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Review Article

Applications of Research Methodology in oral and maxillofacial surgery

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ABSTRACT

It is essential to understand the basics of research methodology, for designing a quality research. The selection of study, the determination of the required sample size, and the selection of appropriate statistical tests to be used in the data analysis are important part of research planning. The purpose of this article is to provide a basic review of research methodology for both the researcher and the clinician for conducting a successful research project.

INTRODUCTION

Research is a process of collecting, analyzing and interpreting information to answer research questions. The research process must have certain characteristics like it should be controlled, systematic, valid, empirical and critical. There are certain steps in research process which must be followed.

STEPS IN RESEARCH PROCESS

1. Formulating the research problem :

It is the first and an important step in the research process. Table 1 showing type of research question according to the type of study.To formulate research problem select the topic of great interest to sustain the required motivation that can be managed within the time and available resources .Topic should be relevant and availability of data should be ensured with no ethical issues.

2. Literature review : Literature review is integral part of research process. It describes prior research on the topic and makes valuable contribution to every step. It bring clarity and focus to the research problem,mprove the methodology of study and broaden investigator's knowledge.

3. Developing the aims and objectives :

Aim is the goal that is set out to attain in the study . It is an overall statement of the study. Objectives are the required tasks to be fulfilled for aim's accomplishment. Example: Aim is to evaluate merits and demerits of physics forcep over conventional forcep for extraction of tooth. To achieve this aim the objectives will be evaluation of fracture of tooth during extraction, evidence of dry socket, inflammation, fracture of buccal plate.

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4. Preparing the research design including sample design

The preparation of the research design for a particular research problem, involves the consideration of the following: the means of obtaining the information, the availability and skills of the researcher with suitable explanation regarding sampling design and data collection. There are several ways of collecting the appropriate data which differ considerably in context of money costs, time and other resources at the disposal of the researcher.

The design should be such that, it should be free of any bias. Systemic errors or bias may occur in study due to inappropriate patient selection, method/criteria. This can be controlled by a good study design and conduct of the experiment. Lesser the systemic error, more valid is the study. 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. Blinding can be done 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.

Sample design:

Sampling can be probability or nonprobability 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. While in non-probability sampling every individual is not ensured an equal chance of getting selected. Non probability sampling methods are quota sampling, convenience sampling, snowball sampling etc.

Sample size estimation:

The sample size estimation is the mathematical procedure for deciding how many individuals or specimen should be included in the investigation from the population. It must be carried out before collecting the data.

Factors affecting sample size:

Study design- Study design has a major impact on the sample size. Descriptive studies need hundreds of subjects to give acceptable confidence interval for small effects. Experimental studies generally need lesser sample while the cross-over designs needs one-quarter of the number required compared to a control group because every subject gets the experimental treatment in cross-overs.

Outcome measure of the study (categorical variable or continuous)- The outcomes measure is critical for the study, larger sample size is required to assess the categorical variable (qualitative) compared to continuous outcome variable (quantitative) study.

Power(1-β): Power is the probability that the test will correctly identify the difference if it is there. Usually, most study accepts 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 due to β error. Type II error is falsely stating that the two variables are equivalent when they are actually different. Power proportionality increases as the sample size for study increases.

Effect size : The minimum clinically important difference between cases and control. We can estimate the effect size based on previously reported or

preclinical studies. If the effect size is large between the study groups then the sample size required for the study is less and if the effect size between the study groups is small, the sample size required is large.

Standard deviation (how much dispersion from the mean we expect) : The standard deviation for sample size calculation is obtained either from previous studies or from pilot study. Larger the standard deviation, larger is the sample size required in a study.

Significance level (α) -Sample size is determined according to 'α' or Type I error - how much error is allowable in a study. Type I error is the probability of falsely claiming the difference in reading but actually there is no difference (false positive), and the null hypothesis is rejected erroneously. Type I error is fixed in advance, and its upper limit of tolerance is known as level of significance. The alpha level used in determining the sample size in most of academic research studies are either 0.05 or 0.01. Lower the alpha level, larger is the sample size and more precise will be our study. For example, a study with alpha level of 0.01 requires more subjects when compared to a study with alpha level of 0.05 for similar outcome variable.

5. Collecting the data: Primary data can be collected either through experiment or through survey. If the researcher conducts an experiment, he observes some quantitative measurements, or the data, with the help of which he examines the truth contained in his hypothesis. But in the case of a survey, data can be collected by any one or more of the following ways:

(i) By observation
(ii) Through personal interview
(iii)Through telephone interviews
(iv) By mailing of questionnaires
(v) Through schedules

6. **Analysis of data:**

The way we analyse the information collected largely depends upon two things: the type of information (descriptive, quantitative, qualitative); and the way we want to communicate these findings to the readers.

7. Hypothesis-testing: The hypotheses may be tested through the use of one or more tests, depending upon the nature and object of research inquiry. Hypothesis-testing will result in either accepting the hypothesis or in rejecting.

8. Generalization and interpretation: If a hypothesis is tested and upheld several times, it may be possible for the researcher to arrive at generalisation, i.e., to build a theory. If the researcher had no hypothesis to start with then he might seek to explain his findings on the basis of some theory known as interpretation.

9. Preparation of the report or presentation of results: The report should be in the form of preliminary pages which includes title, table of contents ,acknowledgements, the main text which includes introduction, summary, main report and conclusion and finally end matter followed by bibliography.

TYPES OF STUDIES

Epidemiological studies can be classified as either Descriptive or Analytic.

The most common types of studies are listed in Table 2.

Descriptive study:

A descriptive study is limited to a description of the occurrence of a disease in a population and is often the first step in an epidemiological investigation. Pure descriptive studies are rare, but descriptive data in

reports of health statistics are a useful source of ideas for epidemiological studies.

Case report and case series study

It is the simplest design in which the author describes some interesting observations that occurred from a small number of patients. When certain characteristics of a group (or series) of patients (or case) are described in a published report, the result is called case-series studies. This type of study design leads to the generation of hypotheses that are subsequently investigated in a cross-sectional, case-control or cohort study

Examples:

- Severe bony ankylosis of TMJ on one side and contralateral adhesion – A case report
- Sinus floor elevation with the crestal approach using a press- fit bone block: Case series

Cross-sectional studies measure the prevalence of disease and thus are often called prevalence studies. In a cross-sectional study the measurements of exposure and effect are made at the same time. Cross-sectional studies are relatively easy and inexpensive to conduct and are useful for investigating exposures that are fixed characteristics of individuals.

Examples:

- Prevalence of oral cancer relation to habits- A cross sectional study
- Health benefits of smoking cessation -A cross sectional study

Analytical study

An analytical study goes further by analyzing relationships between health status and other variables. Apart from the simplest descriptive studies, almost all epidemiological studies are analytical in character. Further divided into observational and experimental.

Observational studies allow nature to take its course: the investigator measures but does not intervene. They include studies that can be called descriptive or analytical.

Case control study

Case-control studies provide a relatively simple way to investigate causes of diseases, especially rare diseases. They include people with a disease (or other outcome variable) of interest and a suitable control (comparison or reference) group of people unaffected by the disease or outcome variable. The study compares the occurrence of the possible cause in cases and in controls. The investigators collect data on disease occurrence at one point in time and exposures at a previous point in time. Design of a case control study is shown in figure 1.

Example:

Reactive arthritis in relation to internal derangements of the TMJ- A case control study

Cohort study

Cohort studies, also called follow-up or incidence studies, begin with a group of people who are free of disease, and who are classified into subgroups according to exposure to a potential cause of disease or outcome.Variables of interest are specified and measured and the whole cohort is followed up to see how the subsequent development of new cases of the disease (or other outcome) differs between the groups with and without exposure. Design of a cohort study is shown in Figure 2.

Examples:

- Inferior alveolar nerve injury in trauma induced mandibular fracture- Prospective observational cohort study

- Dimensional change of the upper lip using dermis fat graft for lip augmentation- prospective cohort study

Experimental or intervention studies involve an active attempt to change a disease determinant – such as an exposure or a behavior – or the progress of a disease through treatment, and are similar in design to experiments in other sciences. Major experimental study designs include the following :

- Randomized controlled trials using patients as subjects (clinical trials)
- Field trials in which the participants are healthy people, an
- Community trials in which the participants are the communities themselves

Examples:

- Biomechanical comparison of osteosynthesis with poly L lactic acid and titanium screw in intracapsular condylar fracture fixation- An experimental study
- The use of a nasogastric tube to facilitate nasotracheal intubation
-

Systematic review is a form of research that provides a summary of medical reports on a specific clinical question, using explicit methods to search, critically appraise, and synthesise the world literature systematically. It is particularly useful in bringing together a number of separately conducted studies, sometimes with conflicting findings, and synthesising their results. Systematic reviews allow us to take account of the whole range of relevant findings from research on a particular topic, and not just the results of one or two studies.

Meta Analysis : Following a systematic review, data from individual studies may be pooled quantitatively and reanalysed using established statistical methods. This technique is called meta-analysis. The rationale for a meta-analysis is that, by combining the samples of the individual studies, the overall sample size is increased, thereby improving the statistical power of the analysis as well as the precision of the estimates of treatment effects.

Guidelines for different studies :

1. STROBE- Strengthening The Reporting Of Observational Studies in Epidemiology

It consists of 22 checklist items that should be include in report of observational studies. Observational studies are suitable for detecting rare disease or late adverse effect of treatment. These studies are either confirm or refute previous findings. The weightage of research depends on critical assessment of its strength and weakness pertaining to design conduct and analysis used. STROBE was developed with an intention to provide guidance on how to report observational research.

2. SQUIRE: Standard for Quality Improvement Reporting Excellence

It is guidelines for quality improvement reporting

3. **CARE**: Guidelines for Case Report writing

4. **CONSORT** (2010)-Consolidation Standard of Reporting Trials

5. **PRISMA-Preferred Reporting Items for Systematic Reviews and Meta-Analyses**

6. **COREQ-Consolidated criteria for Reporting Qualitative research**

7. **ENTREQ-Enhancing Transparency in Reporting the synthesis of Qualitative research**

8. CHEERS-Consolidated Health Economic Evaluation Reporting Standard

Studies least susceptible to bias are placed at the top of the hierarchy, example- RCT

The strength of evidence decreases from controlled observational trials to those without control as susceptible to bias increases.

Data and variable

A variable is any condition that can vary or change in quantity or quality. Variable can be independent variable or dependent, discrete or continuous, alternative (binary) or non alternative variable.

Variables with numbers as values are called **numeric**; variables with names or labels as values are called **nominal.**

The independent variable is under the control of and administered by the experimenter. The behavior that is potentially affected by the treatment and that we measure is called the dependent variable. It is referred to as dependent because changes in it depends on the effects of the independent variable.

Examples of dependent variables are

- Assessment of success or cure
- Apnea hyponea index(AHI)
- Body mass index
- Rapid eye movement
- Pain experience of patient
- Patient satisfaction

Examples of independent variables are

- Age
- Sex
- site
- Race
- Healing mode
- Implant length ,diameter
- Degree of inflammation

Discrete variable has limited or countable number of values and the basic unit of measurement cannot be meaningfully subdivided eg. number of dental students in a class , number of daily admissions of patients in hospital etc whereas continuous variable has an infinite number of possible values and its basic unit of measurement can be meaningfully subdivided.eg height, weight, skull circumference, meter is a unit of length. It can be subdivided into centimeters, millimeters etc.

- Alternative (Dichotomous or binary) data represent measurable categories in that outcome can take only one of two values: yes or no, “improved/notimproved” and “completed task/failed to complete task.” Non-Alternative represent measurable categories in that outcome can take many values. Example is severity of disease level (mild, moderate, severe)

Data and their types :

Data are usually a set of numbers representing variable like body weight, blood pressure etc. Data can be broadly classified into- Qualitative data or Quantitative data.

Qualitative Data:

- Measuring a characteristic for which there is no natural numeric scale (can be subdivided into nominal and ordinal data). Examples are

gender, eye color, a child may or may not show evidence of dental caries at a particular moment in time. In this case the observation describes the presence or absence of a characteristic, and it is therefore qualitative rather than quantitative

Quantitative Data:

- There is a natural numeric scale (can be subdivided into interval and ratio data) Example:- age, height, weight etc
- Variables are classified into two major groups: discrete and continuous.

Scales of measurement – Different scales are shown in Table 3

Statistical test:

Selection of appropriate statistical test is very important for analysis of research data. Statistical tests are according to the type of data we are dealing with, either qualitative or quantitative as shown in Table 4. Broadly statistical tests are divided into two groups: Parametric and Non parametric

Outcome variables in Oral surgery

In most research, one or more outcome variables are measured. Statistical analysis is done on the outcome measures, and conclusions are drawn from the statistical analysis. Examples of outcome variables are shown in Table 5.

Conclusion:

The knowledge of research methodology is essential. Concrete results can be drawn only when a study is valid and reliable while planning any study one must keep in mind the above mention guidelines to prevent bias and errors in the study.

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Table 1 : 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 oral cancer related to habits? **H**ow many people are getting benefits of smoking cessation? **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 are the risk factors for postoperative infections after dental implant placement? **D**oes topical application of placental extract improve mouth opening and wound healing in patients with oral submucous fibrosis?
2) Experimental Studies Evaluating the effectiveness of an intervention and used to test the hypothesis.	**C**omparison of a single noncompression miniplate versus 2 noncompression miniplates in the treatment of mandibular angle fractures?

Table 2: Classification of study design

Descriptive Studies	**I. Observational studies**	**1. Case series**
		2. Cross-sectional
Analytical studies		**3. Case-control**
		4. Cohort
	II. Experimental studies	**1. Controlled trails**
		2. Studies with no control
	III. Meta-analysis	

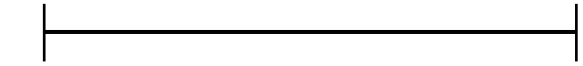
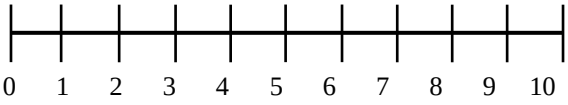
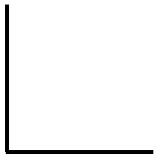
Table 3: Different Scales of measurement

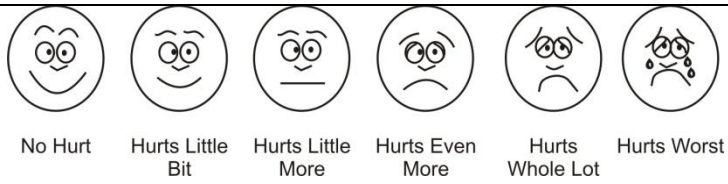
Scales of measurement	Question	Operation that make sense				Examples
		Counting	Ranking	Addition/ Multiplication	Subtraction	
Nominal	Is X different than Y?	yes	-	-	-	Male/female Yes/no Right/left Pain/no pain Swelling/no swelling
Ordinal	Is X bigger than Y?	yes	yes	-	-	Stages of oral cancer Pain scale(mild, moderate, severe) Stages of tumor
Interval	By how many unit X and Y differ?	yes	yes	Yes	-	Body temperature in space infections
Ratio	How many times bigger than Y is X?	yes	yes	Yes	yes	Pulse rate Respiratory rates Temperature in degree Kelvin

Table 4: Statistical tests accordance with the data type and type of scale

Scales	**Interval or ratio**	**Nominal or ordinal**
Data	quantitative	Qualitative
Observational form	Mean, S.D, Range, Variance	Proportions, Percentage, Fractions
Test	Parametric	Non parametric
examples	Student–test (paired or unpaired), Z-test, ANOVA	Chi-square test, fisher test, exact test, Wilcoxon rank sum test, Mann-witney test, Kruskal wallis test.
	Paired t-test- Evaluation of dimensional change in upper lip vermillion show (in millimeters) and lip projection (in millimeters) before and 12 months after lip augmentation using dermis fat graft.	Chi- square test- Comparison of one miniplate versus two miniplate in the mandibular angle fracture to evaluate Postoperative complications including malocclusion, malunion and sensory disturbance
	Student t-test- Evaluation of maximal interincisal opening and lateral protrusive excurtions (in millimeters)	Mann-whitney U test- Evaluation of complication in comminuted mandibular fracture treatment involving open reduction and internal fixation using an intraoral approach.
	ANOVA- Evaluation of the pharyngeal airway space area after orthognathic surgery and distraction osteogenesis of the jaw bones using Lateral cephalograms of the subjects taken pre-operatively (T0), immediate post-operatively (T1) and after a minimum follow-up period of 6 months (T2).	Kruskal wallis test- Comparison of complication rate with different types of mandibular fracture treatment (maxillomandibular fixation, 2-mm miniplates, 2.4-mm AO plates, and 2.7-mm AO plates) and occurrence of complication rates, fracture severity, and type of treatment are recorded.

Table : 5 Examples of outcome variables in oral surgery:

Type of scale	Type of data	Type of test
Visual analog scale(VAS)  No pain — Worst possible pain The VAS is usually presented as a 10-cm line (100mm) anchored by verbal descriptors, and the patient is asked to mark the pain intensity on that line. VAS requires the patient to be able to equate the length of the line with the amount of pain they are experiencing	Quantitative	Parametric test e.g student t-test
Numeric pain scale(NRS  0 1 2 3 4 5 6 7 8 9 10 No pain — Moderate pain — Worst possible pain The NRS is a segmented numeric version of the visual analog scale (VAS) in which a respondent selects a whole number (0–10 integers) that best reflects the intensity of their pain An 11-point numeric scale (NRS 11) with 0 representing one pain extreme (e.g., "no pain") and 10 representing the other pain extreme (e.g., "pain as bad as we can imagine" and "worst pain imaginable")	Quantitative	Parametric test e.g student t-test
Full cup test(FCT)  The FCT was a simple "cup" drawing as described by Ergun et al. The patients were told that the "cup" was completely full if their pain was the most severe and empty if they had no pain at all. The patients were asked to draw a horizontal line in the cup to indicate thepain level, as if the pain "filled the cup". FCT scores were calculated as height of line/height of cup	Quantitative	Parametric test e.g student t-test
Wong-Baker FACES Pain Rating Scale	Qualitative	Nonparametric

 Explain to the person that each face is for a person who feels happy because he has no pain (hurt) or sad because he has some or a lot of pain. Face 0 is very happy because he doesn't hurt at all. Face 1 hurts just a little bit. Face 2 hurts a little more. Face 3 hurts even more. Face 4 hurts a whole lot. Face 5 hurts as much as we can image, although we don't have to be crying to feel this bad. Ask the person to choose the face that best describes how he is feeling. Rating scale is recommended for persons age 3 years and olders		test e.g chi square test
Verbal rating scale(VRS) The VRS comprises a list of adjectives used to denote increasing pain intensities. The most common words used being: no pain; mild pain; moderate pain; and severe or intense pain	Qualitative	Nonparametric test e.g chi square test
2.Parasthesia		
Two point discrimination 2PDT thresholds were obtained with blunt probes calibrated in millimetres on keys around a key ring. 2PDT was applied, without movement on the mucosa. Testing started with orientation of the callipers 2 mm apart followed by a gradual increase in interprobe distance by 1 mm until the patient reported two points by showing one or two fingers. The threshold was estimated at the distance that was reported correctly in three out of five events	Qualitative	Non parametric test e.g chi square test
Pin prick In this test, a sharp dental probe was applied to the skin in a quick pricking movement and pain perception of the patient was assessed. Each test area was pricked three times bilaterally, and subject was asked if any difference was felt between the sides.	Qualitative	Non parametric test e.g chi square test
Light touch This method was used for testing by gently touching (tactile stimulation) the skin and evaluating the detection threshold of the patient. For this test, cotton stickwas used to perform the test	Qualitative	Non parametric test e.g chi square test
Brush direction stroke Patient is asked to tell when he/she feels the brush and to determine the	Qualitative	Non parametric test

direction of movement		e.g chi square test
Thermal discrimination Patient is asked if he/she feels heat or cold	Qualitative	Non parametric test e.g chi square test
3.Swelling Swelling is measure by by using a tape from tragus to the corner of the mouth,from tragus to the pogonion and from outer canthus to angle of lower jaw	Quantitative	Parametric test
4.Trismus Mouth opening interincisal distance	Quantitative	Parametric test

Figure 1: Design of a case control study

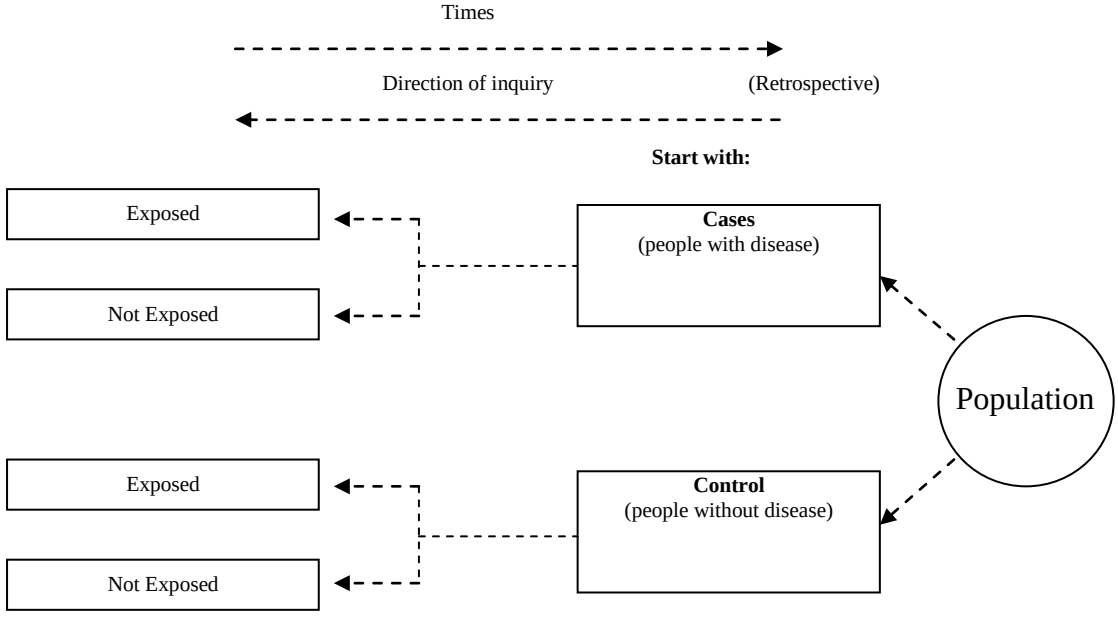


Figure 2: Design of a cohort study