MYBO WEBINAR
WEBINAR-2

Writing a Pharm.D Thesis

Exclusive Mybo Webinar for Pharm.D students

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- Pharm D is a course initiated by the Pharmacy Council of India in 2008.
- Objective was to give a Clinical Pharmacy thrust to the field of Pharmacy in India.
- We are seeing clinical pharmacists doing various roles in hospitals; but there is still a long way to go before we can say "Yes, Clinical Pharmacy is here"
- We must show the world and the health care field, that our presence matters, that where there is a clinical pharmacist, drug interactions are less, and pharmacotherapy is better.

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Pharm D

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Pharm D Project

The syllabus and Regulations of Pharm D has given clear guidelines for the carrying out of the project and for preparation of the project report.

The requirement has been clearly laid out. Colleges and Universities have to work within the ambit of the guidelines, while utilizing the strengths of the experienced teachers available with them.

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Project work

Objective of project work is to allow the student to develop data collection and reporting skills in the areas of community, hospital and clinical pharmacy.

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Objectives

- The objectives of the project work are to make the student learn accurate description of published work of others
- Recording readings/observations/ findings in an impartial manner
- Skills of data collection, analysis, reporting and interpretation.

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Topic

The project topic must be approved by the Head of the Department or Head of the Institution.

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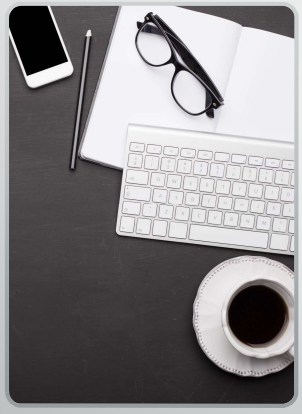
Contents of Report



Project work shall comprise of

objectives of the work,

methodology,

results,

discussions and conclusions.

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Project topic

- It shall be patient and treatment (Medicine) oriented, like
  - Drug utilization reviews
  - Pharmacoepidemiology
  - Pharmacovigilance
  - Pharmacoeconomics
- Project work shall be approved by the institutional ethics committee

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- Reporting: Students have to submit, jointly, to the Head of the Department or Head of the Institution a project report of about 40-50 pages.
- Project report should include certificates issued by the authorized teacher, Head of the Department and the Head of the Institution.

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Contents of Project Report

- Aim and Objectives
- Chapter I: Introduction
- Chapter II: Literature review
  - Plan of work
- Chapter III: Research Methodology
- Chapter IV: Results
  - Tables
  - Statistical Analysis
- Chapter V: Discussion
  - Comparison with past work
- Chapter VI: Summary and conclusions
- Chapter VII: References

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First pages

1. Title page: highlighting the title, names of the candidates, reg. no.s, guides' names, college name and hospital name, month and year of submission.
2. The inner title page containing the same details on white background.
3. Certificate from the Head of the institution
4. Certificate from the Research Directors
5. Certificate from the ethics committees for approval of study
6. Declaration by the student
7. Acknowledgements

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Indices

8. Index highlighting chapter titles and sections titles
9. Index for tables, figures and plates, if any
10. Abbreviations and symbols
11. Materials used in the investigation with their procurement details like name of the company, batch number etc.
12. Equipment used in the study with the model number and other details

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Topic

- Should be of clinical pharmacy orientation
- There must be a role for pharmacist
- Patient counseling
- Finding drug interaction
- Preventing adverse drug reaction
- Studying prescriptions/disease occurrence patterns

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Aim and Objectives

- Brief background
- Need for the study
- Brief statement on proposed work
- Specific objectives

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Aim and objectives

- Aim is the general, overall goal of the work,
- Ex: Studies on interactions between orange juice and anti-hypertensive drugs in diabetic and hypertensive patients
- Objectives are sub-parts of the aim, and in their totality they help in achieving the aim.
- This part should be crisp, sharp and to the point.
- Objectives should flow from the aim and follow a logical order

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Objectives

- Depending on the work, and on the data being collected, sometimes, we have a primary objective and one or more secondary objectives.
- Ex: Primary: To determine whether there is any food-drug interaction between orange juice and anti-hypertensive drugs in diabetic and hypertensive patients
- Secondary: To study the effect of consumption of fruit juice in breakfast on post-prondial blood sugar of patients

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Introduction

- Gives elaborate background of the work
- Puts stress on recent developments
- Reinforces on need for the study and what is the level at which the work stands now.
- One must try not to just copy material from standard text books, attempt must be made to go into review articles, understand their import, and express in one's own words

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Literature Review

- Must contain a brief review of standard, recent literature from peer reviewed scientific journals
- Paragraphs on important, relevant work
- If there is a lot of work in recent times, may be presented in the form of a Table

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Plagiarism

- Plagiarism is usually found in this chapter (introduction and literature review), because authors tend to copy and paste from standard text books or recent scientific papers or review articles.
- Plagiarism is a very wrong practice.
- Read a number of research papers, write down your understanding in your note book, represent it in your own words in literature review, give credit to the original author by giving reference at the end of the chapter/ thesis

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Images, flow charts, models and photos

- Copying images or flow charts or models or photos is also wrong
- Create original diagrams or photos or models
- Taking from standard text books also is not right. Read in the first pages the directions of the publisher.

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Plagiarism checking softwares

- Turnitin
- Ithenticate
- Urkund
- Plagiarism checker X
- Copyleaks
- Grammarly Premium
- Plagscan
- QueText
- SmallSEOTools
- Plagiarisima
- Dupli Checker
- Copyscape
- Plagiarism Detector
- PlagTracker

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Literature survey

- Survey of the most recent literature must be included.
- This should include reviews articles from peer reviewed journals.
- Literature that is most relevant to the work.
- Chronological order, past to the recent times.
- Author must carefully read a paper, understand it and write the results in his/her own words from the paper.

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- There are 2 ways of putting up your literature.
  - Writing in small paragraphs.
  - Writing in tables.
- You can write the name of the first author and give the year in brackets at the end of the sentence.
- Then at the end of the chapter, you give all the references in alphabetical order.
- If multiple works of the same author are being discussed they are listed in chronological order.

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- Another way is to give numbers to the references, and the numbers go in ascending order as the discussion unfolds.
- References are given at the end of the chapter in numerical order.
- If the same reference is used a number of times, the same number is allotted to it, whenever it is used.

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Plan of work

- Gives the different steps in the work in a flow chart

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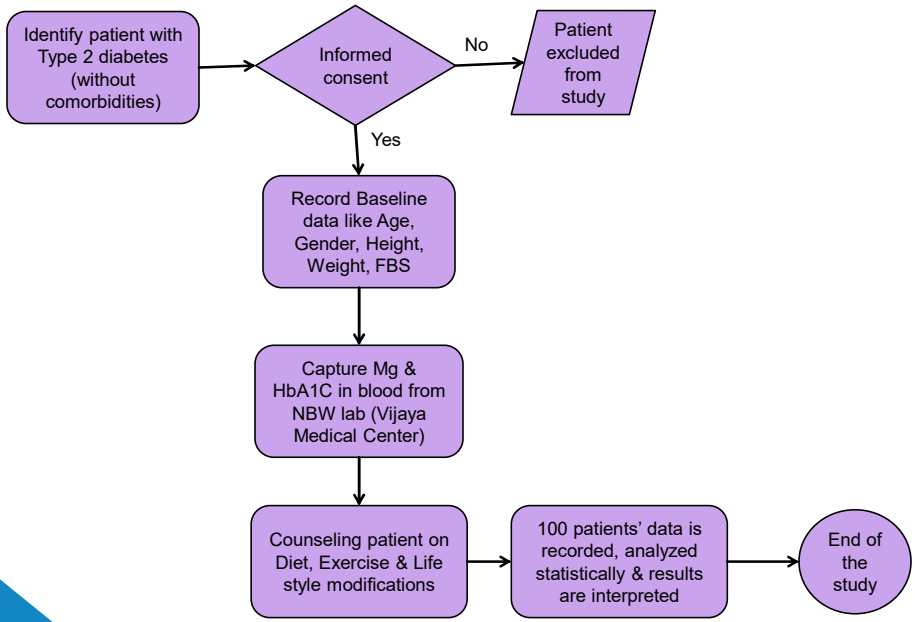
Plan of work



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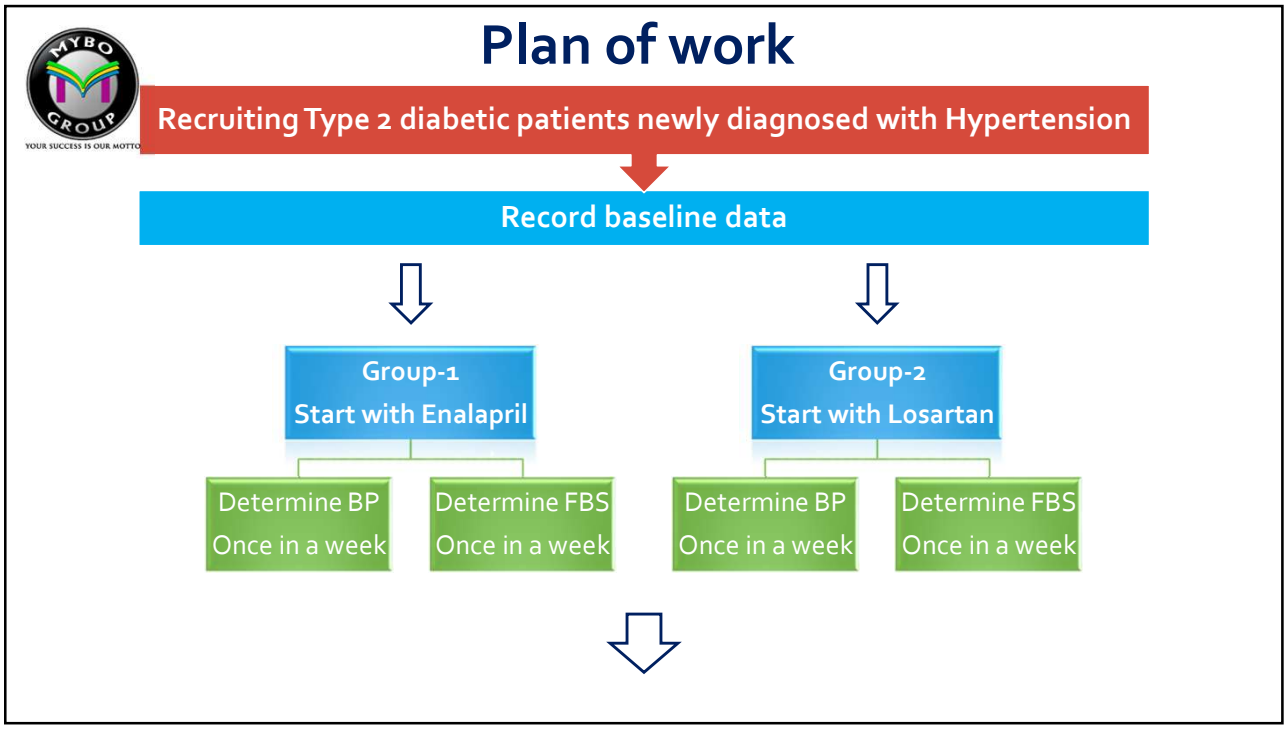
Plan of work
Recruiting Type 2 diabetic patients newly diagnosed with Hypertension
Record baseline data
Group-1
Start with Enalapril
Group-2
Start with Losartan
Determine BP
Once in a week
Determine FBS
Once in a week
Determine BP
Once in a week
Determine FBS
Once in a week

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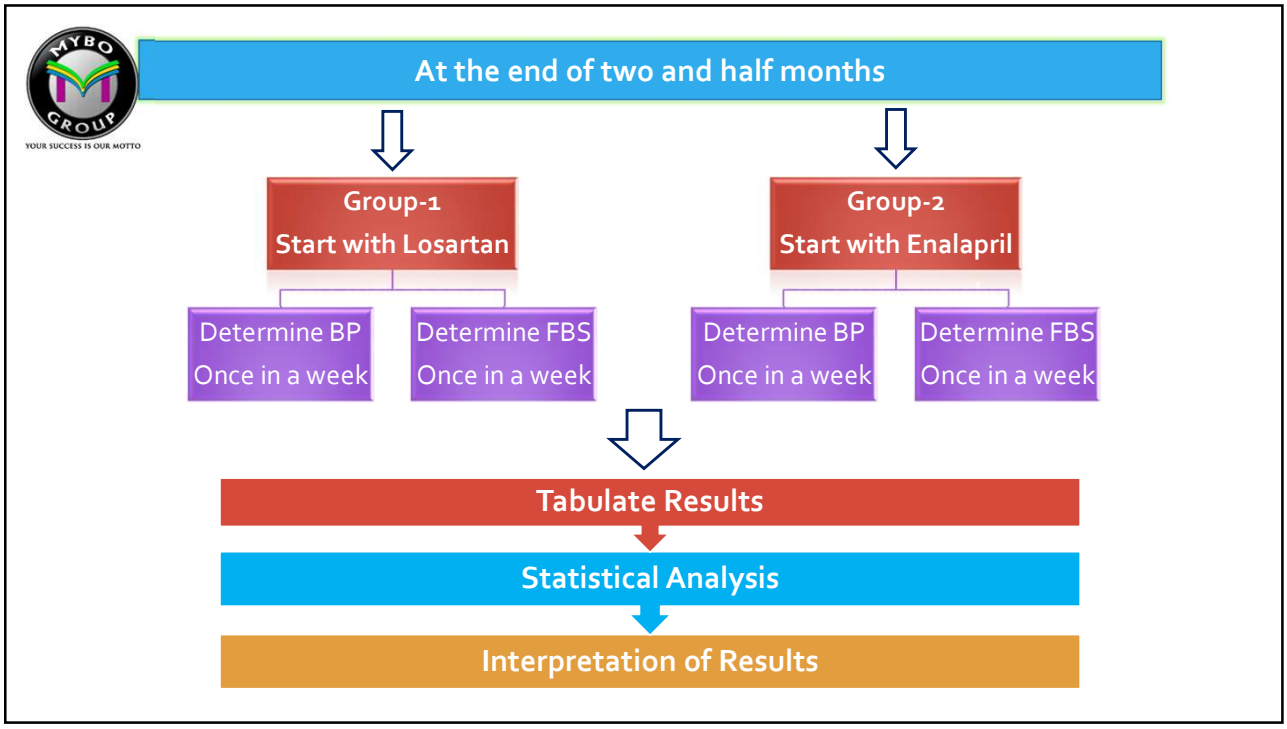
At the end of two and half months
Group-1
Start with Losartan
Group-2
Start with Enalapril
Determine BP
Once in a week
Determine FBS
Once in a week
Determine BP
Once in a week
Determine FBS
Once in a week
Tabulate Results
Statistical Analysis
Interpretation of Results

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Research methodology

- Proposal submitted to Ethics Committee
- Title, Research Design, protocol
- Experimental
- Sample
- Data collection

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Research Design

Research design must tell clearly what type of work it is:

- Observational/ interventional/archival
- Prospective/retrospective/cross-sectional/ longitudinal
- Cohort/case- control/case study/case series
- Open labelled/ single blind/double blind

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Methodology

The proposal to the Ethics Committee contains all these details.

- Title of the research project
- Names of guides (guide from college and guide from hospital)
- Names of Student Investigators
- Duration of research project
- Institutions responsible for the Research Project

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Details of the Research Project

- Title of the Project
- Introduction
- Objectives
- Literature Review
- Study site
- Study Design
- Study population
- Study content
- Steps in the study
- Plan of work
- Inclusion criteria
- Exclusion criteria
- Outcome
- Study method
- Place of Investigation
- Termination of the study

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Experimental

- Contains the procedures followed by the students to collect the data.
- Taking readings of some parameter from the patients : by doing some tests or by noting from their files
- Going through prescriptions
- Studying some databases
- Observing for drug interactions/ADRS
- Interviewing patients with standard questionnaires
- How the patient population being studied is identified and the subjects are taken into the study must be written.
- If any type of sampling, like random/stratified random/systematic/cluster, are involved, sampling procedure must be written.

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Results

- Raw data is first presented of the entire sample of patients studied.
- Next classified tables with descriptive statistics and tables of demographics are given.
- Classified tables with different factors are given.
- T test, Z test, chi square test, Analysis of variance are the usual tests done to bring out the significance of the difference between two or three groups.
- Other non parametric tests may be used if the situation demands.

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Data presentation

- Plots (2D and 3D), histograms, pie charts, tables of numbers, frequency curves
- For comparison plot, more than one data set on the same graph, using the same scale
- Images and flow charts
- Interpolation and extrapolation
- Trend analysis
- Cost analysis

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Data Analysis

- Graphs (histograms, pie chart, dot plot or individual plots, box plots)
- Diagrams (bar diagrams)
- Descriptive statistics
- Parametric and non-parametric tests
- Analysis of Variance
- ODDS ratio
- Relative risk

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COMPARISON BETWEEN INITIAL AND FINAL FBS VALUES OF LOSARTAN

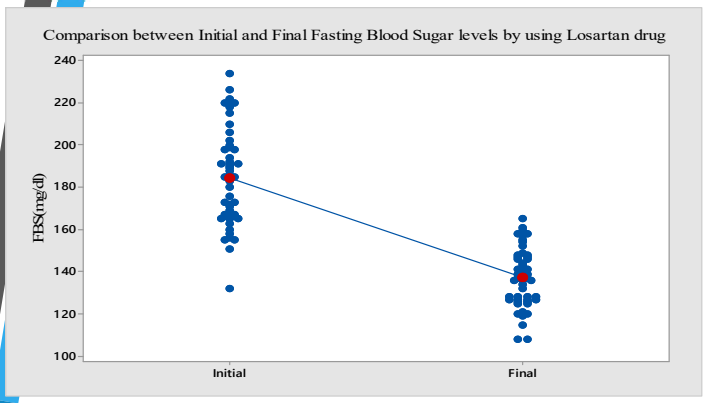

Figure 1.1.Graphical representation of initial and final FBS values of Losartan

INFERENCE:

- It shows that there was a reduction of FBS levels in subjects using Losartan for 2 months.
- The reduced FBS levels indicate that Losartan might be having blood glucose reducing effect.

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Values of Z-test for FBS levels in subjects using Losartan

Losartan	n	Mean	SD	Z-Value	P-Value	Decision
Initial	50	184.5	22.9	12.30	0.000	Significant
Final	50	137.6	14.3			

Table 1.1. Values of Z-test for FBS levels in subjects using Losartan

INFERENCE :It represents that the initial and final levels of FBS in subjects using Losartan were significantly different ($p < 0.05$).

Hence, this indicates that Losartan might be having blood glucose reducing effect.

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COMPARISON BETWEEN INITIAL AND FINAL FBS VALUES OF ENALAPRIL

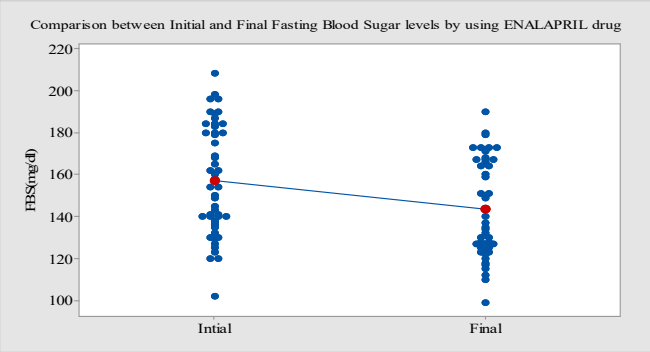

Figure 1.2.Graphical representation of initial and final FBS values of Enalapril

INFERENCE: It shows that there was a reduction of FBS levels in subjects using Enalapril for 2 months. The reduced FBS levels indicate that Enalapril might be having blood glucose reducing effect.

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COMPARISION OF PERCENTAGE REDUCTION IN FBS LEVELS OF LOSARTAN AND ENALAPRIL

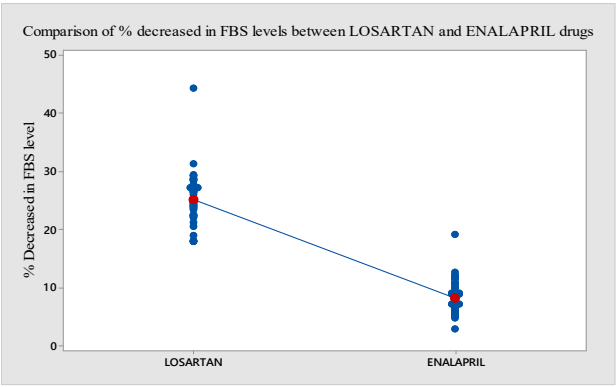

Figure 1.3. Graphical representation of % REDUCTION in FBS levels of Losartan and Enalapril

INFERENCE: This indicates that Losartan might cause more reduction in FBS levels when compared to Enalapril

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Z-test For % reduction in FBS values of Losartan and Enalapril.

Drug	n	Mean	SD	Z-Value	P-Value	Decision
LOSARTAN	50	25.19	4.41	23.12	0.000	Significant
ENALAPRIL	50	8.27	2.7			

Table 1.3. Z-test For % reduction in FBS values of Losartan and Enalapril.

INFERENCE: It represents that the % reduction of FBS values were significantly different ($p < 0.05$) between Enalapril and Losartan. This indicates that Losartan might cause more reduction in FBS levels when compared to Enalapril.

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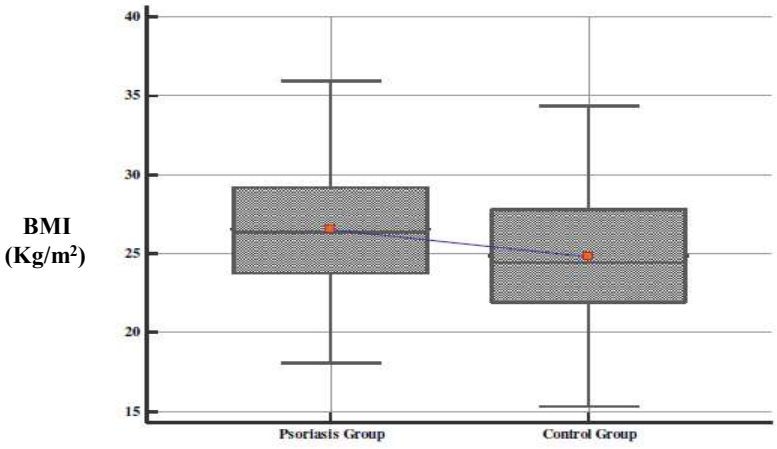

Figure 3.5: Box and Whisker plot of Body Mass Index (BMI) scores in psoriasis and control groups

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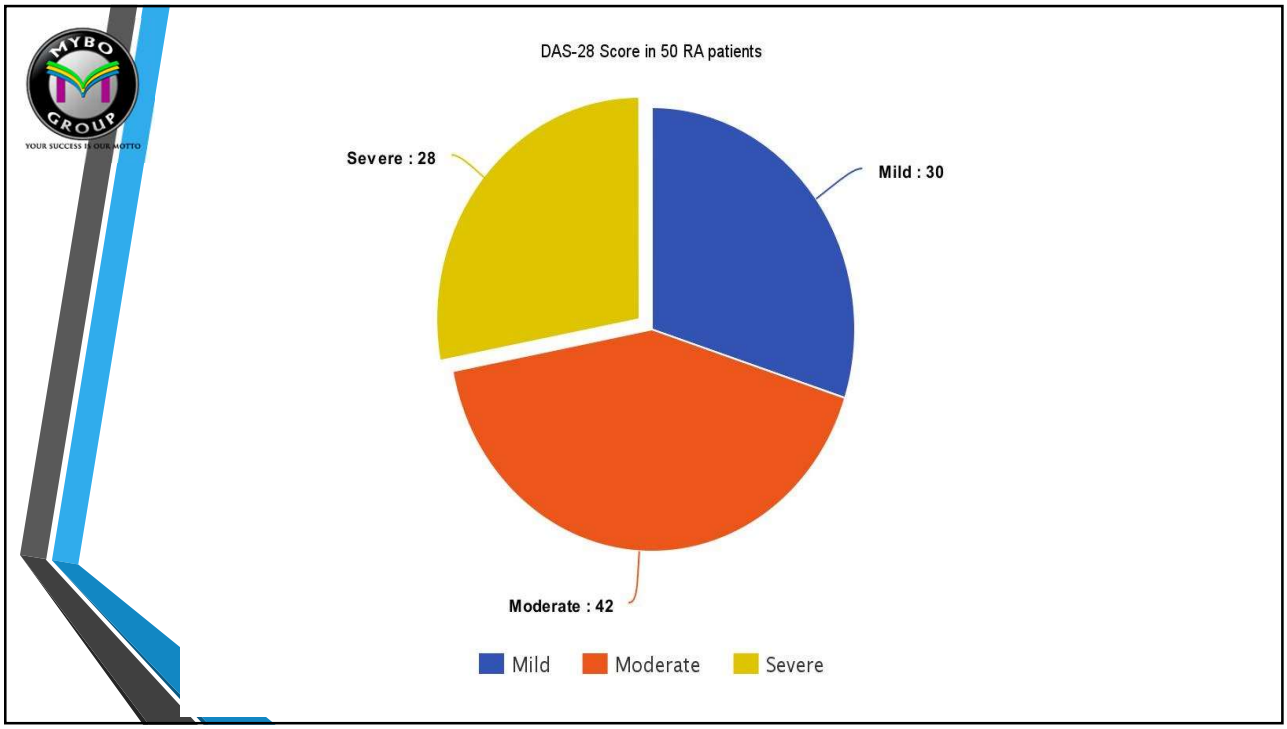
DAS-28 Score in 50 RA patients
Severe : 28
Mild : 30
Moderate : 42
Mild
Moderate
Severe

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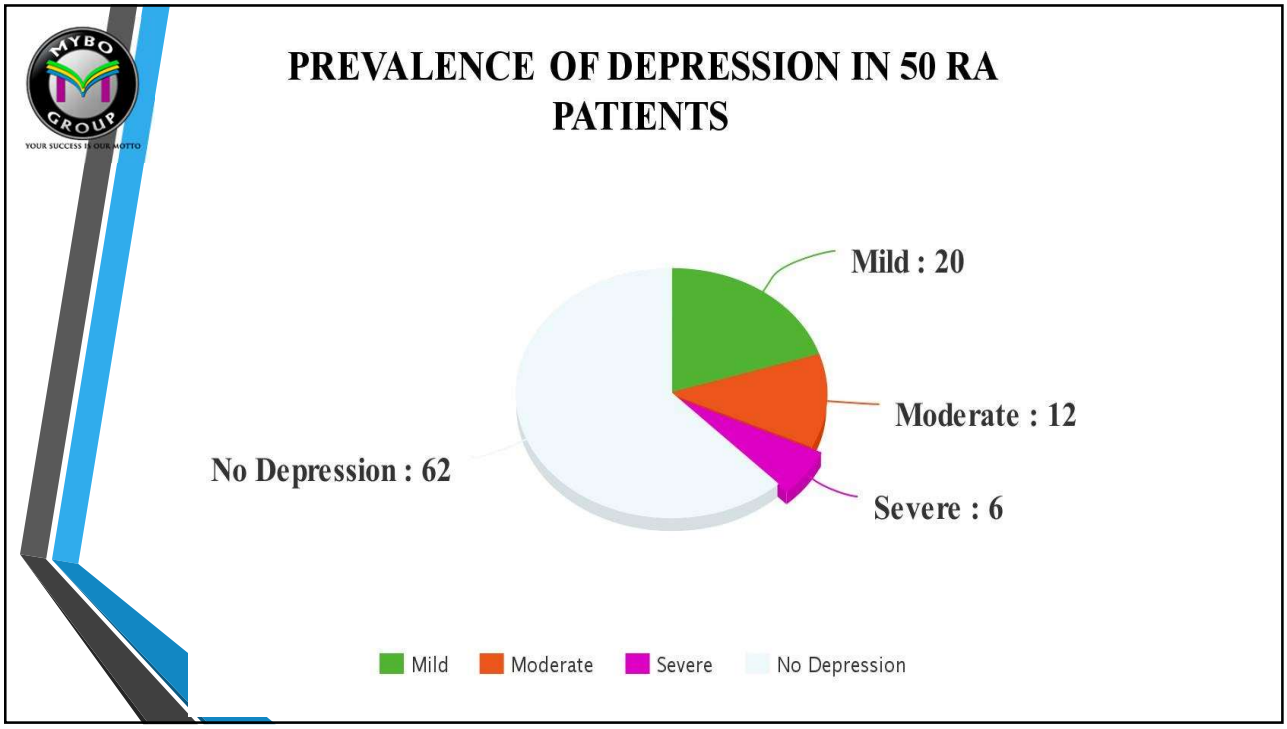
PREVALENCE OF DEPRESSION IN 50 RA PATIENTS
Mild : 20
Moderate : 12
Severe : 6
No Depression : 62
Mild
Moderate
Severe
No Depression

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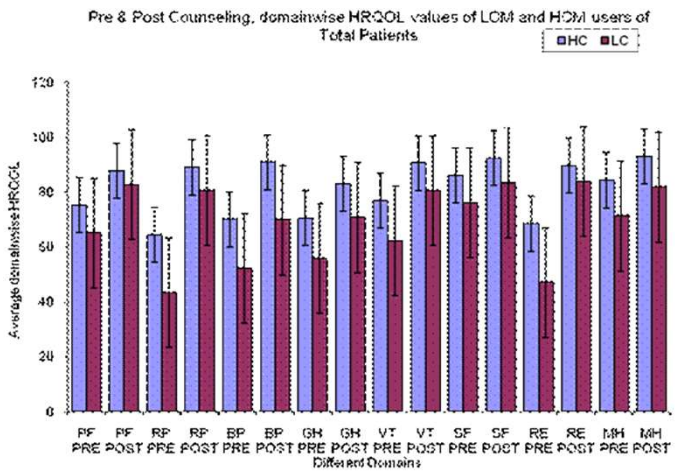

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Qualitative data

- Nominal scale
- Ordinal scale
- Interval scale
- Ratio scale
- Qualitative data must be transformed into quantitative data, as much as possible, by adopting gradation scales.

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Psoriasis Area and Severity Index (PASI) score

- The Psoriasis Area and Severity Index (PASI) was developed by **Fredriksson and Pettersson** in 1978.
- Both intensity and extent (BSA) of the psoriatic plaques are calculated separately for **four anatomical regions** (head, trunk, upper and lower extremities).
- The **intensity** of **erythema or redness, desquamation or scaling and induration or thickness** is rated on a **5-point scale** with 0 indicating no involvement, 1 slight, 2 moderate, 3 severe and 4 very severe characteristics

PASI Score calculation

Psoriasis Area Severity Index (PASI):

- The **percentage of involvement** of the four anatomical regions is assigned a numerical value of 0–6 with 0 indicating no involvement, 1 = 1–9%, 2 = 10–29%, 3 = 30–49%, 4 = 50–69%, 5 = 70–89% and 6 = 90–100% BSA involvement.
- The PASI score varies from 0 to 72. Higher scores indicate severer conditions.
- The area-wise percentage involvement (A) of the involved sites was calculated using the following formula:

PASI = 0.1 (Eh + Ih + Dh) Ah + 0.2 (Eu + Iu + Du) Au + 0.3 (Et + It + Dt) At + 0.4 (El + Il + Dl) Al.

PASI SCORE Calculation

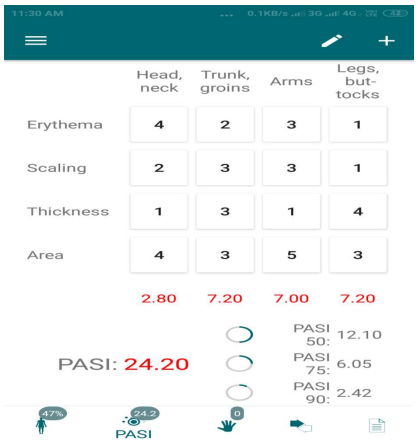

Figure 1.8: Showing total PASI score obtained after data was completely given with four severity levels of erythema (Redness) of skin

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A.U.College of Pharmaceutical Sciences

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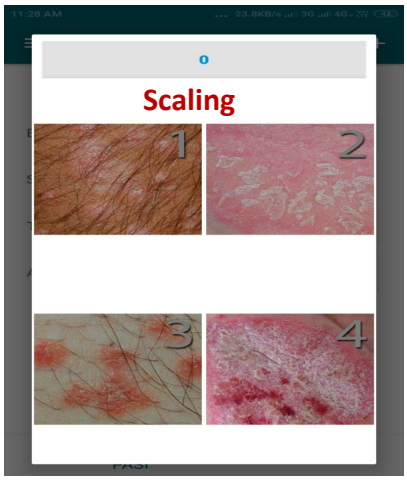
PASI SCORE Calculation



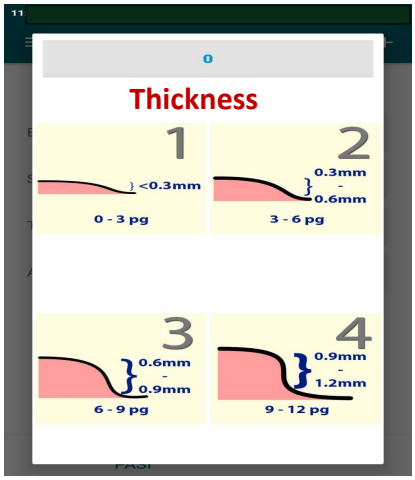


Figure 1.9: Showing total PASI score obtained after data was completely given with four severity levels of scaling and induration (Thickness) of psoriatic skin.

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Odds ratio-Triglycerides

Study population	TG ≥150 mg/dL	TG < 150 mg/dL	Total	Risk	Odds
Psoriasis group	102	30	Total	Risk	Odds
Control group	55	77	132	0.77	3.4
Total	157	107	132	0.42	0.71

Odds ratio	**4.76**
Relative Risk	1.85
95 % CI:	2.7898 to 8.1216
z statistic	5.724
Significance level	**P <0.0001**

Table 1.4: Odds Ratio (OR) and relative risk (RR) for serum TG in cases and controls

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Aim and objectives

Aim

This study aims to assess health-related quality of life, anxiety & depression among patients with RA.

PRIMARY OBJECTIVE:
To evaluate prevalence of anxiety,
Prevalence of depression
& HRQoL in RA patients

SECONDARY OBJECTIVE:
To Identify factors that influence depression

Socio-Demographic factors like Age and Sex

Disease activity in RA patients

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SOURCE OF DATA

- SF-36 Scale, The Short Form (36) Health Survey is a 36-item, patient-reported survey of patient health
- The Hamilton Rating Scale for Depression HAM-D, Hamilton Anxiety Rating Scale (HAM-A)
- DAS-28 Disease Activity Score-28 for disease severity VAS

SAMPLE SIZE

- In the present study the total sample size was 50 subjects suffering with rheumatoid arthritis is selected

INCLUSION CRITERIA

- Subjects who have given informed consent and with proper compliance
- patients who are diagnosed with rheumatoid arthritis (RA active)
- Male or female of age greater than 18 years

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Writing the discussion

- Past tense
- Passive voice
- Avoid first person
- Don't start a sentence with a number.
- Use italics for Latin words.
- Write titles for tables and graphs in the proper way.
- Write references in Vancouver style.
- Work: was done
- Result: is shown

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Vancouver style

- In-text citation: when a researcher is cited, the source is given a number, 1,2,3-----
- We put the number in brackets, after the full stop, or write it as a superscript.
- Ex: results .....clearly proved this point.[3]
- Ex : results --- clearly proved this point. (3)
- Usually, colleges have a conventional format.
- The same format must be consistently followed throughout the thesis.
- Try to always give primary references.

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Vancouver style

- Sometimes, you attribute one statement to a number of workers; example: This argument is advocated by a number of authors. (1-3,6-8)

Or

- This argument is advocated by a number of authors. [1-3,6-8]

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Reference from a journal

Format:

- Author AA, Author BB, Author CC, Author DD. Title of article. Abbreviated title of journal. Date of publication YYYY Mon DD;volume number(issue number):page numbers.
- Example:
- 192. Boudad H, Legrand P, Lebas G, Cheron M, Duchêne D, Ponchel G. Combined hydroxypropyl-β-cyclodextrin and poly(alkylcyanoacrylate) nanoparticles intended for oral administration of saquinavir. **Int J Pharm**. (2001); 218:113-24.

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Thesis

- Author AA. Title of thesis [dissertation]. Place of publication: Publisher; Year of publication. Page numbers.

Text book

- Author AA. Title of book. Edition [if not first]. Place of publication: Publisher; Year of publication. Pagination.

Website

- Author / organization name. Title of the page [Internet]. Place of publication: Publisher; Date or year of publication [updated YYYY Mon DD; cited YYYY Mon DD]. Available from: URL
- Write the date on which you accessed the web site.

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Reference styling softwares

- Mendeley
- EndNote
- Readcube
- Citationsy
- RefWorks
- CiteULike
- Zotero

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Interpretation

- Bring out the inner meaning of your results.
- Do not make statements without support of proof.

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Comparison with past work

- The results and conclusions of the present work must be compared with previous literature.

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Expectations from the students

Skills in:

- Data collection
- Reporting
- Accurate description of published work of others
- Recording the findings in an impartial manner
- Analysis
- Interpretation

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Observational / Interventional

- Research in clinical/community pharmacy/ hospital pharmacy settings may belong to one of the following categories
- Observational
- Interventional
- Archival

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Observational

- In this type of research, the researcher makes an observation of some feature or parameter or aspect in the subject being studied.
- The researcher does not cause any change in the treatment or cause any manipulation of any variable.
- Researcher merely follows the subjects in the study and records the required observations.
- Example: patients' weight or height or blood glucose level or time taken for recovery from an injury or the diameter of an injury – are measured by the researcher and recorded. These are the results in the research.

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Interventional

- Research involves some manipulation of a variable.
- Researcher causes some change in the condition of the patient and records the result of the change.
- Ex: Study involves taking anaemic patients, recording their haemoglobin, giving them oral iron supplements for two months, and finding their haemoglobin level again.

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DESIGN:
Interventional parallel and longitudnal study

- It is a parallel study, because patients are divided in to 2 groups and given with Chlorpheniramine maleate 4 mg and Cetrizine 10 mg.
- It is a longitudinal study, because patient data is collected repeatedly over a period of time.

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Observational	Interventional
Researcher does not cause any change in the subject	Researcher causes some change in the subject or tries the effect of a change in some variable or gives "treatments"
There is no assignment of subjects, as there are no different "treatments"	Subjects are assigned (by randomization) to different "treatments"
Researcher takes as subjects of already existing different classes of patients	Researcher takes a single set of subjects, classifies them into groups (by randomization), and assigns one treatment to one group

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Observational	Interventional
Results or observations depend on many reasons or causes upon which researcher has no control	Results or observations can be clearly assigned to the treatments given
Appears to be a "weak" method of research	A clearly robust method of carrying out research
Safe to the subjects and safe to the researcher	To be carried out by qualified health care workers who can face and intervene in all unexpected situations

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Observational	Interventional
Study of control in BP in two groups of patients, each group taking a different drug as per their doctor's prescription	Randomized clinical trials
Study of effect of patient counseling on a group of diabetic patients	Taking a set of post- operative patients, categorising them into three groups and studying on them effects of stopping antibiotic after two days, four days and six days
Hypomagnesemia in type 2 diabetes mellitus and its relation to glycemic control	Comparing the effect of selected "antihypertensive drugs" (angiotensin converting enzyme inhibitors and angiotensin receptor blockers) on hyperglycemia in "type 2 diabetic patients"

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- **It is always advisable for Pharm D students to undertake observational studies only.**
- They are safe and the Ethics Committee also gives approval as there is no intervention planned with the subjects.
- Small interventions, such as, giving patient counseling, giving fruit juice to the subjects (technically they make the study experimental), may be accepted by the Ethics Committee.

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Archival study

- Archival study is a study involving the records of some event/ patients/ institution which are already there in the office.
- This type of studies are undertaken by health departments to understand the patterns in the occurrence and treatment of a disease.
- Ex: study of effect of gender on the recovery time period from a particular disease

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Archival study

Advantages

- It does not involve subjects, so can be done in one's own time, no constraints
- Any record can be checked any number of times.

Challenges

- Patient records are confidential and concerned health department may refuse permission
- Ethics committee may refuse permission
- Patients concerned may not like someone going through their records

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Types of study Designs

- Case study
- Case series
- Cohort study
- Case control study
- Randomized Clinical Trial
- Cross-Sectional Studies: Carried out at a point of time
- Prospective studies: planned into future
- Retrospective studies: studies on past events

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Case study, case series

Case study

- A study involving a case which is very special.

Case series

- Study of occurrence of a strange type of ,unknown so far type of disease in a few patients.
- AIDS as a disease emerged as a result of reporting of a case series

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Type of study

- It is better for Pharm D students to do observational or archival studies.

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Drug utilization review

- We select a drug or a therapeutic area for utilization review
- Standards of use are determined
- Data collection sheet is prepared and data is collected
- Current prescribing data is collected
- Data is analysed
- Practice is compared with the standard
- Intervention recommended if necessary

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Pharmacoepidimeology

- Studies the patterns of drug use or drug taking behavior in populations
- Medication adherence
- Drug Interactions
- Predictable ADRS
- Sources of data: Medical records, data bases, national data bases coming from national surveys, records of medical shops, published clinical trial data

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- These can be archival, observational or interventional studies
- Involves plotting data over time, descriptive statistics

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Pharmacovigilance

- Studying Adverse drug reactions

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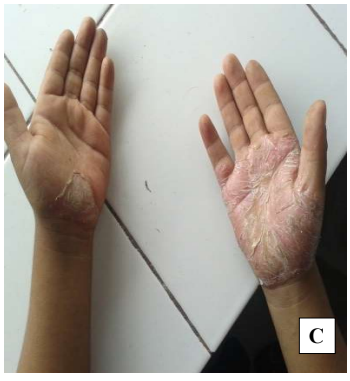
Images of patients with *Psoriasis vulgaris*



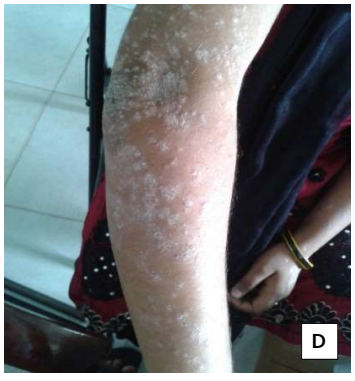


Figure 1-C. A male patient with scaly psoriatic lesions on the palms of both hands and

Figure 1-D. A female patient showing typical psoriatic skin lesions on her Right elbow

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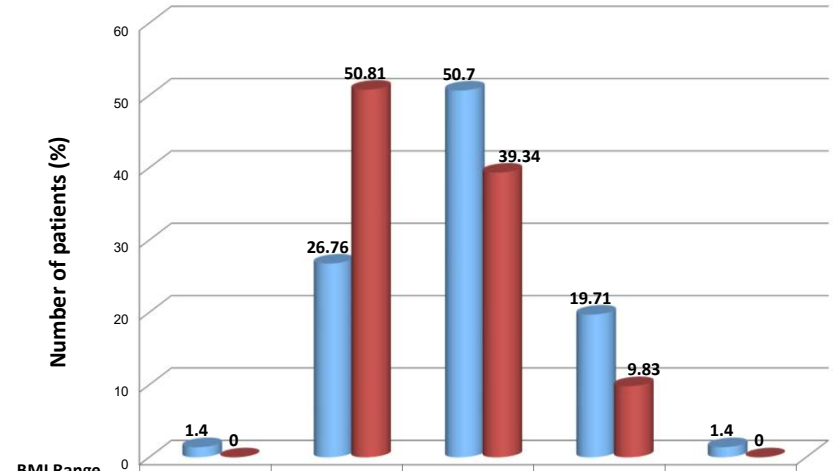

BMI Range	<18.5	18.5-24.9	25-29.9	30-34.9	35-39.9
MALES(N=71)	1.4	26.76	50.7	19.71	1.4
FEMALES(N=61)	0	50.81	39.34	9.83	0

Figure 3.1: Gender-wise distribution of BMI in psoriasis group

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Pharmacoeconomics

- Cost benefit Analysis
- Cost minimization analysis
- Cost effectiveness analysis
- Cost benefit ratio

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Outcomes Research

- Quality of Life Assessment
- SF-36

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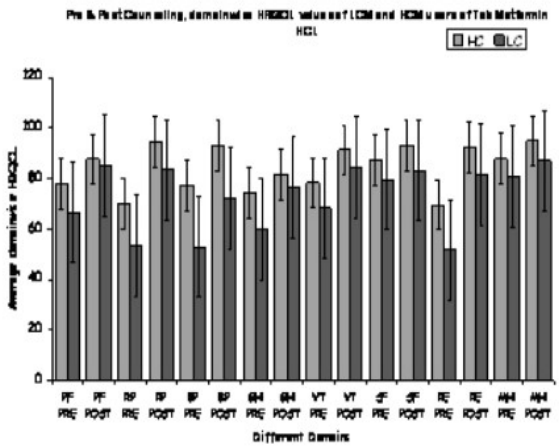
Comparative analysis



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Avoid these errors

- Represent your results in logical order
- Clearly find out where you have to use percentage values and where you have to compare actual numbers.
- Do not use instruments like quality of life scores or questionnaire which are under copyright, without author's permission
- Do not write patients' names in the thesis.

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Contribution to the society

- Every project must have contribution to the society in one way or another.

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References

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Thank you

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