shown in Table-3.

TYPES OF STUDIES -

DESCRIPTIVE STUDY –

Descriptive studies are the first phase of any epidemiological studies focused on entire population. These studies describe the pattern of occurrence of disease. They provide data with regards to the type of disease problems and their magnitude in the particular community, aetiology of disease, planning preventive and curative series. Descriptive studies are used to formulate hypothesis.

CROSS- SECTIONAL STUDIES –

Cross-section studies are used to find out the prevalence of disease. e.g. Prevalence of Cleft Lip and Cleft Palate in India. Cross-sectional study design is best to be used for diagnosis/ screening, occurrence, surveys or establishing norms.

Surveys and cross-sectional studies are planned to observe various pattern like quality of life. Subjects are merely observed and no attempt is made to impose treatment on them. Cross-sectional studies are descriptive studies which can suggest hypotheses for future cohort and case control studies.

ANALYTICAL STUDIES –

Analytical studies are used for testing the hypothesis. Analytical studies, ascertain statistical association between two things by the test of significance. Analytical studies can be either observational type or experimental type. In observational type, we simply observe either retrospectively (case control study) or prospective study (cohort study). So study design is either backward looking or forward looking.

If our research question is - What is the role of flossing teeth in dental care? Then we can design observation study which can be prospective or retrospective. In a prospective study we include the patients who will be flossing the teeth regularly and those not flossing the teeth and examine their dental hygiene at regular time interval. While in retrospective study we include records of subjects who were already flossing teeth regularly and those who are not flossing, we examine them and find the dental carries record.

EXPERIMENTAL STUDIES - These are prospective studies. An experimental study aims to control all relevant variables while altering only the variable under investigation. We test the effectiveness of a drug or a treatment with the conventional methods. The experimental studies are either randomised (avoiding systemic bias) or non- randomised. If our research question is – Which filling material is best in the primary dentition?

Are glass ionomer and resin-based fissure sealants – equally effective?

To answer these questions, we can design experimental study including two groups of

patients using GIC in one group while in the other group, resin based fissure sealant is used and in both the groups, we may find the effectiveness of these materials in prevention of carries (caries).

To design a study, we take different groups of primary dentition and use different filling materials and in each group, we can compare their effectiveness in terms of reduction of caries. Graph-1 shows basic classification for the types of research studies.

CASE-CONTROL STUDIES (RETROSPECTIVE) –

First approach to test a hypothesis is a case control study. They do not establish the etiological factor but simply find the association between the two by calculating the odds ratio (an estimate of relative risk). They are suitable for examining the rare disease. E.g. risk factor associated with root resorption in the patients who have undergone orthodontic treatment. They are not used for calculating the incidence of disease because exposure and risk have already occurred. So we do not know the population at risk.

If odds ratio is 8:1, risk of outcome (eg.malocclusion) is 8 times greater for subjects with any risk factor (eg.abnormal habit).

OR < 1 Beneficial exposure

OR> 1 Hazardous exposure

OR= 1 No association (no difference in exposure between case & control)

COHORT STUDY-

Cohort is a group of individuals sharing common characteristics (study cohort and control cohort). These groups are identified prior to the appearance of disease. These observational studies are used to explore the effect of exposure on outcome(mostly prospective study).

For e.g. Natural variation in exposure and intervention are investigated.

Long cohort studies(mostly prospective) are well suited for measuring incidence of disease. Cohort study is used to find the strength of association of cause and effect by assessing risk ratios and attributable risk from the 2x2 contingency table. (See table-4)

Exposure risk – $\frac{a}{a+b}$

Non– exposure risk – $\frac{c}{c+d}$

Risk ratio – $\frac{\frac{a}{a+b}}{\frac{c}{c+d}}$

Relative risk indicates how more is the disease in exposed people as compared to unexposed people.

Relative risk <1 Beneficial exposure

Relative risk >1 Hazardous exposure

E.g. relative risk of '3' indicates that exposure subjects are 3 times more likely to develop the disease compared to those subject without exposure.

Attributable risk – $\frac{\frac{a}{a+b}-\frac{c}{c+d}}{\frac{a}{a+b}}$

If attributable risk = 80%

80% of outcome among exposed is attributed to the exposure (Outcome among the exposed group is due to exposure).

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-5.

FORMULATION OF HYPOTHESIS- The hypothesis is a statement of prediction of the results of study which the study can then test. In comparative studies, the hypothesis is usually presented in the negative form, for e.g. the use of postal reminders will not affect patient attendance rate. This is known as the null hypothesis and the study seeks to disprove it.

OUTCOME MEASURES- Clinically the outcome of the research question can be in the form of different indices. Table-6 summarizes few examples of such outcome measures.

It is very important that aim and objectives of the study should be based on the research

question. The aim of any study is to answer the research question. For e.g. if the research question is –

-Does going to dentist twice a year, reduces caries?

Our aim is to compare dental caries in patients visiting to dentist twice a year and those who are not visiting twice a year.

The objective will be to compare DMFT index in patients visiting to dentists twice a year and those who are not visiting twice a year. It is at this stage we decide whether out study is qualitative or quantitative or both.

QUALITATIVE AND QUANTITATIVE DATA-

Data can be qualitative or quantitative. Qualitative data can be further divided into nominal and categorical data. In nominal data there is no ranking sequence which one is better or worse than other .eg gender, eye colour or place etc. eg- type of malocclusion.

Data can be said to be dichotomous/binary in which categorical data can be divided into two possibilities only for eg- disease present or absent, answer is yes/no. Ordinal/rank data –here there is some degree of order. One is better or worse than other for eg – mild, moderate, severe, Likert scale (used in questionnaire studies).

Quantitative data is measured on interval scale and ratio scale. In interval scale there is no true zero for eg - B.P, while ratio scale has definite zero. eg – weight. The qualitative study aims to explore and obtain insight, into complex issues such as reason for people attitude or behaviour. The results are described in words other than number. Quantitative studies aim to test a hypothesis. The results are given in number of proportion. Quantitative study design may be used to describe how often the event occurs.

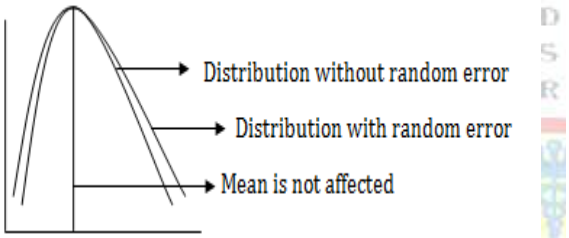


Figure 1: Showing effect of random error

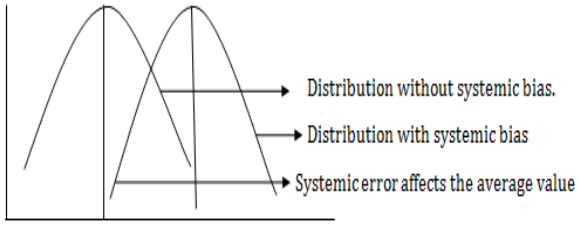
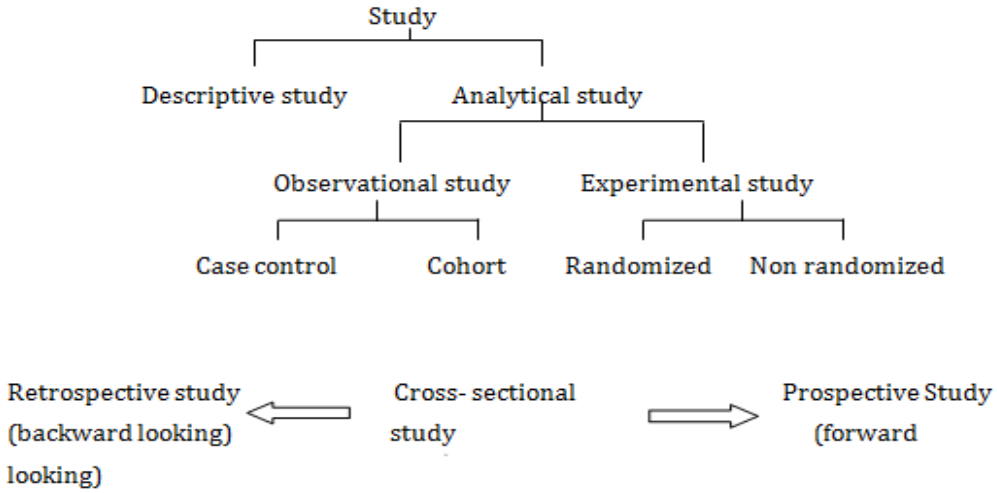


Figure 2: Showing the effect of Systemic Error



Graph 1: Basic types of research studies

Table I : Methods of Removing Bias

Bias	Technique to remove bias
Selection bias 1) Surveillance bias/detection bias- Occur when a particular diagnostic technique or type of equipment is more or less sensitive. 2) Neyman survival bias- Occur due to missing of fatal cases, mild cases of shorter duration 3) Referral (volunteer)bias- Volunteer tends to be more motivated and concerned about their health (bias favours treatment group) 4) Response bias- Occur due to different response or nonresponse of the people to a study or a survey. 5) Berksonian bias- Greater probability of hospital admission for people with two or more disease than for people with one disease eg in hospital based case control studies.	Randomization
Information bias 1) Reporting bias- Occur when some cases (severe) have complete information about exposure than less severe cases. 2) Recall bias (memory bias)- Diseased cases have greater sensitivity for recall exposure than control specially in case control studies 3)Interviewer bias- Interviewer generally devotes more time to cases as compared to controls 4) Hawthorne (attention bias)- Change in behaviour of subjects as they are being observed specially in cohort studies	Blinding(8) Single blinding- subject bias Double blinding- subject bias+ investigated bias Triple blinding- subject bias+ investigated bias+ analyzer bias
Confounding factor -Associated with both exposure and disease, and is distributed unequally in study and control groups. -Mask an actual association or falsely demonstrate an apparent association between the study variables where no real association between them exists.	Randomization, Matching, Stratification, Statistical Modelling

TABLE 2: Sampling Method

Probability sampling		**Non – probability sampling**	
Equal chance of being selected		Equal chances of selection is not ensured	
Type	**Use/type of study**	**Type**	**Use/type of study**
Simple random sampling	- Used for small homogenous population readily available -Community health survey	**Quota sampling**	-Used when we set up a quota for specific type of subjects. For e.g.- we decide to include in our survey 3 Hindus, 6 Muslims, 5 Punjabis, 8 Gujaratis,
Stratified sampling	Large heterogenous population is divided into homogenous subgroups but different sub groups are heterogenos.	**Convenience sampling**	Use results that are easy to get
Cluster sampling	For larger population, having natural groups(village, children of a school) - Clusters are heterogenous, but different cluster are homogenous.	**Snow-ball sampling**	Hidden population or difficult to gain access. For e.g., drug user.
Multi-stage sampling	For large country survey	**Purposive sampling**	Used primarily when there is a limited number of people that have expertise in the area being researched
Multi-phase sampling	Selected for different purpose	**Volunteer sampling**	Self selecting people
Systematic sampling	Used when the population is arranged in some order		

Table 3: Factors affecting sample size.

Factor	Magnitude	Required Sample Size
Standard deviation	Large	Large
	Small	Small
Effect size	Large	Small
	Small	Large
Power	More	Large
	Less	Small
P –level	Large	Small
	Small	Large

Table 4: The 2×2 Contingency table

		Outcome Problems	No Outcome	Total
Exposure Factor	Y	a	b	a+b
	N	c	d	c+d

Table 5: Formulation of the research question

STUDY TYPE	QUESTIONS
i) **DESCRIPTIVE STUDY-** - Case report - Case series - Cross-sectional STUDY Measuring the prevalence of a disease;	**W**hat is the prevalence of caries in school children? **H**ow many people use routine dental prophylaxis? **W**hich 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.	**W**hat is the role of flossing teeth in dental caries? **D**o teenagers with cross bites develop temporomandibular joint disorders? **W**hat are the risk factors associated with root resorption?
2) Experimental Studies Evaluating the effectiveness of an intervention and used to test the hypothesis.	**W**hich filling material is best in the primary dentition? **A**re glass ionomer and resin-based fissure sealents – equally effective?

Table 6: Examples of outcome measures

EXAMPLES OF OUTCOME MEASURES	
CLINICAL OUTCOME MEASURE MEASURING CARIES- DMFT/dmft British Association for the study Clinical caries diagnostic Criteria	**MEASURING ORTHODONTIC TREATMENT NEED-** Index of orthodontic treatment needs (IOTN) Modified index of orthodontic treatment of community dentistry (BASD) needs (modified IOTN) for caries
Measuring Dental Trauma Trauma index	
Measuring enemal defects Or Flourosis Modified dental enemal defect index(DDE) Tooth surface index of flurosis(TSIF) Thylstrup- fejerskov index of fluorosis	**Measuring Of Malocclusion** Index of tooth position (Massler and Frankel, Occlusion index Malalignment index Index of orthodontic treatment complexity Dental esthetic index Little's irregularity index
Measuring Dental Erosion Of Tooth Wear Larsen et al erosion index Lussi erosion index Smith and knight tooth wear index	**Patient Satisfaction** Dental visit satisfaction scale

STEPS IN DESIGNING A STUDY

Thus, 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 -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 snd non parametric)

CONCLUSION - Different study designs are used in dentistry. Study design can be divided into qualitative and quantitative or a combination of both. In qualitative studies results are described in words other than number. Quantitative studies aim to test a hypothesis and results are given in number of proportion.

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