Presentation by

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MD,FIMSA,MAMS

“Fundamental Steps of Research Paper Writing and Identify the Research Topic at Particular Field”

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Post-Graduate Department of Pharmacology
Government Medical College, Jammu (J&K)

Editor In Chief
JK Science Journal of Medical Education and Research (EMBASE)
Associate Editor- Journal Midlife Health (MEDLINE/PUBMED)
Why this topic

• Uniform Writing and submission as per university Guidelines

• No rejection on grounds of style

• To Make IEC/IRB Clearance easy

• Every Institute should ask e copy for archives

• But there is no Replacement To Your Guide

Dr Vishal Tandon
University of Jammu Guidelines

- Teacher Student Ratio- 1:1 or in exceptional case 1:2 only in clinical side for eligible Guide. University of Jammu
- 80% minimum attendance of the training period
- >30 days only medical leave
- >90 days registration/admission cancelled
- IEC Clearance necessary
- Board of Studies Clearance mandatory
- No change of subject of thesis/Guide permitted except under following conditions:
  - plan rejected by board
  - work cannot be completed and is beyond the control of candidate
  - when guide leaves the institution for more than six months
• Four copies to reach controller of examinations through principal well before prescribed period

• No paper to be published or presented before declaration of results

• English, white bond paper 22x28cm, with margin of 3.5 cm with matter only on one side of the paper, font size- 12 or 14, New time roman or arial with references as Index medicus.

• No repetition with same university for last 5 years of the subject/thesis

• Co- Guide
The Thesis Evaluation process typically involves the following criteria:

- **Approved**: At least three examiners must approve the thesis.
- **Returned for improvement**: Two or more examiners have suggested improvements.
- **Rejected**: Two examiners have rejected the thesis.

Additionally:

- **Acceptance of thesis is precondition for written or oral examination**

A candidate whose thesis stand approved but fails in examination shall not have to submit fresh work.
Process of Thesis

Research question

Plan of thesis/Research

IEC/IRB Clearance

Review

Decision

Permission Granted

Rejection

Revision

Dr Vishal Tandon
Process of Research

Completion of Research

Writing of Thesis

Submission of Thesis

Review by external examiner

Decision

Rejection

Revision

Resubmission

Acceptance

Publication

Rejection
CLINICAL RESEARCH WITH INDIAN PERSPECTIVE
CLINICAL RESEARCH WITHIN CLINICAL RELEVANCE OR EXISTING TREATMENT GUIDELINES
CLINICAL RESEARCH WITH SHOULD NOT BE ME TOO RESEARCH
Leadership and Team quality
"Listening is just as important as talking"
"Dear contributor",

"Thank you for submitting your paper to our journal."

"To save time, we are enclosing two rejection slips..."

"...one for this paper and one for the next paper you send us!"

PEANUTS reprinted by permission of UFS, Inc.

Courtesy: Dr. Sanghamitra Pati, Director, ICMR-RMRC, Bhubaneswar
Good example of a Brain Study. If you can read this you have a strong mind.

7H15 M3554G3
53RV35 7O PROV3
HOW OUR M1ND5 C4N
DO 4M4Z1NG 7H1NG5!
1MPR3551V3 7H1NG5!
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YOUR M1ND IS
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B3 PROUD! ONLY
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<td>Unsatisfactory illustrations/tables</td>
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N=347, Indian Pediatrics, 2006 (rejection 50%)
Choosing The Journal For Your Valuable Research
Present or Publish First?
When should you choose the Journal? - First step

- As soon as you start writing, choice of the journal should be in the mind.
- This is because each journal has a somewhat different format. Preparing a manuscript with specific format will help you to avoid unnecessary work later.
- For this you must look at the Instructions to the Authors.
Selecting the right journal

- Is your paper within the scope of the journal?
- Introspect - is there a reasonable chance of your paper getting accepted in that journal?
- Scan a copy of the latest issue of the journal
Rule 1. Instructions to authors

- Get the latest instructions to authors
- Download / print them and READ them carefully.
- Follow them
Appropriateness

• Look at back copies of possible journals
• Have they published similar studies in past?
• Scope/ of research specialty
• Look at the references for your paper
Types of Submission

- Full paper (around 2000-3000 words)
- Short report (around 1000-1500 words)
- Case Report
- Letter or case notification
- Review or educational article
- Editorial
- Comment on current affairs
Choosing your Target Audience(s)

- Fellow professionals
- Professionals in other disciplines
- Boss
- Health service managers
- Policy makers
- General public
- Director of Research
- Research funders
- Panel of "Research Assessment Exercise"
- Public Service Commission/Recruitment agencies
Types of journal: Make Choice as per specialty/ or suitability of your Research


- **Multidisciplinary Journals**: JK Science, JK Practitioners, IJMR, IJMS, JAPI, JIMA

- **General professional** e.g. Journal of Advanced Nursing, Pharmaceutical Journal

- **General NHS** e.g. Health Service Journal
Choosing a Journal

Language
Accessibility/Availability
How many libraries subscribe to the journal?
How many individuals subscribe?
Is it Included in Electronic Databases/?
Is the journal indexed in the relevant electronic databases (e.g. Medline, EMBASE or other agencies)?
Is it also Available On-Line?
What's the Journal's Acceptance Rate?
Who's on the Editorial Board
What's the Journal's "Impact Factor"?
How Long has the Journal Existed?
Prestige: Is it Peer Reviewed?
Editorial Office standards
Cost
Publishing and Distribution factors
IMPACT FACTOR

• A marker of journal quality

• Frequency with which the journal’s articles are cited in the scientific literature

• Quantitative tools for ranking, evaluating, categorizing and comparing journals

• Help in academic evaluation.
• The impact factor 2008 for a journal would be calculated as follows
• $A =$ the number of times articles published in 2006-7 were cited in indexed journals during 2008
• $B =$ the number of articles, reviews, proceedings or notes published in 2006-7
• Impact factor 2008 = $A/B$
Impact Factor of Journal Vs Impact Factor of Research

Dr Vishal Tandon
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<th>S.No.</th>
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Dr Vishal Tandon
Web of Science

Trust the difference

What if you could uncover new connections in research with guaranteed quality, impact, and neutrality?
COST

Costs: For some authors, cost is an important factor.

Many journals charge no fees to authors
Submission fee
An acceptance fee
or a per-published page fee
The cost of publishing color figures
Cost of reprints can be an issue
Time

- Time is an increasingly important issue for all authors.

Editorial Board should ensure that submitting authors receive a rapid decision on whether the manuscript is accepted or not.
Quality Research
Ways to check and avoid Predatory Journals

1. DOAJ - http://doaj.org
2. OASPA – http://oaspa.org
3. COPE – http://publicationsethics.org
5. UNCG Libguide - http://uncg.libguides.com/scholarlycomm
6. WAME- http://www.wame.org/policy-statements#Definition PR
11. Centre for Journalology website : www.ohri.ca/journalology
Uniform Requirements for Manuscripts

**Manuscript Preparation**
- Preparing a Manuscript for Submission to Biomedical Journals
- Sending the Manuscript to the Journal

**References**
- Print References Cited in this Document
- Other Sources of Information Related to Biomedical Journals
To

Dr. R. K. Dikshit
Chief Editor, Indian Journal of Pharmacology,
Department of Pharmacology,
B. J. Medical College,
Ahmedabad 380016, India.
Email: ijp@ijp-online.com

Sub: Submission of manuscript as a full length original research article for the favor of publication in esteemed, Indian Journal of Pharmacology.

Respected Sir,

Kindly, find enclosed here with the manuscript entitled “Comparative Study of Sublingual, Vaginal and Oral Misoprostol in Cervical Ripening for First Trimester Abortion” for the favor of publication as a full length original research article in esteemed Indian Journal of Pharmacology.

The same article not has been under consideration anywhere and is not published already in part or whole (except in the form of abstract) in any journal or magazine. The work described in the manuscript is our own and contribution to this work is significant enough to qualify for authorship. No one who has contributed significantly to the work has been denied authorship and those who helped have been duly acknowledged. Our submission is thus to be considered as a consent for publication in case accepted by Journal in any media (print, electronic or any other) and transfer of copyright in the event of its acceptance for publication.

We have no conflict of interest (financial or other) and study is not sponsored by any one.

Thanking you in anticipation.

With sincere regards

Dated: 10.6.5

Yours sincerely

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Near Arya Samaj, Bakshinagar
Jammu-J&K-180001
09419195126
dr_vishaltandon@yahoo.com
How to submit article

• Electronic Submission Most Common Methods these days
• First Page
• Main Article
• Copy right statement
• Pic
• Names and detail of Reviewers
• Submission by Mail
• Some Journal still ask a print copy and cd or pen-drive
Presentation by

DR. VISHAL R. TANDON
MD,FIMSA,MAMS

“Choosing the Research Question
Identify the Research Topic at Particular Field”

ASSOCIATE PROFESSOR
Post-Graduate Department of Pharmacology
Government Medical College, Jammu (J&K)

Editor In Chief
JK Science Journal of Medical Education and Research (EMBASE)
Associate Editor- Journal Midlife Health (MEDLINE/PUBMED)
The research cycle

1. Develop research question
2. Design study
3. Implement study
4. Analyze results
5. Infer conclusions
I keep six honest serving men
They taught me all I know
Their names are What and Why and When and How and Where and Who

Rudyard Kipling, 1903
Conception of Research Idea

The Important thing is not to stop questioning. Never lose a holy Curiosity

“Albert Einstein”

• Necessity is mother of new inventions
• Previous Preclinical / Clinical Research
• As a Casual thought
• Casual Experience
• NCE- Structure activity change
• Old drug for new indication, route, combinations, mechanism etc
• To improve the current treatment practice.
• Existing Diagnostic, Clinical/ Treatment Challenge
• Emerging Controversies/ Debate
• New Emerging Clinical Challenges/ Diseases
• Volume of any specific Clinical Problem in a region
• Lack of any information on Epidemiological volume of Problem
• Any unusual/not known Clinical experience in a patient compels you for research
• Comparison of new vs conventional technique or biochemical test
Reverse Pharmacology
Back to Preclinical/Clinical Research once again

Examples:

NSAIDs
Estrogens/ HRT
Corticosteroids
International / National Clinical Research Thrust Areas

• HIV
• TB
• OSTEOPOROSIS
• RHEUMATOLOGY
• AGING DISEASES
• CANCER
• OTHERS
• Mural / Extra Mural ICMR Thrust Areas
Power of Literature -
Power of Research

- Pen down Research questions
- Interact
- Read More and more Medical Journal
- Electronic reading
- Register free with almost all free electronic Article and issue alert giving Journals
- Develop Electronic Library In your institute
- Power of Literature – in your PC & Mobile
We all know of the benefits fruit juices provide us with. They are tasty and give us abundant energy apart from fulfilling our daily body need of water, vitamins and nutrients.
What the study says:
A research conducted by Britain's Northumbria University, saw adults with insomnia who drank cherry juice concentrate could sleep better. They attribute the sleep benefits to the melatonin content of the red super fruit - a powerful antioxidant critical for sleep-wake cycle regulation, according to a university statement. The cherry juice concentrate was estimated to contain a significant level of melatonin in the juice and ultimately in the bodies of the participants.

Question: Suppose you want to replicate this study in your setting, and you are writing a proposal for funding. Please state the research question.
Some Interesting Research Questions

• What is the scientific name of Cherry?
• Can that cherry juice be added with alcohol?
• How tasty is cherry juice?
• A resident working for continuously 18 hours will cherry juice remove tiredness and exhaustions after having it?
Components of research question

• **PICO**
• P = Population/patients/problem
• I = Intervention
• C = Comparator
• O = Outcome
Components of research question

- **PICO**
- **P** = patients population (specify: age, sex, disease severity .....................)
- **I** = Intervention/exposure (dose, route, duration)
- **C** = Comparator (standard/ control)
- **O** = Outcome (health outcome), patient-oriented outcome
Research question

• In AIIMS residents with insomnia, does consumption of 30 ml of cherry juice concentrate (diluted with 150 ml of water) 30 minutes before evening meal improve sleep quality and duration, as compared to the same volume of warm milk?
What makes a good research question

**F** • Feasible

**I** • Interesting

**N** • Novel

**E** • Ethical

**R** • Relevant

**S** • Scientifically Sound

• Technical expertise
• No. of subjects
• Manageable in scope
• Affordable (time & money)

• Confirms the existing findings
• Extends existing findings
• Provides new findings

• To scientific knowledge
• To clinical and health practice
• To future research
Bioethics

• Principles of essentiality
• Research is necessary for the advancement of knowledge. Should add new Information
• Rationale: Justification of Research Question
• Principles of precaution and risk minimisation
• Principles of the maximisation of the public interest and of distributive justice
• Principles of non-exploitation
• Principles of voluntariness, informed consent and community agreement
• Respect for persons: dignity and rights of each trial participant
• Participants must be free to withdraw at any time
• Confidentiality must be protected
• Compensation
Common problems Faced in clinical trial

• Less number of patient
• Placebo arm not justified-Critical patients
• Selection Bias and difficulty in comparability
• Bias
  Subjective bias
  Observer Bias
  Evaluation Bias
• Negative results-Should not be hided-they are equally important
• Major loss of follow up
• Major drop outs
• Statistical significance vs clinical significance
Study Designs

Did investigator assign intervention?

Yes

Interventional study

Random allocation?

Yes

RCT

No

Non-RCT

No

Observational study

Comparison group?

Yes

Analytical study

Onset of study & Directionality

Cohort study

No

Descriptive study

Cross sectional study

No
Figure 2: Schematic diagram showing temporal direction of three study designs
Study design

• Longitudinal Trials
• Concurrent parallel study design
• Parallel Design With Placebo
• Parallel Evaluation of a combination Treatment
• Multiple dosages parallel trial
• Add on trial
• Cross over type of study design
• Sequential study design
• Intention to treat
IL-1ra play important role in pathogenesis of Asthma and COPD. Diacerine (50mg od) is an interleukin 1 antagonist widely used in the treatment of OA because of its pain relieving and disease modifying effect. However, it has never been tried in for patients of Asthma or COPD Patient.

Draw Protocol for phase 2 randomized placebo control comparative clinical trial to analyze the efficacy and safety of Diacerine in patients of stable COPD and make the CONSORT for same to be submitted for approval from IEC and ICMR for funding and then to conduct research.
Parallel study design With Placebo

120 PATIENTS

GROUP I n=60
Diacerine 50 mg daily+
Inhaled Salbutamol+
Exercise+ Local T/t

GROUP II n=60
Placebo+
Inhaled Salbutamol+
Exercise +Local Joint T/t

Post Drug **Objective Parameters** like lung functions (FEV$_1$ and FVC, FEV, FEF25-75) And **Subjective Parameters** like improvement in respiratory symptoms, QOL & safety (BP, HR, ADR) were assessed and Compared

**PATIENTS OF COPD WITH OA**

**RANDOMISATION**

**STATISTICAL ANALYSIS**

**INCLUSION CRITERIA**
- Patients above 55 years
- Both sexes
- Patients giving consent
- COPD with OA
- Stable COPD
- FEV$_1$ <60%
- FEV$_1$/FVC Ratio <70%
- One Knee Joint Involved with mild to moderate OA

**EXCLUSION CRITERIA**
- Chronic respiratory disease other than COPD, Asthma
- Unstable respiratory status
- Recent viral, bacterial Pulmonary infection
- Continuous daily oxygen requirement
- Congestive cardiac failure
- Inability to discontinue COPD medication
- Uncooperative
- H/O sensitivity to any of the drugs
- Patients not giving consent
- Patients taking drugs likely to interact with the drugs under study
- NSAID, Corticosteroids, Glucosamine or DA requirement must
Exercise -2

A Gabapentine, a newer anti epileptic drug well established for its analgesic action for neuropathic pain has been recently suggested in few preclinical and early clinical studies to possess anti-emetic effect. However, review of literature suggest that there is no comparative trial in this direction for evaluating its multimodal effect in comparison to conventional pre-anesthetic medications used for preventing pain and as anti emetics like Tramadol and Ondensteron or Metaclopramide as pre-anesthetic medication in patients undergoing laparoscopy cholestectomy.

Draw protocol for phase 2 randomized Open labeled comparative clinical trial to analyze the efficacy and safety of Gabapentine as pain allaying and antiemetic in comparison to Tramadol and Metaclopramide and make the CONSORT for same to be submitted for approval from IEC and ICMR for funding and then to conduct research.
Parallel study design With combination treatment For Efficacy

PATIENTS OF CHOLELITHIASIS PLANNED FOR LAPAROSCOPIC CHOLECYSTECTOMY

200 PATIENTS

RANDOMISATION

GROUP I
n=50
Metoclopramide

GROUP II
n=50
TRAMADOL

GROUP III
n=50
Gabapentine

GROUP IV
n=50
Tramadol+
Metoclopramide

POST-OP ASSESSMENT ON BASIS OF
Pain Score
Vomiting Score
anti emetic and analgesic requirement, Safety Assessment( BP, HR, ADR)

STATISTICAL ANALYSIS

INCLUSION CRITERIA
Patients above 40-60 years
Both sexes
Patients giving consent

EXCLUSION CRITERIA
Drug addicts/analgesic abuse
H/O sensitivity to any of the drugs
Patients not giving consent
Patients taking drugs likely to interact with the drugs under study
Planned open procedure
Longitudinal Trial

Data Usually Compared To Patients Own baseline

With time effect of drug can be studied

Where you can not justify placebo arm like
<table>
<thead>
<tr>
<th>S.N o.</th>
<th>Sampling Interval</th>
<th>TC (mg/dl)</th>
<th>LDL – c (mg/dl)</th>
<th>TG (mg/dl)</th>
<th>VLDL –c (mg/dl)</th>
<th>HDL – c (mg/dl)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0 day</td>
<td>179.78 ± 11.80</td>
<td>117.21 ± 10.9</td>
<td>145.35 ± 15.45</td>
<td>29.07 ± 3.09</td>
<td>46 ± 2.00</td>
</tr>
<tr>
<td>2</td>
<td>3 months</td>
<td>173.21 ± 11.85*</td>
<td>110.07 ± 11.6*</td>
<td>146.7 ± 15.08</td>
<td>29.5 ± 3.00</td>
<td>46.07 ± 2.43</td>
</tr>
<tr>
<td>3</td>
<td>6 months</td>
<td>169.85 ± 11.07**</td>
<td>108.28 ± 11.5**</td>
<td>145.5 ± 15.07</td>
<td>29.1 ± 3.01</td>
<td>45.85 ± 2.98</td>
</tr>
</tbody>
</table>

Values are expressed as mean ± SEM, * (p<0.05), **(p<0.01) Statistically significant from baseline
Presentation by

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“Title Writing”

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Editor In Chief
JK Science Journal of Medical Education and Research (EMBASE)
Associate Editor- Journal Midlife Health (MEDLINE/PUBMED)
Writing the Research Paper

- Necessary IEC Certificates
- Title
- Abstract
- Key Words
- Running Title
- Introduction
- Review of literature
- Aim & Objectives
- Materials and Methods
- Statistical Methods
- Results
- Discussion
- Limitation of the study
- Conclusion
- References
- Figs & Table
- Appendices
Title: Purposes

• To draw the attention of a prospective reader
• To induce him / her to read the entire paper or at least the abstract

• To make electronic retrieval of the article both sensitive and specific
Title of Thesis or Research

Simple and concise, but informative
Interesting and eye-catching
Accurate and specific about paper’s content
State the subject in full
Indicate study design, animal species
Grammatically correct
Should not State results or conclusion or objectives
Title

Must be informative, specific & short. 150 characters

- Will determine whether paper gets read
- Avoid long title (see previous article in journal)
- Avoid abbreviations
- Avoid repetition of aims and objective
- Should not conclude the study

What constitute a good title?

“fewest possible words that adequately describe the contents of the paper”
Exercise -1
What is wrong in the title
Comment and write the better version

• To Evaluate Efficacy And Safety of Caralluma Fimbriata In Overweight And Obese Patients With Or Without Associated Co-Morbid Conditions in Jammu Region
Efficacy and Safety of *Caralluma Fimbriata* In Overweight and Obese Patients: A Randomised Double Bind Placebo Control Study
Exercise -2
What is wrong in the title
Comment and write the better version

Metformin increases cancer specific survival in colorectal cancer patients-National cohort study.
• An Effect of Metformin on cancer specific survival in colorectal cancer patients- A National cohort study
Exercise -3
What is wrong in the title
Comment and write the better version

• Is fasting plasma glucose in early pregnancy a better predictor of adverse obstetric outcomes than glycated haemoglobin?
Fasting plasma glucose Vs glycated haemoglobin in early pregnancy for prediction of adverse obstetric outcomes : A Comparative Clinical Study
First Indian study evaluating role of biochemical investigations and diagnostic tools in detection of adverse drug reactions.
• Role of biochemical investigations and diagnostic tools in detection of adverse drug reactions: A Retrospective Observational Study
Hands On Exercise

• Read the abstract and write most appropriate Title of the study
• Abstract-1
• Abstract -2
• Abstract -3
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“Abstract Writing and Key Words”

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Abstract

• A Precise, accurate, Structured or Unstructured summary of the paper

• Purposes
  ▪ Included in several abstracting services (including Medline)
  ▪ Helps readers browse and decide
Abstract

• A brief statement of chief points
• Short but intelligible
• Informative and interesting
• Avoid unnecessary detail
• Should convey Every thing of the original work precisely
• Accurate
• Should generate Interest to read full paper
Abstract

Structured/unstructured
Length: 150-250 words
No references or abbreviations
Include main statistical conclusions
Structured abstract

• Background
• Objective
• Methods
• Results
• Conclusion
BACKGROUND: Atypical antipsychotics are used for the treatment of acute mania, either as monotherapy or in combination with lithium or divalproex, which have a better tolerability profile as compared with typical antipsychotics. Asenapine, a newer atypical antipsychotic, has been found to be effective for the treatment of mania, with efficacy similar to olanzapine.

OBJECTIVE: The objective of the study was to compare the efficacy and safety of asenapine and olanzapine when used in combination with divalproex in patients with acute mania.
METHODS: One hundred twenty patients aged 18 to 55 years, diagnosed with manic episode, were randomized to receive either flexible dose of sublingual asenapine (10-20 mg/d) or tablet olanzapine (10-20 mg/d), in combination with valproate 20 mg/kg per day for a period of 6 weeks. Efficacy was measured as change in Young Mania Rating Scale and Clinical Global Impression-Bipolar using intention-to-treat analysis with last observation carried forward, and safety was measured using Udvalg for Kliniske Undersøgelser scale and Modified Simpson-Angus Extrapyramidal Side Effects Scale.
RESULTS: There was a significant reduction in Young Mania Rating Scale and Clinical Global Impression-Bipolar scores over time in both groups, with a significantly higher reduction in the olanzapine group as shown by the group × time interaction effect. Higher weight gain, increased sleep and appetite, and tremors were seen in the olanzapine-treated patients as compared with asenapine-treated patients; however, tongue hypesthesia was seen in the asenapine group only.

CONCLUSIONS: This study found that asenapine was an effective and well-tolerated atypical antipsychotic alternative to olanzapine in combination with divalproex for the short-term management of acute mania.
A cross-sectional descriptive observational study was undertaken to evaluate the adherence/compliance rates of most commonly prescribed anti-rheumatic drugs among women in a tertiary care teaching hospital in North India. Hundred women on anti rheumatic treatment for rheumatoid arthritis diagnosed by American College of Rheumatology (ACR) criteria were evaluated at one point analysis for adherence/compliance/satisfaction.
Dissatisfaction rate with the anti rheumatic treatment was significantly high \( p<0.0001 \) among 68% of the women. Non compliance/ non adherence rate was also recorded very high among 52% and interrupted compliance rate was noticed among 6% of the women suffering from RA. Switch over rate to other treatment or doctors was also significantly \( (p<0.0001) \) very high among 66% of the women. Switch over to alternative treatment, treatment under quacks and intermittent self medication was recorded by 12%, 4% & 16% respectively. Among the self medication 12% of the women took corticosteroids and 4% preferred taking intermittent NSAIDs. Treatment compliance is not very good with anti-rheumatic drugs among women patients of RA due to multi-factorial reasons.
Keywords

• Words or short phrases used for cross-indexing, and retrieval
• 3-10 identifiers representing main concepts included in the article
• Exclude words already in title
• Arrange alphabetically
• References of an Article gives insight for Key words
Key words

• Keywords will help readers or indexing agencies in cross-indexing the study.

• Use terms from the latest Medical Subject Headings (MeSH) list of Index Medicus.
Workshop Module

Read The Given Article and

• Write the title of the study
• Write Structured Abstract in 250 Words
• Write appropriate Key Words

• Exercise -1, 2, 3
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“Introduction Writing and Reviewing the literature”

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Sir Bradford Hill’s Questions

I  Introduction  Why did you start?
M  Methods       What did you do?
R  Results       What did you find?
A  and
D  Discussion    What does it all mean?
Purpose of Introduction

• The purpose of the Introduction should be to supply sufficient background information to allow the reader to understand and evaluate the Context of the present study without needing to refer to previous publications on the topic.

• The Introduction should also provide the rationale for the present study. Choose references carefully to provide the most salient background rather than an exhaustive review of the topic.
Summery How to write Introduction

• Essentially this section must introduce the subject
• Should reflect Volume of the problem
• Give a concise background of the study
• Do not review literature extensively but provide the most recent work that has a direct bearing on the subject. Reflect the gap in the knowledge briefly
• Rationale and Justification for research aims and objectives must be clearly mentioned without any ambiguity.
• What new It is adding
• Significance and relevance of study
• The purpose of the study should be stated at the end.

Dr Vishal Tandon
Introduction: Why did you start?

• Review pertinent literature to orient the reader
• Define lacunae in current knowledge
• Provide rationale for your study
• Brief, clear, to the point
• Written in present tense
• Key references: support information
Thesis Vs Paper

Thesis vs. Research Paper

<table>
<thead>
<tr>
<th>Research Paper</th>
<th>Thesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Limited space</td>
<td>• “Unlimited” space</td>
</tr>
<tr>
<td>• Specialized context</td>
<td>• Broad context</td>
</tr>
<tr>
<td>• Tackles a specific question</td>
<td>• Tackles a large question</td>
</tr>
</tbody>
</table>
Example

We wish to suggest a structure for the salt of deoxyribose nucleic acid (D.N.A.). This structure has novel features which are of considerable biological importance.

Problems

• Historical details
• Frequently too long
• Too general and vague
• Contains ‘discussion’ material
• Mechanism
• Imitative
• No need to arrange references in chronological order which is usually done in review section
The Introduction
What Not to Include

- Do not include information that is not directly relevant to your study
- Problems other than the one being examined
- General information about the country
- Chemical Structures
- Details of the research design
Exercise Module-1

Adverse drug reaction (ADR) has been implicated as a leading cause of considerable morbidity and mortality worldwide. The prevalence rate of ADRs has been reported to range from 0.16 to 15.7 per cent\(^1\). Morbidity related to ADRs is also well known and causes a large number of hospital admissions\(^2\).

Further, ADR related hospitalization in emergency and intensive care units (ICU) is very high among high risk population like elderly population with multiple co-morbidities\(^3\).

Morbidity related to ADRs can be permanent sometimes to the extent of 20.4 per cent of admissions in ICU\(^4\). Besides, ADRs are known to pose huge economic burden on individual, society and nation at large\(^5\).
Drug-induced diseases (DID) also called as iatrogenic diseases, are well known but least studied entity. Some of the risk factors of DIDs are multiple chronic diseases, multiple physicians, hospitalization, medical or surgical procedures, long duration of medicine use, advancing age, female sex and a particular class of drugs. Most of these DIDs are largely preventable, if strict vigilance and proper periodic clinical and diagnostic monitoring are undertaken. There are studies from the West regarding DIDs, however information from India is lacking.

Hence, the current study was undertaken to analyze the profile of DIDs in a tertiary care teaching hospital at Jammu, India.
Exercise Module-2

Vitex-negundo (VN) Linn (verbenaceae) is a large aromatic shrub (1), found throughout India mainly at warmer zones. It have been studied for its analgesic(2), anti-inflammatory(3), anti-convulsant (4) and anti-oxidant (5) activities.

LD50 dose of VN is in non-toxic range (6)

Seeds of VN posses hepatoprotective (HP) action against Carbon Tetrachloride induced liver damage (7)

Tuberculosis continue to be a major health problem globally. Short course combination of Isoniazid (INH), Rifampin (RMP) and Pyrazinamide (PZA) is highly effective (8)

Antitubercular treatment (ATT) induced hepatotoxicity is a major concern (8,9) Conventional drugs for ATT induced hepatotoxicity are often inadequate10 Efforts to explore HP effect of any natural product carries a great clinical significance
Review of literature

• How far similar research problem has been studied
• Understand limitations in those studies
• Critically assess the required modifications
• WIDE TO NARROW TO SPECIFIC
Common agencies

- Pubmed central
- Pubmed
- DOAJ
- Cochrane database
- NLM
- **Science Free Medical Journals List**
- Biology & Medicine Online Journals

- EMBASE
- Indexcopornicous
- Google's
- Google's scholars
- Yahoo search
- Indmed
Writing Review of literature

• Avoid Cut copy paste
• Chronologically write Findings of the previous study
• Till the latest reference
• Conclude your review
• Always better to review western/Indian/regional data
• End the review with rationale justification for conducting study
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How To Setup Aims and Objective In research Paper

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Hypothesis

- A statement that describes the expected outcome of the research or study

- Not needed in descriptive studies
What Are Objectives

• Objectives are concise statements of the major and minor questions that the trial is designed to answer

• In all areas of research asking the right question is perhaps the most important part of research
How many Objectives

• One or two maximum three
• Too Many Objective become difficult to meet and study start becoming directionless and purposeless and it decreases the chance of its successful completion
Stating the objectives

• Reason for doing the study
• Clearly phrased in operational terms

• Use action verbs: To determine, to compare, to verify, to describe, to establish, To evaluate, To find correlation, analyze

• Avoid verbs: To appreciate, to comprehend, to realize
What Come first Trial Objective or Design

- Design is the framework with which the trial objectives will be met

- The design is generally established after the trial objectives
Information to include

• An expression describing an overall approach (To assess, to compare, to determine etc)
• Names of all medicine being evaluated
• Dose / dose range/ Regimen
• Disease being evaluated
• Type of patient being evaluated
• Purpose – Efficacy safety, pharmacokinetic
• Specific purpose- Superiority to placebo / Equivalence / Non Inferiority
• Parameters to be measured

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Always better to have

- **Primary Objective**

- **Secondary Objectives**
OBJECTIVE: To evaluate prevalence of Vitamin D deficiency and establish any correlation between diabetes and vitamin D deficiency among postmenopausal women
Objective: To evaluate the satisfaction/adherence/compliance rates of most commonly prescribed anti-rheumatic drugs among Indian women.
Rheumatological disorder (RD) in Indian women above 40 years of age: A cross-sectional WHO-ILAR-COPCORD-based survey.

OBJECTIVE: To evaluate rheumatological profile among Indian women above 40 years.
Adverse drug reactions profile of antimicrobials: A 3-year experience, from a tertiary care teaching hospital of India.

Objective: To evaluate adverse drug reaction (ADR) profile of antimicrobials over 3-year period.
Comparative evaluation of efficacy, safety and haemostatic parameters of enoxaparin and fondaparinux in unstable coronary artery disease

• **Primary Objective:** To compare the efficacy of Enoxaparin (EX) and Fondaparinux (FD) in patients with Unstable Coronary Artery Disease (UCAD).

• **Secondary Objective:** To compare the safety of Enoxaparin (EX) and Fondaparinux (FD) in patients with Unstable Coronary Artery Disease (UCAD).
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Material and Methods

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Methods

What did you do?
Methods

- Study Design
- Randomization
- Time and duration of study
- Place of study and collaborating Department
- IRB/IEC Clearance
- Clinical trial registration Number
- Informed consent
- Define study population and number
- Explain protocol clearly
- Detail of Baseline Clinical/Biochemical Screening
- Inclusion criteria
- Exclusion criteria
- Define Study Groups allocation Clearly
- Detail of Methods with original references
- Clearly define if any modification made
- Basis of Dose selection – Important
- Principles of precaution and risk minimization
- Assessment of Outcomes- primary and secondary
- Very Important to Define Parameters of Evaluation and their Time protocol and their interpretation
- CONSORT – Flow diagram
Informed consent

• Verbal Informed Consent
• Written informed consent
• From every subject
• Vulnerable Population
• Reverse consent
• Before any study related procedure
• And documented on IRB/EC approved form
Inclusion criteria

• A set of characteristics present in person that make him eligible for participation in a clinical research
  – Informed consent given
Exclusion criteria

• A set of characteristics presence of which makes a person unsuitable for participation in a clinical research
  – Age, sex, weight, social economic status,
  – e.g. age < 30 yrs or >60 yrs
  – H/o allergy to any study drug
  – Impaired renal functions
  – Impaired hepatic functions
  – Heart failure
  – H/o alcohol abuse, tobacco
  – Diet and nutrition
  – Pregnancy/lactation
  – Concomitant diseases
  – Previous medicine
  – Geographical location, environment status
RCT
Eliminates Selection Bias and allow comparability

• Drawing up a protocol
• Select suitable population (Ref or target)
• Select suitable sample (Experimental or study population)
• Make necessary exclusion (Not eligible or do not consent)
• Randomization
• Manipulation
• Fallow up
• Assessment of outcomes
Blinding

- Single blinding
- Double blinding
- Triple blinding
Results

What did you find?

Answers
Results: The components

- Text  Story
- Tables  Meat
- Figures  Drama
Results

• Start with demographic and baseline results
• Results of all experiments in natural order in subsections similar to methods and parameters evaluated
• Do not duplicate information text, tables, figures
• Statistical analysis
Results

• *Should not include*
  – Any methods
  – Data for which methods are not included
  – Interpretation of data
  – References
## Results: Tables

### Table I. Parts of a table

<table>
<thead>
<tr>
<th>Stub</th>
<th>Column heading</th>
<th>Column heading</th>
<th>Column heading</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Row identifier**

**BODY**

**Row identifier**

*Footnote:*
## How to handle data in excel sheet

<table>
<thead>
<tr>
<th>Randomization</th>
<th>Drug</th>
<th>Age</th>
<th>Sex</th>
<th>YMRS Baseline</th>
<th>YMRS 3 Weeks</th>
<th>YMRS 6 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>O</td>
<td>24</td>
<td>1</td>
<td>27</td>
<td>20</td>
<td>7</td>
</tr>
<tr>
<td>2</td>
<td>A</td>
<td>38</td>
<td>2</td>
<td>34</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>3</td>
<td>O</td>
<td>55</td>
<td>1</td>
<td>35</td>
<td>18</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>O</td>
<td>25</td>
<td>2</td>
<td>22</td>
<td>13</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>A</td>
<td>40</td>
<td>2</td>
<td>35</td>
<td>15</td>
<td>4</td>
</tr>
<tr>
<td>6</td>
<td>O</td>
<td>27</td>
<td>2</td>
<td>38</td>
<td>16</td>
<td>7</td>
</tr>
</tbody>
</table>
Results

• Results may be presented in the form of
• Frequency distribution tables or
• Using diagrams such as bar diagram, pie chart, pictogram, histogram, line diagram, scatter diagram etc.

Base line Characteristics
# Table 3: Mean Difference (% Change) From Respective Baselines Observed With Olanzapine and Asenapine on YMRS Score at Week 3 and 6

<table>
<thead>
<tr>
<th>Variable</th>
<th>Drugs</th>
<th>Statistical Inference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Difference of YMRS</td>
<td>Olanzapine (Mean ± SEM) (% Change)</td>
<td>Asenapine (Mean ± SEM) (% Change)</td>
</tr>
<tr>
<td>At 3 Weeks</td>
<td>-17.60 ± 0.93 NS   (51.30)</td>
<td>-16.89 ± 0.75 NS      (51.31)</td>
</tr>
<tr>
<td>At 6 Weeks</td>
<td>-26.40 ± 0.65***   (76.94)</td>
<td>-24.64 ± 0.69***      (74.86)</td>
</tr>
</tbody>
</table>

The data is shown in Mean ± SEM; YMRS: Young Mania Rating Scale
Paired ‘t’ test in comparison to respective baselines * p<0.05; ** p<0.01; *** p<0.001
Comparison between the groups at Baseline, 3 weeks and 6 weeks with Unpaired Student ‘t’ test † p<0.05; †† p<0.01; ††† p<0.001; # NS = Non Significant
**Fig. 1 EFFECT OF OLANZAPINE Vs ASENAPINE ON YMRS SCORE IN PATIENTS OF ACUTE MANIA**

The data is shown in Mean ± SEM; YMRS: Young Mania Rating Scale

Paired ‘t’ test in comparison to respective baselines * p<0.05; ** p<0.01; *** p<0.001; NS = Non Significant

Comparison between the groups at Baseline, 3 weeks and 6 weeks with Unpaired Student ‘t’ test

† p<0.05; †† p<0.01; ††† p<0.001; # = Non Significant
Figure 3. Section of the liver tissue of rats treated with VNE (100 mg/kg. wt) and antitubercular drug challenge showing macrovesicular fatty change (H&E, 100 X)
Discussion

- First answer question posed in introduction
- Compare studies in agreement
- Discuss weaknesses and discrepancies
- Lay down Possible reason in discrepancies
- Lay down Possible Hypothesis / Explanation of the findings
- Discuss Unexpected Findings also
- Explain what is new without exaggerating
- Discuss perspectives, implications, Impact on available research and clinical practice
- Limitations of study
Avoid:

Repletion of results

Too verbose, theoretical texts that are irrelevant to the research problem*

Inadequate discussions on the significant results

Failure to justify negative results
Conclusion

• Be specific
• No hypothesis
• Finally conclude major results findings of study as per research question
Efficacy and Safety of Asenapine Versus Olanzapine in Combination With Divalproex for Acute Mania: A Randomized Controlled Trial

OBJECTIVE: To compare the efficacy and safety of asenapine and olanzapine when used in combination with divalproex in patients with acute mania.

CONCLUSION: This study found that asenapine was an effective and well-tolerated atypical antipsychotic alternative to olanzapine in combination with divalproex for the short-term management of acute mania.

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References

“A Reference is a technique to give credit to the individuals for their creative and intellectual works that the author is using to support the research. These are also useful in avoiding misplacing of information and plagiarism”
Referencing Styles

Some important referencing style in the medical sciences are:

- American Psychological Association (APA)
- Chicago-style
- Harvard Style
- Vancouver Style
References Vs Bibliography
Citation of References inside the Text in thesis

• In Introduction- No Chronological Order to be followed
• In review- To follow chronological order and list from old till latest
• Methods: Original References To be cited
• In discussion- No Chronological Order to be followed
• Results and conclusion: No References to be cited
Chacko SA et al. (2012) in their prospective cross sectional epidemiological study documented that higher serum 25(OH)D concentrations may be inversely associated with adiposity, triglycerides, triglyceride: HDL-cholesterol ratio, and metabolic syndrome but are not associated with LDL and HDL cholesterol, insulin, glucose in postmenopausal women.

Most recently it was documented that low Levels of 25-Hydroxy Vitamin D and active 1,25-Dihydroxyvitamin D is independently associated with Type 2 Diabetes Mellitus in older Australian men. (Hirani V et al, 2017)
Mental Health is a state of harmony between the individual and the surrounding world, a state of harmony between oneself and others, a coexistence between the realities of self and that of other people and that of the environment (Sartorius A, 1983).
Acute mania is a medical emergency and needs an early and appropriate management which should provide effective control and prevention of activities that have potential for adverse consequences (Bauer FG & Pfennig AM, 2005).

Dr Vishal Tandon
Divalproex efficacy in reducing symptoms of mania and psychosis is comparable to olanzapine (Zajecka Z et al, 2002).
Reference checking facility on the www.journalonweb.com website

• The manuscript submission web site offers the authors a method where they can check the correctness of the references they have used
• The following slides will demonstrate how to use it
Citing References in the text

• References should be numbered using Arabic numerals in box parentheses e.g. [1] in the order of appearance in the text as a superscript.

diameter of 6 to 7 mm and the renal artery measures 2.8 mm.\textsuperscript{[11]} WT surgery is a safe and partially standardized procedure. However, major bleeding and vascular injuries can occur. The frequency of vascular injuries has been reported as 1.5% in the NWTS-3 and 4.\textsuperscript{[12, 13]} Severe hemorrhage occurs at a higher rate. Further, there exists a hidden surgical mortality.\textsuperscript{[14]}
• Journal article on the Internet


Exercise Module 1– Writing References

• Study of the Biomechanical and Histological Properties of the Abdominal Aorta of Diabetic Rats Exposed to Cigarette Smoke

• Barão FTF, Barão VHP, Gornati VC, Silvestre GCR, Silva AQ, Lacchini S, de Castro MM, De Luccia N, da Silva ES.


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Exercise Module 2– Writing References

• **Zidovudine**-induced nail hyper-pigmentation in 45-year-old women prescribed for HIV/tuberculosis co-infection.

• Tandon VR, Sadiq S, Khajuria V, Mahajan A, Sharma S, Gillani Z.

Exercise Module 3– Writing References
Simple

*Use* simple words

*Use* short sentences

*Use* short paragraphs

When you are out to describe the truth, leave the elegance to the tailor.

*Einstein*
Language

• *Precise*

• *Familiar*

• *Concise*

• *Smooth (fluid) & connected*
  Smooth and logical flow of thoughts
Irritants to Editor

- Different address of the journal
- Instruction of journal not followed
- Grammatical typographical mistakes
- Old references
- Structure of submission not followed
- Phone calls for acceptance letter
- Every week sending e mails for status
- Reference not cited in serial, in text
- Table, figures –no legends
Irritants to evaluator

• Plagiarism
• Grammatical Typographical mistakes
• Very Old references
• Structure of Submission not fallowed
• Reference not written in uniform style
• Table and Figs- not cited and no legends or they Lack description
• Wrong citation
• Results repeated in discussion
• Conclusion- not drawn in accordance to results
How to Improve

• Good writing is rewriting
• Self review after a gap of few days
• Peer Review
• Your supervisor/professor is not here to teach you basic grammar and spelling
• Use grammar check software
  • http://www.grammarcheckforsentence.com

• Plagiarism Checker software-
  https://www.quetext.com/
Unethical Publication practices

Gift Authorship
Pressured Authorship
Ghost Authorship
Duplicate Submission
Salami Publication
Plagiarism

Publications adding no new information

Scientific Fraud

Fabrication (altering truthful information)
Falsification (Inventing information where none previously existed)

Dr Vishal Tandon
Necessary Certificates

• Brief bio-data
• **Guide**- Certifying originality of Research and supervision
• **HOD**- Certifying availability of work facilities for the research work in the department
• **Head of Institution**- Certifying availability of work facilities for the research work in the Institution
• **IEC/IRB certificate**
• **Conflict of interest Declaration if any**
• **Acknowledgements**
• **Informed consent**
• **Preserve date at least for five years**
Dealing with rejection
Three golden rules of replying to referees’ comments*

- Respond completely
- Respond politely
- Respond with evidence
- Respond promptly

*Williams HC. How to reply to referees’ comments when submitting manuscripts for publication. J Am Acad Dermatol 2004;51:79-83
<table>
<thead>
<tr>
<th>No.</th>
<th>Comment</th>
<th>Page no. in original Ms.</th>
<th>Reply Action taken/ Explanation</th>
<th>Page no. in revised Ms.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>The abstract is not structured. Conclusions not given.</td>
<td>2</td>
<td>Abstract is modified and structured. Conclusions included.</td>
<td>2</td>
</tr>
<tr>
<td>2.</td>
<td>Authors have used the method of Rao &amp; Gupta to estimate the drug PK-403. This is not an appropriate method.</td>
<td>3</td>
<td>We do not agree with the referee. Recently it has been pointed out that this method is equally useful (reference enclosed). Many workers have used this method – list of papers enclosed.</td>
<td>3</td>
</tr>
</tbody>
</table>
Outright rejection

Identify reason for rejection

Fatal Flaw

Inappropriate to pursue publication

No chance of publication success

Submit to a more appropriate and probably a lower impact journal

Incorporate reviewers & editorial comments. Better than reasonable chance of publication success.

Reasonable chance of publication success

Not suitable for journal

Give up

No chance of publication success
Workshop Module

• Critically Comment on the given research Publication and Height the limitation and strength of the study and specifically comment on the
• Write the title of the study
• Structured Abstract
• Key Words
• Rationale and Justification
• Ethical Issues
• Inclusion and exclusion criteria
• Study design
• Randomization
• Blinding
• Statistical Test Used
• Results Discussion and Conclusion