IADVL

IADVL SIG-Dermatology Clinical Research Newsletter

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INTRODUCTION

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Dear IADVLites,

We hereby present to you the second newsletter by SIG Dermatology Clinical Research 2020-22. The newsletter comprises of interesting write ups by experts in the field, like Dr Kingshuk Chatterjee, Dr Shekhar Neema, Dr Inderpal Singh and Dr Sarita. The editorials penned down by Dr Ajith Kumar and Dr Rahul Mahajan, motivate you to carry on with re-search and the mind tickling quiz by Dr Rahul stimulates you to go back to basics of searching and researching.

With the third wave of COVID-19 gripping the country, it may be difficult to conduct full fledged research activities, but we, SIG Dermatology Clinical Research, would encourage all to make the best use of the available resources, and utilize the spare time towards positivity and productive materials.

Here's wishing everyone a safe and COVID-free year 2022, and may we continue to carry on reading, writing, discussing and researching.

Happy reading.

Dr Anupam Das

EDITORIAL

Dr Ajith Kumar K
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We are here with another news letter from SIG-Dermatology Clinical Research.

Though we planned to come out with frequent Newsletters Covid derailed all our plans for 2021-22 and unfortunately we had to reschedule our activities. It was a great experience to work with SIG members who have expertise in different areas of dermatology but with uniform interest in disseminating scientific temper among fellow dermatologists .

This issue of Newsletter contains 4 articles .

Dr Kingshuk Chatterjee writes about how to select a research question. This will definitely be helpful for young researchers especially the postgraduates who is trying to initiate a new research project. Dr Shekhar Neema discusses a very important issue which is faced by all researchers. He discusses how to choose a statistical test. He explains the seemingly complicated topic in a very simple way. Dr Inderpal sigh answers the question" why informed consent is important?' another question being asked by researchers frequently. Dr Sarita discusses how she evolved herself as a researcher. This article will be an eye opener to every young researcher in the field. A quiz by Dr Rahul Mahajan will be helpful to stimulate the neurons of research enthusiasts .

Let me wish all IADVLites a Great New year and thank each one you for the cooperation with my team during the last 2 years.

Dr. Ajith Kumar K.

FOREWORD

Dr Rahul Mahajan

Ethics in Publication

Medical professionals are trained to treat patients; however, invariably due to the inquisitiveness of their mind, they often perform the dual work of researchers and clinicians. The moot reason for medical research ought to develop and expand knowledge, share information with community. In addition, it helps to develop one's career too. It is expected that scientific works are conducted and reported honestly, objectively and fairly. Ethical breaches can be intentional or unintentional; however,ignorance cannot be an excuse for committing misconduct. Hence, investigators and authors need to conduct responsibly, be aware of ethics and never indulge in unethical activities. These include

1. Statutory and Ethics Approval - Since medical research invariably involves experimentation on living beings (humans or other animals), the Declaration of Helsinki requires that all medical researches be submitted to and approved by an ethics committee. Hence, the responsibility for obtaining ethics approval before conducting medical research lies with the researchers.

2. Informed Consent - As with ethics approval, obtaining informed consent is an ethical and legal requirement for research involving human participants along with providing them detailed information about their rights and the study's potential risks and benefits.

3. Plagiarism - Plagiarism refers to using other peoples' ideas and words without clearly acknowledging the source of that information. It's plagiarism whether you use a whole document, a paragraph, a single sentence, a distinctive phrase, a specialized term, specific data or a graphic element of any kind. It is *not* enough to cite the reference somewhere in the text. Always seek permission from the Copyright owner. Departments /Library have softwares to check for plagiarism.

4. Fabrication - It refers to a grave misconduct involving addition of data or observations that were never gathered by the authors while conducting their clinical research and/or experiments.

5. Falsification - It is another grave misconduct arising out of the changing of research data to support one's own claims or hypothesis.

6. Conflict of interest - This refers to a situation in which a financial or other personal academic considerations have the potential to disproportionately impact the primary purpose of research studies.

7. Authorship Issues - Authorship issues one needs to be aware of include Gift authorship (whose contribution is based solely on a tenuous affiliation with a study), Guest authorship (who make no discernible contributions, but are listed to help increase the chances of publication), and Ghost authorship (who contribute substantially but are not acknowledged).

8. Multiple submission - It refers to the unethical practice of submitting a manuscript that is already submitted and still under consideration at another journal, which clogs the peer-review process.

9. Duplicate/Redundant/Salami publication - Redundant publication refers to republication of copyrighted material with additional or new data or information; republication of part or parts of an already published article. *Salami publication refers to publication of numerous publications f*rom a single research, or data collected over same time period (single study) and published as several manuscripts.

Concluding, many of these deviations from ethical behaviour often result from ignorance, desire to “get ahead”, career prospects, pressure from seniors, character issues, and lack of knowledge on ethics. Hence, researchers should rely on accuracy and truthfulness of data, and should avoid hedging and presumption.

HOW TO CHOOSE STATISTICAL TESTS?

Dr Shekhar Neema

Introduction

Statistical tests are the heart of research and choosing the right statistical tests is of paramount importance for the validity of the result. Poor choice of statistical tests can lead to wrong conclusion. The type of statistical test should be chosen at the time of study planning and can be modified after data collection, if required. We will discuss how to choose a statistical test, but before that we need to know certain definitions and assumptions.

Definitions

1. **Population:** The population is the entire group from which sample is derived and the conclusion of the study is applicable to this population.
2. **Sample:** It is the group from which data is derived. For a statistical test to be valid, sample should be representative of the population and should be large enough to represent the population.
3. **Statistic and parameter:** Statistic is a measure that is observed in the sample while parameter is observed in the population. From a given statistic, population parameter is calculated.
4. **Null hypothesis:** It assumes that there is no difference between two groups. In an experimental study, null hypothesis is assumed and rejection of null hypothesis is taken as proof of difference between groups.
5. **Data and variable:** Variable is defined as an attribute of the sample (eg. Blood pressure is a variable). Data is a specific measurement of variable (recording blood pressure in every patient from a sample is data).

After data is collected, data can be presented as descriptive statistics which describes the dataset like frequency of a particular event or inferential statistics which tests a hypothesis or estimates the population parameter.

The choice of statistical tests depends on

a. **Type of variable:** The variable can be quantitative or categorical.

   Quantitative data: It can be measured or counted (eg. blood pressure, weight, height, number of patients of a specific disease). The quantitative data can be discrete or continuous. A discrete variable can be counted but the value can not be less than 1 while continuous variable can be in fraction too.

   Categorical data: It represents grouping (category). It can be binary, nominal or ordinal. Binary groups can be gender, yes, no and so on. Nominal data is when there is no order or rank between the groups (eg blood groups).

Ordinal data is when data can be arranged in a specific order or rank. (eg visual analog scale – pain of 4 is more than 2) Most scales used in dermatology like VASI, SASAD, Hurley staging are ordinal data. Sometime the scale can be considered quantitative when the data is numeric and is continuous. A common example is psoriasis area and severity index (PASI).

b. **Number of groups:** A statistical test also depends on the number of groups. These variables are also known as independent or predictor variables and dependent or outcome variables. Independent variables are those which we manipulate to see the outcome. Dependent variable is the outcome. (For a study on effect of a drug on re-pigmentation in vitiligo; the drug is an independent or predictor variable, while percentage re-pigmentation is the outcome or dependent variable). Control variables are those which we like to keep constant to see the effect of dependent variable on outcome.

Statistical tests (inferential statistics) are performed to find the relationship between dependent and independent variables. The tests can be used for comparison, correlation or regression.

1. Comparison: These tests assesses the difference between outcomes in two groups. Example: Difference between means (t test) or difference between proportions
2. Correlation: It assesses the association between quantitative continuous variables without commenting on cause and effect. Example: **Pearson 'r'** whether higher BMI is associated with severe psoriasis? It also talks about the strength of this association.
3. Regression: It assesses the cause and effect relationship between variables.
   Example: Simple or multiple linear regression.

The performance of statistical tests requires certain assumptions. These assumptions must be met for statistical tests to be valid.

1. Sample size large enough to represent a population
2. Variance of each group should be similar
3. Normal distribution: The data should follow normal distribution and should fit into bell shaped curve.

Parametric tests can be applied when these assumptions are met. Parametric tests are more rigorous, and their results

are more generalisable. If the assumption of homogeneity or normality is not met, non-parametric tests should be used. In case, sample is heterogenous or sample size is small, it is better to use non-parametric tests.

The parametric tests used in inferential statistics can be chosen as follows:

1. Dependent and independent variables are categorical – **Chi-square test**
2. Independent variable is categorical, dependent variables is quantitative – **comparison of mean**
    a. Two different groups – **Unpaired t test**
    b. Two data from same sample (before and after intervention) – **Paired t test**
    c. More than 2 groups – **Analysis of variance (ANOVA)**
3. Independent and dependent variables are quantitative continuous data – **Simple regression** (one independent variable) or **multiple regression** (more than one independent variable). **The Pearson's r (correlation)** can also be performed on this type of data.
4. Independent variable is continuous but dependent is binary categorical– **Logistic regression**

The **non-parametric tests** are performed when the above discussed assumptions about the data are not met.

1. Independent and dependent variables are categorical – **Chi-square or Fisher's exact test**
2. Independent and dependent variables are continuous – **Spearman r (like Pearson r)**
3. Independent variable is categorical, dependent variable is quantitative – **same as t test**

    Groups from different population – **Wilcoxon rank sum test** (like independent t test)

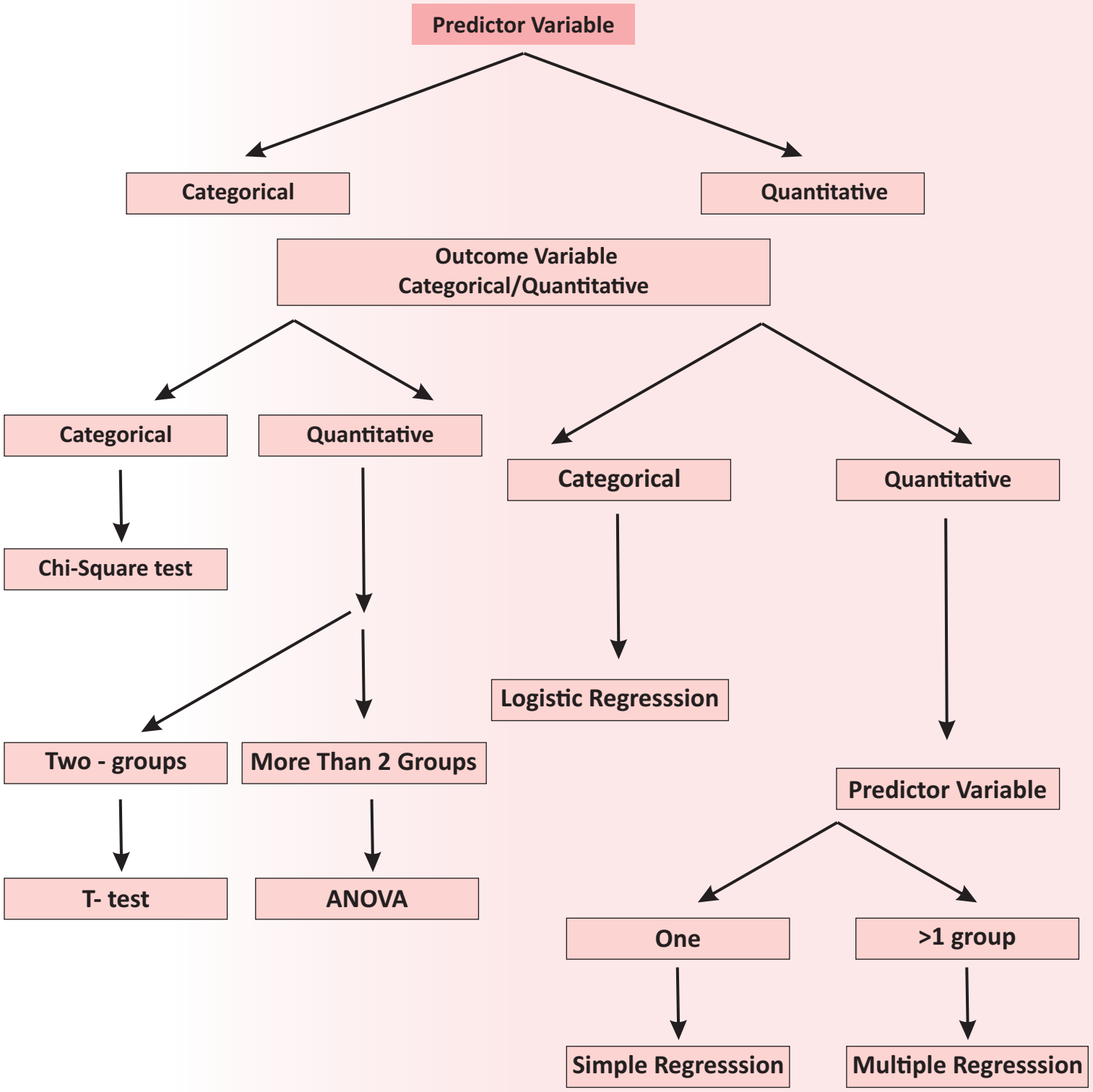
    Groups from same population – **Wilcoxon signed rank test** (paired t test)

    Three or more groups – **Kruskal Wallis test** (same as ANOVA)

The flow chart for statistical test is given below. The corresponding non-parametric tests can be applied in case the data does not meet the assumptions for parametric tests.

Conclusion

The understanding of various statistical terms and choice of correct statistical test a very important step in analysing the data. Wrong choice of statistical test may lead to wrong conclusions from the study followed by rejection of the manuscript by the journal.



Suggested reading:

1. Kim N, Fischer AH, Dyring-Andersen B, Rosner B, Okoye GA. Research techniques made simple: Choosing appropriate statistical methods for clinical research. Journal of Investigative Dermatology. 2017 Oct 1;137(10):e173-8.
2. Ranganathan P. An Introduction to Statistics: Choosing the Correct Statistical Test. Indian Journal of Critical Care Medicine: Peer-reviewed, Official Publication of Indian Society of Critical Care Medicine. 2021 May;25(Suppl 2):S184.
3. Beath A, Jones MP. Guided by the research design: choosing the right statistical test. The Medical journal of Australia. 2018 Mar 5;208(4):163-5.

CHOOSING A RESEARCH QUESTION: HOW TO GO AHEAD?

Kingshuk Chatterjee
MBBS, DNB (DVL), MNAMS, IFAAD, FAGE, FRCP (Edinburgh), FRCP (Glasgow)

Prologue: In simple words, research can be defined as a scientific and systematic method of looking for new knowledge. Unfortunately, when it comes to modern medicine, especially dermatology, things become a little complicated. While our understanding about the different facets of dermatological disorders have grown by leaps and bounds in last few decades, large parts of the therapeutic modalities are still based upon unproven dogma. Here comes the importance of Evidence Based Medicine (EBM) to eliminate eminence based guidelines from the decision-making spectra of all the stakeholders namely the patient, the dermatologist, the governing bodies and the Pharmaceutical industry.

What counts as Research? While simple observation of patients and their diseases (Case Reports, Case Series and Cross-Sectional Studies)) has been kept out of the ambit of research, they play a critical source of data and hypothesis generation. While hypothesis about the best form of treatment are usually tested with Randomized Clinical Trials (RCT's), observational and qualitative methods may be employed to test other type of hypothesis. Few research questions may not require generation of new data but can be answered by analysing or combining data in a different way. This approach forms the basis of Meta-analysis and Systematic Reviews.

Why to do a Research?

Purist Reasons	Pragmatic Reasons
Generating a new Hypothesis	Recognition among Peers
Testing a Hypothesis	Publish and Present
Generating credible and valid data	Professional Promotions
Establishing Superiority or Non-Inferiority of a new diagnostic or therapeutic modality	Generating credibility before application of Research Grants
Establishing the safety and efficacy of a new therapeutic modality	Generating credibility of being included in policy making committees of Government or prominent organizations
Establishing the sensitivity and specificity of a new investigation	

Why to develop a Research Question?

A research question forms the foundation of a research. It outlines the perceived knowledge deficit within a subject area or field of study. This, a research question can make or break a study. A poorly scripted research question adversely affects the study design, leading to futile conclusions, devoid of clinical significance, hampering the potential for publication. A clinically relevant and answerable research question helps to conduct a appropriately designed study to generate credible and valid data from the particular population of interest.

What is a Research Question?

A research question can be defined as an Uncertainty (Data Needs) in the population that the investigator wants to resolve by making measurements in the study population. A clearly framed research question is crucial to decide the most optimal design for the study as well as the selection criteria, definition of outcomes and the ideal time for outcome measurement. Thus, a research question is actually a focussed and succinct version of a general uncertainty about a health issue. Therefore, a research question:

1. Frames problem in specific clinical terms
2. Focusses on one issue at a time
3. Is written in clear everyday language
4. Should link the potential action, to be taken if the question is answered
5. Is started as a question!

Characteristics of a Good Research Question:
A research question should pass the "So What?" test. The ideal characteristics have been described in form of the **FINER** criteria:

F	Feasible	• Adequate number of subjects • Adequate technical expertise • Affordable in time and money • Manageable in scope
I	Interesting	• Getting the answer intrigues investigator, peers and community
N	Novel	• Confirms, refutes or extends previous findings
E	Ethical	• Amenable to a study that institutional review board will approve
R	Relevant	• To scientific knowledge • To clinical and health policy • To future research

While they appear ideal in black and blue, unfortunately they are contradictory and highly subjective in real world. What is feasible may not be interesting or novel and vice versa and an ethical question may not be relevant and novel and so on. So a more practical approach is known as the PICOT format:

P	Population (patients)	• What specific patient population are you interested in?
I	Intervention (for intervention studies only)	• What is your investigational intervention?
C	Comparison group	• What is the main alternative to compare with the intervention?
O	Outcome of interest	• What do you intend to accomplish, measure, improve or affect?
T	Time	• What is the appropriate follow-up time to assess outcome

The more precise and well defined the above parameters be, the higher the chances of developing a research question in accordance to the FINER criteria. The primary research question should be driven by a hypothesis rather than the data. This can be interpreted in the form that the research question and hypothesis must be developed before the start of the study.

How to generate the idea?

Emerging on the edges of Specialization, after traversing through 14-15 subjects of MBBS course, forms a crucial juncture in a Doctor's life. While doing a thesis is purported to introduce a young resident into the world of research methodology, the sudden transition of a student to scholar might come with inherent difficulties. By the time a resident gets the idea of ideal research, he/she is facing the guide, Institutional ethics committee, the University with the trap of timelines! This makes a basic orientation of Research Methodology imperative for every Doctor in making, preferably at an early stage of his/ her career. The knowledge is equal if not more important than the clinical/ surgical acumen as it helps us to identify useful and relevant informations and organize and interpret them in a meaningful way. So if we tabulate the major sources of scientific informations available, they provide a pool of ideas to formulate a research question:

1. Scholarly but not overtly critical review of work of others in the area of interest (Published Articles/ Dissertations/ Conference Proceedings/ Books)
2. Attending Research Meetings and Conferences
3. Sceptical attitude about prevailing beliefs
4. Innovation (New Technologies to old issues)
5. Keeping a roaming imagination
6. Networking with Mentors/ Peers

How to transform an idea in a research question?

It is important to know "where the boundary between current knowledge and ignorance lies." The challenge in developing an appropriate research question is in determining which clinical uncertainties could or should be studied

and alsorationalizing the need for their investigation. Some useful steps to conceive a research question are:

1. Review of available information
2. Identify the knowledge gap
3. Raise a question
4. Decide worth of investigation by a peer review
5. Define measurable exposures and outcomes
6. Sharpen the initial question
7. Fortify the question by specifying details

Broad scopes of a Research Question:

A. Descriptive questions:
   1. Involve observations to measure quantity
   2. No comparison groups/ intervention

B. Analytical questions:
   1. Involves comparisons/ interventions to test a hypothesis

Example of a good Research Question:

1. Broad Idea: Is Apremilast useful in Psoriasis?
2. Review of available information: Mechanism of action of Apremilast, How Apremilast interferes in pathogenesis of psoriasis
3. Identify the knowledge gap: Efficacy and long-term safety of Apremilast in Psoriasis
4. Raise a question: Is Apremilast a safe and effective treatment option in Psoriasis? [Rather vague; need to define "Apremilast" and "Psoriasis"
5. Decide the worth of investigation by peer review: What is the need for a new drug in Psoriasis? What is the level of improvement in Psoriasis in terms of PASI or other objective assessment methods? What is the optimal dosage, form and duration of treatment for Apremilast? What are the risks? What are other benefits?
6. Define measurable exposures and outcomes:
   a. Exposure: Limited Psoriasis involving <20% BSA; could be in young adults
   b. Outcome: Psoriasis Area and Severity Index (PASI)
7. Sharpen the initial question: Does Apremilast help to improve PASI in young adults suffering from Limited Psoriasis?
8. Fortify the question by specifying details: Study population, Operational definition of variables and study design
   We wish to know whether Apremilast in form of oral tablet, in a dose of 30 mg twice daily for 6 months is a safe and effective treatment for Limited Psoriasis in young adults? [Analytical Question]

So the final Research Topic can be: Efficacy and safety of Oral Apremilast in Limited Psoriasis in young adults: A Randomized, Triple blind, Placebo Controlled Trial

Take Home Points:

A. A good Research question is always:

1. **S**tated in Advance (A Priori): Written at outset; focussed on the primary objective
2. **S**pecific: No ambiguity about study participants/ variables
3. **S**imple: Single exposure and outcome

B. Development of a research question is the fundamental aspect of a research project

C. Critical appraisal of research question used in a study is vital to the application of findings in clinical practice

D. Focussed resources, time, in depth understanding and dedication to these crucial aspects will help to formulate a good research question

Conclusion: A well framed, novel research question is the linchpin for a credible research. Time and effort dedicated to generate and frame an appropriate research question will always ensure a timely completion of the research work and generation of conclusive evidences.

Further Reading:

1. Wyatt J, Guly H. Identifying the research question and planning the project. Emerg Med J 2002; 19: 318–321.

2. Farrugia P, Petrisor BA, Farrokhyar F, Bhandari M. Research questions, hypotheses and objectives. Can J Surg 2010; 53: 278-281.

LEARNING ON THE WAY

Dr. Sarita Sasidharanpillai

I am someone trying to learn research on the way. I receive rejections of my manuscripts. I am just sharing my thoughts that are formed by my experiences of past 15 years or so. If it could be of some use to residents and fellow dermatologists, I would be very happy.

Why should I do research and publish it?

Apart from all the obvious reasons including for getting my degree, getting a promotion and to earn the respect of peer group, this is one way to serve humanity. Considering ourselves to be the fortunate ones, who got a chance to work in the fields of our choice, we owe this to the society. One argument against going for materialistic gains in life is that we would never be able to take it with us when we say the final good bye. But this becomes the beauty of doing authentic research and publishing 'We won't be able to take it with us when we leave... It will remain here for ever!' It is a way to reach across time and space to future generations!

What is my area of interest?

You don't have to go in search of it. It will come to you, provided you are sincere in your outpatient and inpatient work. See your patients, write their case sheets carefully, document the progress, follow up the histopathology slides and try to understand the journey of the disease. Listen to your patients, they would tell you much more than any textbook can tell you, but of course, in their words. Try to understand what they are conveying, translate it into scientific language in your mind and you will find there are so many unanswered questions in medical literature. Your patients will guide you; they are your greatest teachers. Serve them with respect and gratitude.

I have a topic in my mind. How should I go forward?

A. Literature search-

1. To know the parameters to be measured so that you don't miss to evaluate what is carried out by all others – Recent articles
2. To find out the gaps in existing knowledge- Read up all the available data on the topic, from beginning till the most recent ones to identify the threads that were never followed up.....and go for them!
3. Unless you don't have a thorough knowledge in the field, you won't identify a hitherto unreported manifestation when it presents to you, or vice versa, a finding perceived as novel by you might have been already known to every one else
4. Please keep yourself upto date in the field; if you feel a recently reported finding is of significance and needs to be

assessed in your patients, you can always get a permission for modification of protocol and incorporate that too in your methodology.

5. To get an idea on how to word your manuscript - the art of writing

B. Involve a statistician- From the stage of designing the study

Statistics is much more than Chi-square test and P value. An expert in statistics, will help you to choose the study design and determine the sample size. They are not the experts in the topic you choose to study. But they are, in the analysis of data. Sit with them, talk to them about what you are trying to do. Make sure both of you are talking about the same thing. They will help you to formulate your objectives and fine tune your methods. Give them the respect and credit that are due to them. Let them be the co-authors and let them know it from the planning stage. They deserve more than a mention in the acknowledgement section.

If the study warrants data collection from other department(s), please make sure you have co-investigator(s) from the concerned departments. They too should be included in the discussion from the planning stage. Any difference of opinion could be discussed and sorted out at the planning stage itself. The role and responsibility of each investigator should be clearly delineated, should be known and should be acceptable to all before the first patient is recruited. If possible, try to have a person sharing an interest in the topic as the co-investigator.

C. Writing up the protocol:

Read thoroughly - all studies in the past 2 to 3 years. As mentioned, this is to understand the parameters that you need to assess and include. If not, towards the end of the study, you may realize that an important parameter, that was evaluated by all your predecessors was not assessed by you. So it will end up as a work inferior to all the previous studies. Please avoid that. Get the protocol reviewed by your co-investigators and your seniors. Those who walked before you would be able to direct you. Please try to learn from their mistakes. Please look for criticism. And modify the protocol whenever needed. Because it would help to avoid many difficulties in the execution stage. Always define any sub-classification used in protocol. If you categorise the study participants into those having mild, moderate and severe disease, please specify - ie, define severe, moderate and mild disease (eg. Those with systemic involvement - severe disease, those with constitutional symptoms, but without systemic involvement- moderate disease, those with cutaneous manifestations alone - mild disease). Similarly if you want to say mild, moderate and severe inflammation in histopathology specimen, define that also (eg. severe inflammation- inflammatory infiltrate occupying more than 20% of dermis, mild inflammation- inflammatory infiltrate occupying less than 5% of dermis).

Carefully prepare the proforma for data collection. It is the most important tool in a study. Please start with consent of study participant, identifiers, clinical history and then proceed to general examination and clinical examination findings.

This is to be followed by the details of required investigations.

D. Getting relevant approvals

Get approval from research and ethics committees of the institution. Also make modifications as advised by the research and ethics committees. If any intervention is involved, make sure to register with clinical trial registry, which is mandatory for publication.

E. Patient evaluation:

Please be methodical. Please ensure you get written informed signed consent from your patients, including consent for clinical images. Always remember that consent is required not only for publishing, but also for capturing a clinical image. And consent for capturing an image is not enough for publishing the same. Please inform the patient that though all efforts would be taken to conceal the identity during publication , this can not be guaranteed. Clearly convey to the patient that he has all the right to refuse and it would in no way affect the treatment or care received by him. Never ever use a patient's image without appropriate consent.

Carefully evaluate the patients and document the findings. Never tamper with the data. If you are seeing features not yet described, or getting values that are different from those already reported, don't get upset! Please verify whether the evaluation parameters adopted by you are correct and whether the readings are taken correctly. Please double check whether your study participants are chosen correctly. Get the opinion of your seniors. If you erred somewhere, make the corrections. If not, proceed as before. Document the features as you see them. Many a times, we rely on data derived from another population, which may not be the same in our population. You could be the first to bring it to the attention of medical fraternity. Never miss that chance by tampering with your data.

F. Statistical analysis:

Sit with the expert in statistics and analyse the data. Discuss again and make sure no communication gaps exist between the clinician and the statistics expert that can adversely affect the outcome of the study. Please ensure that both of you are looking for the same thing.

G. Writing up

1.Introduction: Keep it to about 200 to 300 words. Start with the definition of the condition you have studied. Just add a couple of sentences on what is known about it. When was it described for the first time. What is the current status of knowledge on it ? Why did you think of studying it ? - Could be because there is not much information on the condition from the country. Or could be because certain aspect like histopathology or dermoscopy is not well studied yet. Or some hitherto unreported features you were observing in your patients over a period of time have prompted you to take this up.

2.Materials and Methods: Please make sure that you have explicitly stated about receiving approval of institutional ethics committee, receiving written informed consent from individual study participant (both cases and controls in a comparative study) and have mentioned the clinical trial registry number if the study is interventional. Every editor looks for these in methods section. Define your study population (whether you have included consecutive patients or not), mention the setting of your study and the study period (eg. We included consecutive patients aged above 18 years who attended the dermatology outpatient department of a tertiary care centre from January 2018 to December 2019 and who received a clinical diagnosis of vitiligo vulgaris). This should be followed by exclusion criteria. Exclusion criteria refers to patients who satisfied the inclusion criteria and then excluded from the study. In the mentioned study on patients aged above 18 years, age below 18 is not an exclusion criteria since they were already excluded by the inclusion criteria. Patients who were receiving systemic or topical therapy for vitiligo in the past three months could be the exclusion criteria. If the study included a control group, specify whether they were age and gender matched and from where they were recruited (eg. We recruited age and gender matched, healthy controls from the bystanders accompanying the patients attending the dermatology outpatient clinic during the study period).

Please elaborate on randomisation (how it was done) if that was part of the study design. A properly prepared protocol can help to avoid the confusion in writing up this section of the manuscript. Please make sure that you have defined all the sub-classifications in the manuscript, as already mentioned, so that the methodology becomes replicable in another setting.

As last paragraph of this section, mention the soft ware (eg. Data were entered in Microsoft excel sheet and analysed with SPSS version 18) and the statistical methods used.

3. Results: Start by describing your study participants - Age and gender distribution, other demography details, any co-morbidities noted in study participants. Then start describing about the condition studied- Clinical features, investigation results. In results, only state what you saw. The explanation can be there in the discussion part.

4. Discussion: Please don't restate results here. Discussion deals with the comparison between your observations and what is known in literature. If your result section stated that 'Study participants included 35 males and 14 females with male to female ratio of 2.5:1', the discussion may say 'The male predilection documented by us was comparable to previous Indian studies, but was higher than the same noted in foreign literature.' Similarly you write the essence of each important data in the result and compare with available literature. Also you can give an explanation (if you are able to find one) for any particular feature noted. For eg. 'More than 40% of patients manifesting severe disease as observed in the study could be a reflection of the patient profile seeking treatment in a tertiary care center.' If you cannot think of a reason for any disparity noted, may just state that '……. noted by us was discordant to most of the previous studies and the

reason for the disparity remains unclear.' Even an unexplained disparity is a contribution to literature and can form the basis of a future study by someone else or yourself....

5. Limitations: Please state the limitations and don't worry about the limitations. They don't belittle your study. In fact, identifying the limitations increases the value of the paper. A study based in a referral centre itself is a limitation, since most likely it has collected information on severe cases alone. Retrospective study design is a limitation since it is based on the information documented by several clinicians at different time periods.

6. Conclusion: Please ensure that the conclusion does not go beyond the results. Speculation can not be a conclusion. If the study on dermatology life quality index (DLQI) showed that DLQI is adversely affected in patients with psoriasis, please don't conclude that 'A proper psychological support can improve the DLQI in patients with psoriasis' since the study did not assess DLQI in patients with psoriasis before and after psychological intervention.

7. References. Write your references properly. Include references for all scientific statements.

H. Choosing the journal

While choosing the journal to submit your work, never go for the journals that offer quick and easy reviews or accept without modification. Always remember, your work is going to be your legacy. Let it be scrutinised thoroughly so that only its best version gets published.

Once you decide the journal, go through their guidelines carefully and stick to them. Please prepare your manuscript adopting the subheadings suggested by them. While writing your manuscript, please use short and simple sentences and avoid lengthy complicated ones.

Please write your references as per the particular journal's format. If it is three authors followed by et al, stick to that. If they require six authors followed by et al, prepare like that. Please use expansions for short forms when they appear for the first time in text.

Short forms when used in tables should be expanded in foot note. Please do write descriptive legends for tables and figures.

Eg. Instead of 'Figure 1: showing skin lesions of Darier disease', may write Figure 1: showing dirty warty papules on the chest and neck of a patient with Darier disease.'

All these show the editor that the manuscript is prepared carefully. This may give the impression that the paper is prepared by some one who plays by the rule.

A very good writing cannot save a poorly conducted work. A very well conducted study, even if poorly written, can be acceptable after a few revisions, since every editor looks forward to a great article and would be proud to have one in his journal. However, a very good writing plays a major role in the decision received by a mediocre work. And most of the studies usually fall into this category.

QUIZ

Dr Rahul Mahajan

1) Which of the following is incorrect ?

A. Cross-sectional study does not establish causality.

B. Descriptive studies assume no hypothesis.

C. Analytical cross-sectional studies tends to establish association between two parameters

D. Direction of association can be established in analytical cross-sectional studies.

2) Any systematic error in the design, conduct, or analysis of a study that results in a mistaken estimate of an exposure's effect on the risk of disease is called:

A. Confounding

B. Bias

C. Interaction

D. Stratification

3) The purpose of a double-blind or double-masked study is to:

A. Achieve comparability of treated and untreated subjects

B. Reduce the effects of sampling variation

C. Avoid observer and subject bias

D. Avoid observer bias and sampling variation

4) Randomization of study subjects in a clinical trial is most helpful for controlling for which of the following?

A. Placebo effect

B. Recall bias

C. Non-compliance

D. Effect modification (interaction)

E. Confounding

5) In an experimental design, the dependent variable is:

A. The one that is not manipulated and in which any changes are observed
B. The one that is manipulated in order to observe any effects on the other
C. A measure of the extent to which personal values affect research
D. An ambiguous concept whose meaning depends on how it is defined

6) Panel and cohort designs differ, in that:

A. Cohort studies involve quantitative research, whereas panel studies are qualitative
B. A panel study does not need rules to handle new entrants to households
C. Only a cohort study will suffer from sample attrition
D. A panel study can distinguish between age effects and cohort effects, but a cohort design can only detect ageing effects

7) Which of the following studies is considered a gold standard for analytical epidemiology?

A. Ecologic study
B. Cross-sectional study
C. Case-control study
D. Cohort study
E. RCT

8) An open label randomized controlled trial means:

A. Everyone participating in the trial is aware of assigned treatment
B. Patients are ignorant of assigned treatment
C. Investigators are ignorant of assigned treatment
D. Patients, investigators and data evaluators are ignorant of assigned treatment

9) Which of the followings is used to know the cut-off values of a diagnostic accuracy test (disease positive versus disease negative):

A. Positive predictive value
B. Negative predictive value
C. Likelihood ratio
D. Receiver operating characteristic

10) Method used for comparison of a new test with an available gold-standard test is:

A. Regression analysis/Likelihood test
B. Correlation analysis/Bland and Altmann test
C. Baltin and Altimore method
D. Kimorov and Samletor technique

11) If a study is "reliable", this means that:

A. It was conducted by a reputable researcher who can be trusted
B. The measures devised for concepts are stable on different occasions
C. The findings can be generalized to other social settings
D. The methods are stated clearly enough for the research to be replicated

Answers- 1-d, 2-b, 3-c, 4-e, 5-a, 6-d,7-d, 8-a, 9-d, 10-b, 11-b.

INFORMED PATIENT CONSENT FOR RESEARCH AND PUBLICATION WHY DOES IT MATTER?

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Introduction

"Informed Consent" arose as an ethical issue in medical research after outrage at the atrocities committed by the notorious "Nazi Doctors" under Hitler's regime.[1] According to Declaration of Helsinki, in medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing.[2]

Why informed consent is important for research?

In studies involving human participants, written informed consent is important for the following reasons[3]:

- These documents serve as a permanent record of details that the participant may wish to know even after they have consented to taking part in the study (e.g., whom to contact if they want to withdraw).
- The information in such documents is more detailed (e.g., telephone and fax numbers) and cannot be effectively conveyed through a conversation with the participant.
- Ethics committees or institutional review boards may not have the resources to monitor the conversations in which consent is sought from the participants. Therefore, written informed consent is often essential for the study to obtain ethical approval from such bodies.
- Informed consent forms can serve as legal documents and can be used as evidence (by either party) in the case of a lawsuit related to the study.
- If participants are made aware of the fact that the researcher is following appropriate ethical practices, they are more likely to trust the researcher, which can lead to long-term benefits. "To put it simply, if we cannot guarantee sound research in general and patients' safety in particular public support for gene therapy and other potentially lifesaving treatments will evaporate. Volunteers will not show up." [4]

- Those who want to use the data for the participants later (e.g., for a follow-up study) could use these documents to obtain the contact details of the participants.
- Failure to obtain informed consent at the beginning of your study can be very costly. For instance, in one case in the US, over 5 million blood samples had to be destroyed because prior informed consent had not been taken.[5]

Why informed consent is important for publication?

According to uniform requirements for manuscripts submitted to biomedical journals, patients have a right to privacy that should not be violated without informed consent. Identifying information, including names, initials, or hospital numbers, should not be published in written descriptions, photographs, or pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that an identifiable patient be shown the manuscript to be published. [6]Moreover, many reputed journals consider failure to obtain informed consent sufficient grounds for rejecting a manuscript. For instance, the American Journal of Psychiatry states, in its guidelines for authors: "If your submission does not contain written informed consent or Institutional Review Board approval, it will not be reviewed."[7] Other journals like the Journal of the American Medical Association require that the methods section of a paper mentions the formal review and approval/waiver by an appropriate institutional review board or ethics committee.[8]Obtaining and reporting informed consent are essential for your research and manuscript respectively. Doing so establishes your credibility as a scientist and writer. At present, journal editors "will not publish a manuscript, however scientifically or educationally worthy, when anonymity cannot be absolutely guaranteed or informed written consent has not been obtained."[9]The BMJ policy has long been that consent should be obtained in all case reports unless the patient and family are untraceable and the case has been anonymised to such a degree that neither the patient nor anyone else could identify them with certainty.[10]The Journal of Medical Ethics policy on patient consent for case reports is that consent from the patient or from surrogates (for incompetent patients) should be sought for case reports published. Case reports may be published in the absence of patient consent in the following circumstances:

- Cases in the public domain, where all details have previously been published
- Cases where it is not possible to seek consent (patient and family deceased or uncontactable)
- Cases where it is not appropriate to seek consent (eg. would harm the patient)

In the later two situations, authors are expected to make a case to the editors that they have anonymised or modified the case sufficiently to minimise or remove risk of harm to the patient. Second, they need to demonstrate that there is a sufficient public interest to outweigh any possible harm.[11]

According to the British Medical Journal Ethics Committee[12]

- Publication of any personal information about a patient will normally require the consent of the patient. This will be so even if identifying details are removed.
- Personal information about a patient will not be published over the patient's refusal, except in the most exceptional circumstance of over-riding importance to public health.
- Publication without the consent of the patient will be permitted if all of the following conditions are met:

a. The patient who is the focus of the article is untraceable without an unduly burdensome effort and it is also impossible or unreasonable to expect consent to be obtained from the patient or the patient's next of kin.

b. The article contains a worthwhile clinical lesson or public health point which could not be as effectively made in any other way. (Worthwhile is intended to sit on a spectrum between "interesting," which is the publication threshold with patient consent, and "over-riding public health importance," which is the publication threshold over patient refusal.)

c. A reasonable person in the patient's position would not be expected to object to the publication of the case. (This requires an assessment of the intrusiveness of the disclosure and the potential that it has for causing the patient, or the patient's family, embarrassment or distress. Particular attention must be paid to differences of cultural and social attitudes. It must not be assumed that what is a matter of indifference in one society will have the same status in another.)

d. The risk of identification of the patient is minimised by measures designed to prevent the identity of the patient being revealed either to others or to the patient himself or herself. These measures will include anonymisation of the case or the author, or both.[12]

Audiovisual presentation of information for consent

Use of pre-recorded audiovisual information about clinical intervention presented to the patient to facilitate informed consent process is known to increase the knowledge and willingness of the subject to participate in clinical trials.[13]

Audiovisual recording of consent process

Audiovisual recording of consent may be mandatory in clinical trials, for interventions involving some risk, and major dermatologic surgeries. The subject's willingness to agree for the consent process to be taped must be recorded as a separate line on the consent form.[14]The subject is given both verbal and written information regarding audiovisual recording of consent. Patient has the right to withdraw the consent for recording at any time before, during, or after recording. Non participation in recording shall not affect the treatment offered. If the patient withdraws the consent for audiovisual recording after the recording, the recording should be erased, and patient informed accordingly in writing.

Informed consent for photography

The publication without consent of photographs will require particularly scrupulous attention to anonymisation. Concealing the eyes of the subject is often considered inadequate to conceal the identity of a subject. Make sure that you have a signed informed consent that specifically mentions the possible use of image for publication. Consent is essential where facial identity cannot be masked. However, it is prudent to have explicit consent for photography in all cases.[15]

Informed consent in special scenarios

A parent can give consent in case of children less than 18 years. Legally acceptable representative (LAR) can give consent in incapacitated persons and in those with neuropsychiatric conditions.[16]There are many challenges to obtaining informed consent among children in orphanages and other vulnerable children. A LAR or foster parent or head of the institute which cares for the child in that order may be able to give consent when the minor decides to participate (informed assent).[16]

Documentation and storage

The informed consent form should be dated and signed by the patient or LAR, the researcher, and an independent witness. An independent or impartial witness is a person who is independent of the study, and who cannot be unduly influenced by the staff involved in the trial. Usually the next patient or their relative can be an impartial witness. A copy of informed consent should be handed over to the patient, and the original copy should be preserved by the researcher with the study documents for at least 3 yeras.[17]Audiovisual recordings made for research purposes are a part of medical records. Hard copies of records should be stored in a locked area. In ensuring safe storage of documents and recordings, institutional policies and guidelines should be adhered to.

Conclusion

Informed consent must be viewed as a continuous dynamic process during the research. Knowledge gained by the participant has great effect on their compliance and retention in the study. It builds communication channels with research participants. An informed consent process with emphasis on patient comprehension is a step towards improving the quality of clinical research. A well-informed patient is the foundation of a well-informed consent.

References

1. Pedroni, J. A., & Pimple, K. D. (2001). A Brief Introduction to Informed Consent in Research with Human Subjects. Available at http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.92.6284&rep=rep...
2. 59th WMA General Assembly, Seoul. (2008). World Medical Association
3. Declaration Of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. Available at http://www.wma.net/en/30publications/10policies/b3/17c.pdf
4. Resnik, D. B. (2009). Do informed consent documents matter? Contemporary Clinical Trials, 30(2). 114–114. doi: 10.1016/j.cct.2008.10.004. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2670580/

5. Shalala, D. (2000). Protecting research subjects—what must be done. New England Journal of Medicine, 343(11) 808–810.
6. Akst, J. (2009). Consent issues nix blood samples. The Scientist. Available at http://www.the-scientist.com/?articles.view/articleNo/27876/title/Consent-issues-nix-blood-samples/
7. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Privacy and Confidentiality. Available at http://www.icmje.org/recommendations/browse/roles-and-responsibilities/protection-of-research-participants.html
8. The American Journal of Psychiatry. Guidelines For Authors On Preparing Manuscripts. Available at http://ajp.psychiatryonline.org/ajp_ifora.aspx
9. Journal of the American Medical Association. Instructions for Authors. Available at http://jama.jamanetwork.com/public/InstructionsForAuthors.aspx
10. Levine, S. B., &Stagno, S. J. (2001). Informed consent for case reports: The ethical dilemma of right to privacy versus pedagogical freedom. Journal of Psychotherapy Practice and Research, 10. 193–201. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3330645/
11. BMJ. Patient consent and confidentiality.https://www.bmj.com/about-bmj/resources-authors/forms-policies-and-checklists/patient-confidentiality
12. Wilkinson D, Savulescu J. A case of consent. Journal of Medical Ethics 2015;41:143-144.
13. Synnot A, Ryan R, Prictor M, Fetherstonhaugh D, Parker B. Audio-visual presentation of information for informed consent for participation in clinical trials. Cochrane Database Syst Rev. 2014 May 9;2014(5):CD003717.
14. Chauhan RC, Purty AJ, Singh N. Consent for audio-video recording of informed consent process in rural South India. Perspect Clin Res. 2015 Jul-Sep;6(3):159-62.
15. Kaliyadan F. Image quality for publication. Indian J Dermatol Venereol Leprol. 2016 Jul-Aug;82(4):367-70.
16. Gupta UC, Kharawala S. Informed consent in psychiatry clinical research: A conceptual review of issues, challenges, and recommendations. Perspect Clin Res. 2012 Jan;3(1):8-15.
17. Rao KH; IADVL Dermatosurgery Task Force. Safer practice of dermatosurgery. Indian J Dermatol Venereol Leprol. 2008 Jan;74 Suppl:S75-7.

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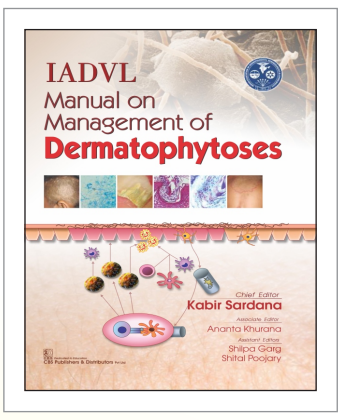

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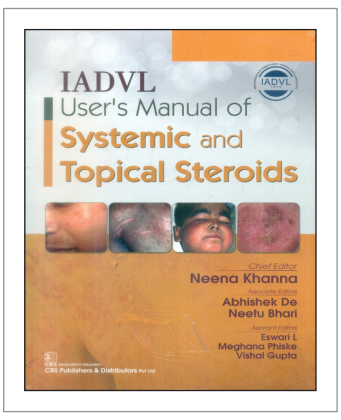

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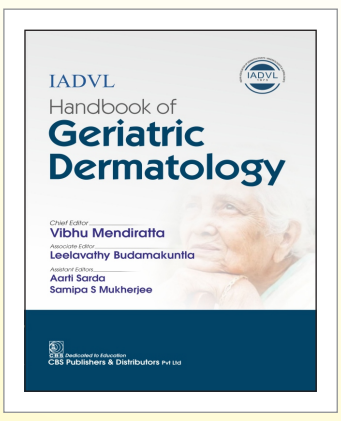

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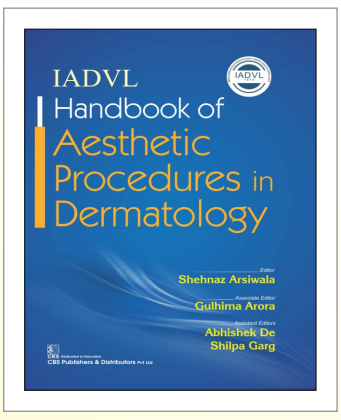

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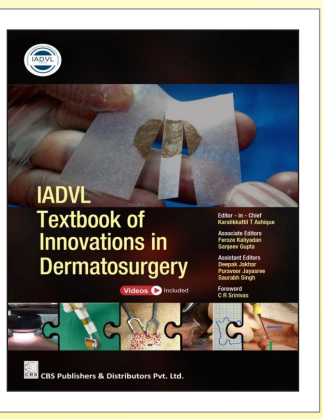

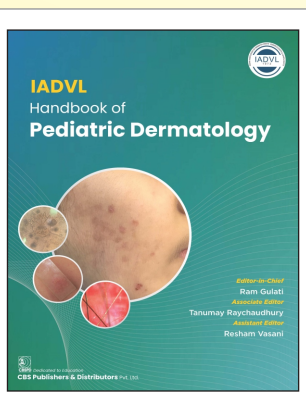

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