



# A SINGLE BLIND CLINICAL TRIAL TO EVALUATE THE SAFETY AND EFFICACY OF COMPOUND UNANI FORMULATION IN MANAGEMENT OF DAUS' SADAF (PSORIASIS)

DR. SYED SOFIAN AHMED<sup>1</sup>, PROF. MOHAMMED AHSAN FAROQUI<sup>2</sup>, DR. ABDUL LATEEF SIDDIQUI<sup>3</sup>

1. P.G Scholar, Gntc, 2. P.G Professor Gntc, 3. Assistant Professor, Gntc  
Department of Moalijat (General Medicine)  
Government Nizamia Tibbi college, Charminar, Hyderabad, T.S

## ABSTRACT

### Background and Objective:

**Daus'sadaf/ Taqashur-e-jild**, Psoriasis is one the common diseases of the skin, It is characterized by having sharply demarcated scaly red, coin-sized skin lesions most often on the elbows, knees, scalp, hands and feet. Symptoms include itching, irritation, stinging and pain. Signs to diagnose psoriasis are Koebner phenomenon and Auspitz's sign, There are two key factors which play a important role in Aetiology of psoriasis, 1. Autoimmune: - Naïve t cells, il12 & il23, 2. Genetic factors: - family history found Upto 30%.

However the **Daus'sadaf** commonly developed for those who has losed their body immunity or Quath-e-Muddabir-e-Badan (Defensive Mechanism) due to abnormal maintenance of "Sitta Zarooria" many caused alternate the Tabiyath (immunity) and abnormal changes will take place in the humorous and temperament. In Unani concept their might be accumulation of abnormal Sauda and Safra Mutahirqa (jala huwa safra) into the skin, Hence the objective of the study is to Relief nature of the disease through Unani medicine.

**Methods: -** The study was designed as A Single Blind clinical trail with a sample size 40 patients

❑ **Joshanda:**-21 days

Beeq-e-azkhar, Beeq-e- badiyan, Beeq-e-kibr, Beeq-e-karafs, Beeq-e-kasni, Charaita, Shahitra, Aftimoon, Bisfaj, each 5 grams (OD Dose Before meals 21 days)

❑ **Musafiyat:**-30 days

1. Qurs-e-sartaan kafoori, one tab BD (after food)
2. Arq-e-murakab musafi khoon, 60ml BD (after food)

❑ **Zimad Drugs (Local application):** During whole duration of treatment.

Ashaq 5 grams, Muqil-e-arzaq 5 grams, Zarvand mudharij 5 grams, Roghan-e-gul 20 ml, Moom-e-zard 20 grams

Apply zimad for a period of (51) days and response of treatment observed, First follow up after using 21 days joshanda (decoction) and then follow up for every 15 days, and noted in the case sheets. Similarly the treatment and response of the lesions measured by PASI Score and Data Analysed statically.

**Result:-** In this present clinical study of psoriasis the maximum response out of (40) cases, (24) patients i.e. 60% patients got good response, the satisfactory patients were (10) i.e. 25% and poor response patients were (6) i.e. 15%. P value is <0.0001\*.

**Interpretation and Conclusion:-** The study revealed that usage of this Unani medicine got good response in decreasing the sign and symptoms of psoriasis like redness, thickness, itching, and scales. No clinical significant side effects were observed in this study; these results conclude that the drugs used in this study are easily available, safe and effective.

**Key words:-** Koebner phenomenon, Auspitz's sign, Quath-e-Muddabir-e-Badan, Sitta Zarooria.

## INTRODUCTION

### **Daus'sadaf/ Taqashur-E-Jild (Psoriasis):**

The Word Psoriasis Comes From A Greek Word "Psora" Which Means Being Itchy And "Iasis" Means Condition<sup>1</sup>. It Is Characterized By Having Sharply Demarcated Scaly, Red, Coin-Sized Skin Lesions. Most Often On the Elbows Knees, Scalp, Hands and Feet. Symptoms Include Itching, Irritation, Stinging And Pain. Rarely, The Entire Skin Surface Of The Body May Be Involved<sup>2</sup>. Signs to Diagnose Psoriasis Are Koebner phenomenon<sup>3</sup> And Auspitz's Sign<sup>4</sup>. In Unani Concept Our Ancient Physician Suggest In **Daus'sadaf/ Taqashur-E-Jild** There Might Be Excess Accumulation Of Abnormal Sauda And Safra Mutahirqa (Jala Huwa Safra) Into The Skin. There Are Two Key Factors Which plays an important Role in Aetiology of Psoriasis.

1. Autoimmune: - Naïve T Cells, IL12 & IL23<sup>5,6</sup>,

2. Genetic Factors: - Family History Found Upto 30%<sup>5,6</sup>.

It Is Universal In Occurring, Incidence Is 1 To 3 % Of The World Population (As Per W.H.O Report), Prevalence Ranges Upto Between 0.09 – 11.43 % (As Per W.H.O Report)<sup>7</sup>, It Effects Either Sex Usually 3<sup>rd</sup> Decade Of Life<sup>8</sup>.

In Modern System Of Medicine The Treatment Of Psoriasis By The Use Of Systemic Agents Inclusive Of Retinoid Or Immune Suppressive Including Ciclosporine, Applying Topical Retailers Which Includes Emollients, Corticosteroids, Diet D Agonists Or Vulnerable Tar Or Dithranol Arrangements And Ultraviolet Remedies Which Include Puva And Ultraviolet B Which Not Only Causes Side Effects Like Renal, Hepatic Toxicity, Suppressing The Immune System But Also Leads To One Of The Causative Factors For The Development Of Skin Cancer<sup>9</sup>. Hence An Alternate System Of Medicine Like Unani Can Be Used For The Treatment Of Psoriasis As Various Drugs Possesses The Functional Properties Like Muhallil, Munjiz E Akhlat E Galiza, Mussaffi Khoon Etc. Which Are Safe As Well As Effective.

As These Formulations Have Important Functional Properties Like Munzij E Akhlat E Galiza, Musaffi Khoon Etc, As Mentioned In The Unani Texts, Are Selected For The Treatment Of Psoriasis.

### Aim And Objectives Of Research

- To Evaluate The Safety And Efficacy Of Compound Unani Formulation In Cases Of Psoriasis.
- To Relief Nature of the Disease through Unani Medicine.

### Historical Background

- ✓ In The Egyptian Papyrus (300 BC), Hippocratic Descriptions (460-377 BC) 1, 2, 3 Similar Features Are Mentioned But As A Curse of Divine Forces. Even On Commentary Of Bible (70 Ad) It Is Described As A Leprotic Manifestation And Even Up To Middle Ages All Chronic Scaling Conditions Were Considered Leprosy In Either Way<sup>10,11</sup>.
- ✓ Hippocrates And His School (460-377 BC) Provided Meticulous Description Of Many Skin Disorders 1, 2. In Their Description, Dry Scaly Eruptions Were Grouped Together Under The Heading Of "Lopoi". This Group Probably Included Psoriasis And Leprosy<sup>10,11</sup>.
- ✓ Between 129 And 99 BC The Word "Psore" (Meaning Desquamatic Condition) Was First Used By Scholars For Eyelid Corner Of The Eyes And Scrotum With Excoriation And Pruritis, Though He Called Psoriasis But Probably It Was A Type Of Eczema, And Until The Psoriasis Was Recognized As Entity Distinct From Leprosy.
- ✓ In All Ancient Texts It Is Described Either With Leprosy Or With Chronic Skin Presentations Such As Scaling And Chronic Itching And It Is Always Intermingled With Eczema Particularly Dry Eczema Or A Lichenified Or Parchmentised Lesion. But As The Fundamental Medical Knowledge Evolved, The Terminology Of Disease Became More And More Objective; It Was Similar In Case Of Psoriasis.
- ✓ Dry White Scales Over the Effected Parts With Talc (Abrak) Was Termed By Eminent Unani Physician [98-171 Ad] As "Talaq" Rhazes (Razi) (850- 731 Ad) Has Given More Profound Description Of Disease Presentation And Even The

Management Under The Heading Of Taqashur-E-Jild<sup>14</sup>.

- ✓ The Description Of Ibne Rushd (1126-1198 Ad) Is Also Important Particularly In Terms Of Pathognomonic Features Which Are Due To Excessive Abnormal Black Bile<sup>13</sup>, But He Has Described The Disease As A Variety Of Leprosy
- ✓ The Greek Physicians Like Akbar Arzani (1722 Ad) And Azam Khan (1813-1902 Ad) Have Given Vivid Description Under The Headings Of Taqashure-Jild And Qashf-E-Jild Was Taqasshur-E-Jild<sup>12</sup>. The Treatise of Azam Khan, Ekseer-E-Azam, Is A Great Milestone And Torch Bearer For The Understanding Of The Disease Relatively In More Objective Way.

#### **Unani Concept**

- ✓ **Daus'sadaf / Taqashur-E-Jild (Psoriasis)** Is One The Common Diseases Of The Skin, It's Far Characterised With The Aid Of Having Sharply Demarcated Scaly, Red, Silvery Skin Lesions Most Usually At The Elbows, Knees, Scalp, Hands And Feet. It Has Multi Factorial Etiology 1-2% Of The Overall Population Are Usually Affected.

#### **Synonyms:**

Urdu: Chambal<sup>16,17,18,19</sup>

Arabic: Daus'sadaf<sup>16,17,18</sup>

English: Psoriasis

- ✓ The Historical Physicians of Their Proper Books It Is Stated That the Psoriasis Is Likewise Known As "Taqashur-E-Jild".
- ✓ Similarly, It Is Far Noted That The Word Of Psoriasis Derived From Greek: "Psora" Method "Itch" "Sis" Means Movement Or Circumstance.
- ✓ They Also Referred To Numerous Terms In Unani As According To The Pathological Lesions And Type. Those Are-
  1. Taqashur-E-Jild<sup>12,13,14</sup>
  2. Daus'sadaf<sup>16,17,18</sup>
  3. Chambal<sup>16,17,18,19</sup>
  4. Qooba-E-Muteqasharra<sup>20,21</sup>
  5. Qashaf-E-Jild<sup>12,21</sup>

#### **Pathogenesis (Unani):**

- ✓ The Tabaith (Immunity) Or Human Nature Relies Upon On.
  1. Anasir (Factors) 2. Mijaz (Temperament) 3. Humours (Body Fluids) 4. Aza (Organs) 5. Arwa (Pneuma) 6. Qua (Faculties Of Electricity) Those Are The Six Factors Chargeable For The Existing Of The Human Body And Preserve Of The Fitness. The Lose Of Any Or The Lose Of "Sittazarooria"
    1. Hawa (Atmospheric Air)
    2. Makul Vo Mashroob (Foods And Drinks)
    4. Harkath-O-Sukoon Badni (Bodily Or Body Actions And Repose)
    4. Harkath-O-Sukoon Nafsani (Intellectual & Psychic Actions And Repose)
    5. Naum-O-Eqza (Sleep Wakefulness)
    6. Istefaragh-E-Ihtebas (Evacuation and Retention) Then The Tabaith (Immunity) Becomes Weak.
- ✓ Moreover, In Line With Hippocrates the Human Frame Contains (Four) Important Sort Of Akhlath (1). Dam (Blood) (2) Balgham (Phlegm) (3) Safra (Yellow Bile). (4), Sauda (Black Bile) All These Fluids Include After The Ordinary Mixing Or Arkhan In Line With Qualitative And Quantitative Blending Of Which (Homeostatic) Constitute Fitness And Un Proper Share And Irregular Distribution According To Their First-Class And Amount Constitute Disorder. Therefore, It's Miles Called Abnormal -Tabiyah (Odd Immunity).
- ✓ However, Then The Tabiath Is Atypical The Defensive Mechanism Of The Frame Is Lost For A Specific Person Furthermore Ibn-E-Sena Stated That Each And Absolutely Everyone Has Been Given A Selected "Mijaz" (Temperament) Which Isn't Shared By Different Man Or Woman. So, Such People Affected From Numerous Kinds Of Diseases Who Have Lose Of Their Body Immunity. And The Environment Dealers:
  1. Al-Bilad (Geographical Situation) 2. Al-Masakin (Residential)
  3. Al-Senath (Occupational) And Their Associated Sellers May Additionally Reason Increase For Chronicity Of Disease.
- ✓ On This Daus'sadaf Is The Atypical Blending Of Black Bile (Sauda) And Yellow Bile (Safra) Can Also Motive Effected The "Bashra" (Pores And Skin) And Inflammatory Modifications Has Been Advanced With Swelling, Black Shade Redness With Dry Silvery Vivid Scales And It May Be Developed In A Specific A Part Of The Frame Inclusive Of Scalp, Joints, Folds And Many Others Or There Might Be A Generalized Psoriatic Lesion May Be Advanced Through The Body Consisting Of Gonads And Many Others. And It Seems Like Geographical Maps.
- ✓ "Ibn-E-Zohravi" Said That When The Black Bile Expanded In Quantity And Fine May Also Evolved Taqashur-E-Jid / Daus'sadaf. Every Other Physician Mohammed Tabri Described That The Dryness Of The Lesion Of Psoriasis Reason Extra Abnormal Black Bile And It Is Also Referred To As "Rutubath-E-Mohetarika" (Oxidized Black Bile)<sup>12</sup>.
- ✓ "Ali Bin Abbas Majosi Describe That Mixing Of Phlegmatic Substance Within The Blood May Also Triggered Formation Of Silvery Bright Scales On The Lesion And Itching<sup>15</sup>.
- ✓ Concluding It Is Said That Whenever Pleasant And Quantity Of "Sauda" Accelerated The Blood Temperament Of The Frame Altered And Additionally Altered The Diverse Styles Of Hormonal And Enzymatic Secretion And Also Secrete The "H" Like Substance (Balghami Madda) And Seeking To Dispose Of Causative Substance Of "Daus'sadaf And Gathered The Floor Of The Skin With Dry, Silvery, Vivid Scales.

#### **Aetiology**

- There Are Two Key Factors Which Play A Important Role In Aetiology Of Psoriasis
- 1. Autoimmune: - Naïve T Cells, IL12 & IL23
- 2. Genetic Factors: - Family History Found Upto 30%



- Hla-Bw17- High Familial Tendency
- Hla-Bw13- Appear To Have Mild Effects & H/O Streptococcus Infection
- Hla-Bw22- Strongly Associated With Psoriasis
- Hla-Bw38- With Exhibiting Psoriasis & Distal Arthritis<sup>22</sup>.
- Triggering Factors Includes: - Stress, Trauma, Allergens, and Medication Reactions.

### **Pathological Changes Of Skin**

- Many Changes Occur In The Skin<sup>23</sup>
- Epidermis: -
  - Acanthosis: - Increase Thickness of Stratum Spinosum & Granulosum Seen In Psoriasis.
  - Parakeratosis: - Nucleated Cells Seen Stratum Cornium
- Dermis: -
  - Capillaries Are Dilated, Twisted, And Closer to the Surface of the Skin.
  - Large Number Of Inflammatory Cells Are Present In All Layers Of The Skin.
  - Langerhan Cells And Lymphocytes Are Also Increased.
  - The Main Abnormality Is The Increased Epidermal Cell Turn Over.

### **Clinical Features**

- It Is Varying According To Type Of Psoriasis First Initial Symptom Is Red Spots On The Body, Pain, Itching.
- Well Defined Erythematous Plaque
- Silvery Scales/ White Scales over the Lesion.

#### Signs: -

- Auspitz Sign: - Removal of Psoriatic Scales Frequently Pin Point Bleeding From the Lesion<sup>24</sup>.
- Membrane Of Berkeley: - When The Scales Are Completely Scraped Off, The Stratum Mucosum Is Exposed And Is Seen As A Moist Red Surface Through Which Dilated Capillaries Can Be Seen As Red Spots.
- Candle Grease Sign: - When Lesion Is Scraped With The Point Of Dissecting Forceps, Candle Grease Like Scale Can Be Repeatedly Produce Even From The Non Scaly Lesion.
- Koebner's Phenomenon: - Appearance of Skin Lesions on Lines of Trauma<sup>25</sup>.

### **Types Of Psoriasis<sup>26</sup>**

- 1. Plaque Psoriasis
- 2. Guttate Psoriasis
- 3. Inverse Psoriasis
- 4. Pustular Psoriasis
- 5. Erythrodermic Psoriasis
- 6. Psoriatic Arthritis.

### **Plaque Psoriasis**

- Most Common Type Known As Psoriasis Vulgaris.
- It Is Appear As Raised, Inflamed Red Skin Covered By Silvery Patches Or Scales.
- Site: - Elbow, Knee, Scalp, Lower Back, Hands And Feet.

### **Guttate Psoriasis**

- Characterized By Eruption Of Small 0.5 To 1.5 Cm In Diameter.
- Manifests at Early Age.
- Site: - Upper Trunk And Proximal Extremities
- Streptococcal Throat Infection Frequently Proceeds.

### **Inverse Psoriasis**

- Localized In The Major Skin Folds, Such As Axilla, Inguinal And Sweating Areas.
- Scaling Is Usually Minimal Or Absent And The Lesion Appears Glossy, Smooth & Bright Red.
- Commonly Seen In Obese Client.

### **Pustular Psoriasis**

- It Is Uncommon Mostly Appear In Adult.
- It Appear As Pus Filled Lesion Surrounded By Red Skin.
- Site:- Hands & Feet
- It Is The Serious Condition In All Type Of Psoriasis.

### **Erythrodermic Psoriasis**

- The Disease Affects All Body Sites.
- Erythema Is Most Prominent Features With Superficial Scaling/ Peeling That May Appear Like Burning.

### **Psoriatic Arthritis**

- This Condition Involves Both Skin And Joints.
- Commonly Involves Fingers, Hands, Toe, & Feet.
- Nail Psoriasis: -
- Commonly Seen In Psoriatic Arthritis.
- It Appears As Pitting Small Bit Nail, Yellow Brown Nail, Tender & Painful Nail With Chalk Like Debris Built Under The Nail.

### **Method Of Management And Unani Treatment**

Causative Factors Which Are Chiefly Responsible For Producing The Disease Should Be Treated<sup>27</sup>.

As Seasonal Change Have Direct Effect On Remission & Exacerbation Of Psoriasis. Similarly Food, Drinks, Stress Are The Causative Factors For The Disease, Six Essential Factors (Asbab-E-Sitte Zarooriya) Has To Be Well Maintained Like Hawa (Atmospheric Air). Makool-O-Mashroob (Food And Drinks), Naum-O-Yagza (Sleep And Wakefulness), Harkath-O-Sukoon-E-Badni (Physical Activity & Rest), Harkath-O- Sukoone Nafsani (Psychological Activity And Rest)<sup>28</sup>. Psoriasis Can Be Treated With Following Method Of Treatment.

1. Llj Bil-Ghiza (Treatment With Diet)
2. Llj Bil-Dawa (Use Of Medicine)
3. Llj Bil-Tadbeer (Regimental Therapy)
4. Maj Bil-Ghiza (Treatment With Diet)

The Psoriasis Diet Is Based On The Idea That Eating Particular Foods Imitates The Intestinal Tract, And Causes Excessive Yeast To Develop. The Yeast Interferes With The Body's Ability To Absorb Vital Nutrients And Toxins Enter The Body. The Toxins Then Trigger The Auto-Immune System Which Ultimately Results In Outbreaks Of Psoriasis<sup>29</sup>.

### **Methodology:**

The Present Study Entitled "A Single Blind Clinical Trial to Evaluate the Safety and Efficacy of Compound Unani Formulation in Management of Daus' Sadaf (Psoriasis)" Was Carried Out In O.P Dept. Of Moalijat, Govt. Nizamia General Hospital.

Total Clinical Trials Conducted on 40 Selected Patients Of psoriasis Under the Age Of 18- 60 Years.

**Inclusion Criteria:**

- Both Sexes
- Patient With Symptoms Like
  - i. Erythema,
  - ii. Itching,
  - iii. Thickening And
  - iv. Scales.
- And With Auspitz Sign (Positive)
- Duration: - Patient Suffering From Psoriasis within 1 Year.

**Exclusion Criteria:**

- Pregnant & Lactating Women
- Patient Suffering From Psoriasis More Than 1 Year.
- Uncontrolled Dm
- Co-Morbid Condition Like Cardiac, Respiratory, Renal Disorders And Carcinomas
- Mentally Retard Patients.

**Withdrawal Criteria:**

- Patient Who Are Not Follow Up Properly.
- Patients Showing Sensitivity towards Drugs.
- Patients Who Are Not Follow Dietary Instructions.

**Laboratory Investigations:**

- Complete Blood Picture
- Erythrocytes Sedimentation Rate
- Random Blood Sugar
- Liver Function Test
- Renal Function Test
- C- Reactive Protein
- Absolute Eosinophilic Count

**Selection of Patients:**

Patients Already Diagnosed With Psoriasis As Well As Those With Sign And Symptoms Of Psoriasis Are Taken For Research Work. The Patients Are Advised For Laboratory Investigations And Then Selected According To Inclusion And Exclusion Criteria By Randomization. During Selection Procedure The Patient's Present Complaint, Present And Past History, Family History, Drug History, Social History Are Thoroughly Studied And Noted On The Case Sheet. The Patient's General, Local, Systemic And Vital Examination Is Performed And Noted On The Case Sheet.

**Parameters:**

PASI Scale

**Study Design:**

Single Arm Study.

**Sample Size:**

Sample Size Was Fixed As 40 Patients

**Allocation of Patients into Groups:**

A Total of 40 Patients Were Allocated

**Duration of Protocol:**

The Duration of Protocol Is 51 Days

**Observation and Follow Up:**

First Follow Up After Using 21 Days Joshanda (Decoction) And Then Follow Up For Every 15 Days.

**Criteria for Selection of Drugs**

Decoction, Musafiyat And Zimaad Are Selected For The Study. These Drugs After Through Examination Of Their Quality.

**Decoction Formula Contains:**

- Beeq-E-Azkhar, 5 Grams
- Beeq-E- Badiyan, 5 Grams
- Beeq-E-Kibr, 5 Grams
- Beeq-E-Karafs, 5 Grams
- Beeq-E-Kasni, 5 Grams
- Charaita, 5 Grams
- Shahitra, 5 Grams
- Aftimoon, 5 Grams
- Bisfajj, 5 Grams

**Method Of Preparation:** The Entire Above Drugs Are Soaked In 250 ml Of Water Over Night And Boiled In Morning So That The Water Becomes Half Of Its Volume I.E., 125ml, Then The Drugs Were Filtered And Cooled Then The Joshanda (Decoction) Is Taken Orally In The Morning Before Meals.

Same Procedure Repeated Every Day For 21 Days.

**Musafiyat: - 30 Days**

3. Qurs-E-Sartaan Kafoori, One Tab Bd (After Food)
4. Arq-E-Murakab Musafi Khoon, 60ml Bd (After Food)

**Zimad Drugs (Local Application):** During Whole Treatment

Ashaq 5 Grams, Muqil-E-Arzaq 5 Grams, Zarvand Mudharij 5 Grams, Roghan-E-Gul 20ml , Moom-E-Zard 20 Grams.

**Method Of Preparation Of Ointment:** Ushaq, Muqil Arzak, Zaravand Mudhiraj Are Boiled In A Roghan E Gul Until Are The Drugs Get Totally Dissolved And Then Add Mom E Zard And Stirrer Until It Get A Ointment Form.

Name Of Drug	Unani Name	English Name	Botanical Name	Temperament	Action	Chemical Constituents	Dose
Beeq-E-Azkhar	Azkhar	Lemon Grass	Cymbopogon Schoenthus	Hot, Dry (2, 3)	Nervine Stimulant, Anti Inflammatory, Astringent, Anti Convulsant, Concoctive Of Phlegm, Yellow And Black Bile.	Monoterpenes, Piperitone, Geraniol.	5grams

<b>Beeq-E-Badiyan</b>	Badyaan	Fennel	Foeniculum Vulgare	Hot, Dry (2 <sup>nd</sup> Degree)	Hepatoprotectant, Antispasmodic, Concoctive Of Phlegm, Anti Inflammatory, Carminative, Galactagogue.	Coumarins, Flavinoids, Ascorbic Acid, Sterols.	5grams
<b>Beeq-E-Kibr</b>	Kibr	Caper Bush	Capparis Spinosa	Hot, Dry (2 <sup>nd</sup> Degree)	Deobstruent, Anti Inflammatory. Demulcent, Diuretic, Emmenagogue, Carminative.	Myristic Acid, Stearic Acid, Palmitoleic Acid.	5grams
<b>Beeq-E-Karafs</b>	Karafs	Celery	Apium Graveolens	Hot, Dry (2 <sup>nd</sup> Degree)	Deobstruent, Diuretic, Carminative, Liver tonic, Anti Inflammatory.	Alkaloids, Glycosides, Tannins, Furocoumarins, Apiumoside.	5grams
<b>Beeq-E-Kasni</b>	Kasni	Chicory	Cichorium Intybus	Hot, Dry (1, 2)	Hepato-Tonic, Blood Purifier, Diuretic, Laxative, Astringent.	Glycosides, Flavanoids, Cichoriosides, Cichoriolides.	5grams
<b>Charaita</b>	Chiratia	Indian Gentian	Swertia Chirata	Hot <sup>2</sup> , Dry <sup>2</sup>	Anti Helmentic, Antipyretic, Laxative, Galactagogue, Blood Purifier	Chiraita Contains Two Intensely Bitter Principles Ophelic Acid And Chiratin, Both Amorphous And Indistinctly Crystalline Yellow Substance. Tannin Is Absent	5grams
<b>Shahitra</b>	Shahitra	Fumitory	Fumaria Officinalis Linn	Dry <sup>2</sup> , Moderate Hot And Cold	Diuretic, Blood Purifier, Antipyretic	Protein, Alkaloid, Sugar, Lognin, Sodium, Potassium, Magnesium, Calcium	5grams
<b>Aftimoon</b>	Aftimoon	Codder	Cuscuta Reflexa Roxb	Hot <sup>2</sup> , Dry <sup>2</sup>	Purgative, Astringent, Expectorant, Carminative, Aphrodisiac, Diaphoretic, Anti Helmentic, Diuretic	Scoparone, Melanettin, Quercetin, Hyperoside, Dulcitol, Leutolin, Cuscutin, Cuscotalin, Bergenin, Kaedmpferol, Amarbelin, Beta Sitosteol	5grams



<b>Bisfajj</b>	Bisfajj	Common Polypody	Polypodium Vulgare Linn	Hot2 Dry1	Melanagogue And Phelmagogue	Resins Tannins, Steroid, Flavonoids, Alkaloids, Glycosides, Protein, Reducing Sugars, Iron, Calcium Magnesium, Potassium, Sulphur,	5grams
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### For Local Application

<b>Ushaq</b>	Ushaq	Gum Ammonia	Dorema Ammoniacum	Hot2, Dry1	Effective In Diseases Of Joints, Nervine Tonic, Potent Diuretic, Resolvent In Case Of Swellings And Tumours.	Ammoresinol, Salicylic Acid, Butyric Acid, Doremin, Ammodoremin.	3-5 grams
<b>Muqil Arza</b>	Muqil	Mukul, Oleo Gum	Commiphora Wightii	Hot2, Dry2	Effective In Various Phlegmatic Disorders, Demulcent, Anti Inflammatory,	Steroids, Guggulsterol, Guggulsterone, Myrecene, Allylcembrol.	3-5 grams
<b>Zaravand Mudhiraj</b>	Zaravand	Indian Birthwort	Aristolochia Rotunda	Hot2, Dry3	Anti Inflammatory, Hepatoprotectant, Resolvent (Particularly In Disorders Of Liver And Spleen), Deobstruent.	Aristolamide, Aristolochic Acid, Aristolactam.	5-7 grams
<b>Roghan Gul E</b>	Roghan E Gul/ Gul E Surkh	Rose	Rosa Damascena	Cold, Dry	Anti Inflammatory, Cardio tonic, Hepatoprotective, Exhilarant, Purgative.	Glycoside, Flavanoids, Citronellol, Geranial, Hydrosol.	Upto 10 ml
<b>Mom Zard E</b>	Mom E Zard	Bees Wax	Cera Alba	Hot, Wet Or Moatadil / Equable	Anti Inflammatory, Sedative, Resolvent, Moisturizing And Exceptional Healing Properties.	Oleate Esters, Triacotanyl Palmitate, Cerotic Acid, Cetyl Stearate.	500-1mg Internally. 10-12 grams For External Use.

### Efficacy Assessment:

The Assessment of Efficacy Is Done With the PASI Score As Follows,

**Psoriasis Area And Severity Index (Pasi):** Frederickson And Patterson Created The Pasi In 1978 As A Method To Evaluate The Clinical Efficacy Of A New Treatment For Psoriasis<sup>30</sup>. When Using The Pasi Psoriatic Plaques Are Graded Based On Three Criteria Redness R, Thickness T, And Scaliness S. Severity Is Rated For Each Index On A 0-4 Scale (0 For No Involvement Up To 4 For Severe Involvement). The Body Is Divided Into Four Regions Compromising The Head (H), Upper Limbs (U), Trunk (T) And Lower Limbs (L). In Each Of These Areas, The Fraction Of Total Surface Area Affected Is Graded On A 0-6scale (0 For No Involvement Up To 6 For Greater Than 90% Involvement)<sup>31</sup>. The Various Body Regions Are Weighted To Reflect Their Respective Proportion Of Body Regions Are Weighed To Reflected Their Respective Proportion Of Body Surface Area. The Composite Pasi Score Can Then

Be Calculated By Multiplying The Sum Of The Individual Severity Scores For Each Region By The Weighted Area Of Involvement Score For That Respective Region And Then Summing The Four Resulting Quantities.

### Severity:

Psoriasis Is Usually Graded As Mild, Moderate And Severe. The Degree Of Severity If Generally Based On The Proportion Of Body Surface Area Affected, Disease Activity (Degree Of Plaque Redness, Thickness And Scaling) Response To Previous Therapy And Impact Of The Disease On The Person.

### Skin Section:

For The Pasi The Body Is Divided Into Four Sections Each Of These Areas Is Scored By Itself And Then The Four Scores Are Combined Into The Final Pasi. The Four Areas Are The Legs Which Have 40% Of Person's Skin, The Body (Trunk Area, Stomach, Chest, Back) At 30%, and the Arms At 20% And The Head At 10%. Area Measurement: For Each Skin Section the Amount of Skin Involved Is Measured As A Percent of the Skin Just In That Part of the Body (Not the Whole Body and Then Assigned A Score 0-6)<sup>32</sup>.

### Area Coverage Score

0%	0
<10%	1
10-29%	2
30-49%	3
50-69%	4
70-89%	5
90-100%	6

So If The Head Is 50% Covered The Area Score Of The Head -A Head Would Be 4. The Area Score For The Other Three Skin Sections –A Upper Limbs, A Trunk, A Lower Limbs, Are Calculated Accordingly.

### Severity Measurement:

The Severity Is Measured By Three Different Parameters, Erythema (Redness), Scaling And Thickness. Again Each Of These Is Measured Separately For Each Skin Section These Are Measured On A Scale 0-4 From None To Maximum According To The Chart.

None	0
Mild Some	1
Moderate	2
Severe	3
Maximum	4

So If the Head Psoriasis Only Somewhat Red E Head Score Would Be 1.

Likewise The S Head [Scaling Of The Head] T Head Are Calculated.

When All The 40 Of The Above Scores Are Figured Out We Are Ready To Calculated Pasi. For Each Skin Section, Add Up The Three Severity Scores, Multiply The Total By The Area Score And Multiply That Result By The Percentage Of Skin In That Section As Follows.

Head (E head + S head + T head) X Area Head X 0.1 = Total Head

Upper Limbs (E UI+ S UI+ T UI ) X Area UI X 0.2 = Total UI.

Trunk (E Trunk+ S Trunk+T Trunk) X Area Trunk X 0.3 = Total Trunk.

Lower Limbs (E LI + S LI + T LI) X Area LI X 0.4 = Total Legs.

Finally The Pasi Is Total Head + Total Upper Limbs+ Total Trunk + Total Lower Limbs That's It. This Pasi Will Range from 0 (No Psoriasis) To 96 (Covered Head To Toe With Complete Redness, Scaling And Thickness).

When Conducting A Clinical Trial For Treatment For Psoriasis. A Predetermine Primary Endpoint Is Required On Which The Efficacy Of The Drug Will Be Assessed This Endpoint Must Demonstrate That Patients Achieve Clinically Meaningful Success. Determining A Definition For "Clinically Meaningful Success" Is Somewhat Problematic In Psoriasis. For Patients With Severe Psoriasis, Clinicians Typically Consider At Least 75% Improvement In Disease To Be Clinically Meaningful Improvement Indicative Of Success. This Has Been Translated Into 75% Improvement In The Pasi Score; However, It Is Clear That Patients With Far Lower Improvement In The Pasi Score Also Can Have Clinically Meaningful Improvement In Their Disease, And There Is Strong Evidence Demonstrating That 50% Improvement In Pasi (Pasi 50) Is Also Clinically Meaningful Endpoint.

### Severity of Disease

PASI Score Ranges from 0-72.

Pasi <7 Mild Psoriasis

Pasi 7 To 12 Moderate Psoriasis

Pasi >12 Severe Psoriasis

Grading Redness (Erythema)	Grading Thickness (Induration)	Grading Scales
 <b>ERYTHEMA = 0</b> No Redness	 <b>INDURATION = 0</b> No Thickness	 <b>SCALING = 0</b> No Scale
 <b>ERYTHEMA = 1</b> Light Red	 <b>INDURATION = 1</b> 0.25 mm MILD	 <b>SCALING = 1</b> Mainly fine scale, some of lesion covered
 <b>ERYTHEMA = 2</b> Red, but not Deep Red	 <b>INDURATION = 2</b> 0.5 mm MODERATE	 <b>SCALING = 2</b> Coarser, thin scale, most of lesion covered
 <b>ERYTHEMA = 3</b> Very Red	 <b>INDURATION = 3</b> 1 mm SEVERE	 <b>SCALING = 3</b> Coarser, thick scale, most of lesion covered, rough
 <b>ERYTHEMA = 4</b> Extremely Red	 <b>INDURATION = 4</b> 1.25 mm VERY SEVERE	 <b>SCALING = 4</b> Very thick scale, all of lesion covered, very rough

### Observation And Results

An Observational Study To Relief Nature Of The Disease Through Unani Medicine.

- *Sample Size: 40*
- *Confidence Interval Is 95%, Hence P Value <0.05 Is Considered Significant*
- *Test Performed: Dependent T-Test*

**Statistical Methods:** Descriptive And Inferential Statistical Analysis Has Been Carried Out In The Present Study. Results On Continuous Measurements Are Presented On Mean  $\pm$  Sd (Min-Max) And Results On Categorical Measurements Are Presented In Number (%). Significance Is Assessed At 5 % Level Of Significance. The Following Assumptions on Data Is Made,

- Assumptions:**
1. Dependent Variables Should Be Normally Distributed,
  2. Samples Drawn From the Population Should Be Random, Cases Of The Samples Should Be Independent

The One-Way Analysis Of Variance (Anova) Is Employed To Determine Whether There Are Any Statistically Significant Differences Between The Means Of Three Or More Independent (Unrelated) Groups. The One-Way Anova Compares The Means Between The Groups You Are Interested In And Determines Whether Any Of Those Means Are Statistically Significantly Different From Each Other. Specifically, It Tests The Null Hypothesis:

$$H_0: \mu_1 = \mu_2 = \mu_3 = \dots = \mu_k$$

Where  $\mu$  = Group Mean and  $K$  = Number Of Groups. If, However, The One-Way Anova Returns A Statistically Significant Result, We Accept The Alternative Hypothesis ( $H_a$ ), Which Is That There Are At Least Two Group Means That Are Statistically Significantly Different From Each Other.

Assumptions for Anova Test:

1. The Dependent Variable Is Normally Distributed In Each Group That Is Being Compared In The One-Way Anova

2. There Is Homogeneity Of Variances. This Means That The Population Variances In Each Group Are Equal.

3. Independence Of Observations.

The **Paired T-Test** Is Used To Test The Null Hypothesis That The Average Of The Differences Between A Series Of **Paired** Observations Is Zero. Student T Test (Two Tailed, Dependent) Has Been Used To Find The Significance Of Study Parameters On Continuous Scale With In Each Group.

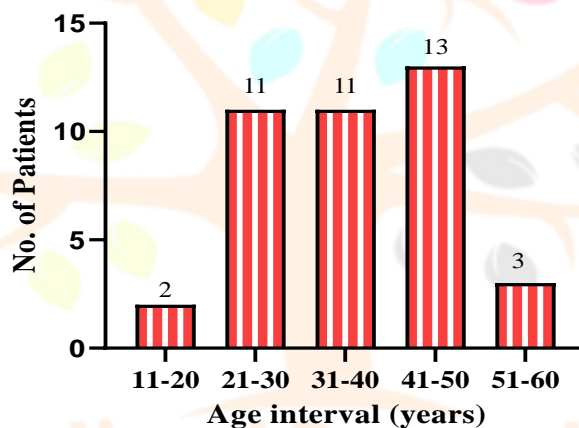
Paired Proportion Test Has Been Used To Find The Significance Of Proportion In Paired Data. Smaller Percentage Of Improvement Becomes Significant At Lower Tail Compared To Higher Tail. E.G., Improvement From 10% To 20% Is Difficult Than the Improvement From 80% To 90%

<https://Home.Ubalt.Edu/Ntsbarsh/Business-Stat/Other applets/Pairedprop.Htm>

Software Use: Spss, Version 24.

**Table 1: Distribution of Patients According To Age**

S. No	Age Interval (Year)	No. Of Patients	Percentage
1	11-20	02	5
2	21-30	11	27.5
3	31-40	11	27.5
4	41-50	13	32.5
5	51-60	03	7.5



**Figure 1: Distribution Of Patients According To Age**

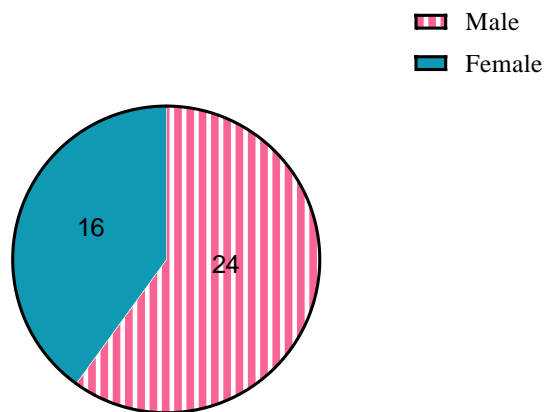
#### Observation

- No. Of Patients Attended Under The Age Group Of 11 To 60 Years.
- Under The Age Group Of 11 To 20 Years (2) Patients Got Treatment I.E. 5%
- Under The Age Group Of 21 To 30 Years (11) Patients Got Treatment I.E. 27.5%
- Under The Age Group Of 31 To 40 Years (11) Patients Got Treatment I.E. 27.5%
- Under The Age Group Of 41 To 50 Years (13) Patients Got Treatment I.E. 32.5%
- Under The Age Group Of 51 To 60 Years (3) Patients Got Treatment I.E. 7.5%

**Table 2: Distribution of Patients According To Gender**

S. No	Gender	No. Of Patients	Percentage
1	Male	24	60
2	Female	16	40





**Figure 2: Distribution of Patients According To Gender**

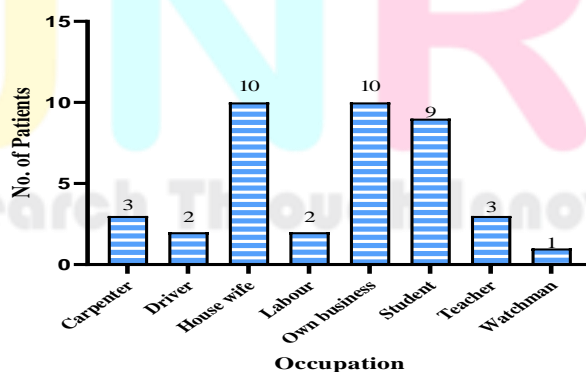
**Observation**

A Total Number of Male Patient Is 24 I.E. 60%

A Total Number of Female Patient Is 16 I.E. 40%

**Table 3: Distribution of Patients According To Occupation**

S. No	Occupation	No. Of Patients	Percentage
1	Carpenter	03	7.5
2	Driver	02	5
3	House Wife	10	25
4	Labour	02	5
5	Own Business	10	25
6	Student	09	22.5
7	Teacher	03	7.5
8	Watchman	01	2.5



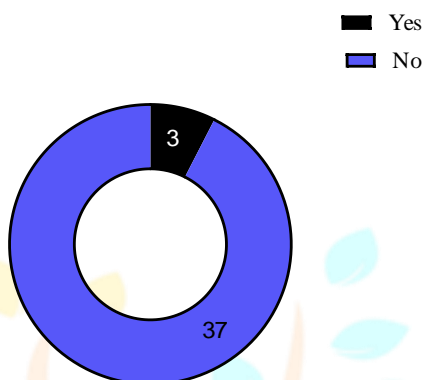
**Figure 3: Distribution of Patients According To Occupation**

**Observation**

Total Number Of Carpenter Patients Is 3 I.E. 7.5%, Total Number Of Driver Patients Is 2 I.E. 5%, Total Number Of House Wife Patients Is 10 I.E. 25%, Total Number Of Labour Patients Is 2 I.E. 5%, Total Number Of Own Business Patient Is 10 I.E. 25%, Total Number Of Students Patient Is 9 I.E. 22.5%, Total Number Of Teacher Patient Is 3 I.E. 7.5%, Total Number Of Watchman Patient Is 1 I.E. 2.5%.

**Table 4: Distribution Of Patients According To Family History**

S. No	Family History	No. Of Patients	Percentage
1	Yes	03	7.5
2	No	37	92.5



**Figure 4: Distribution of Patients According To Family History**

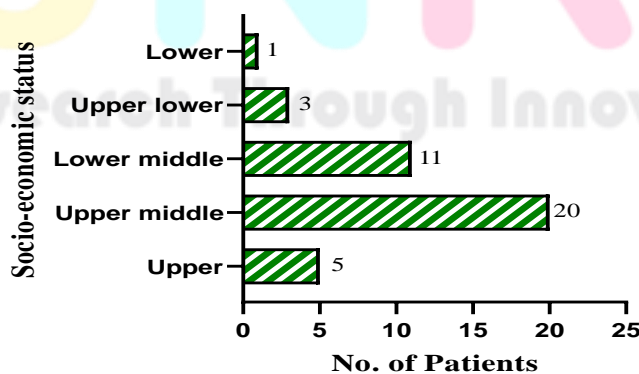
**Observation**

Total Number of Family History Patients Is 3 .I.E 7.5%

Total Number of No Family History Patients Is 37 I.E. 92.5%

**Table 5: Distribution of Patients According To Socio-Economic Status**

S. No	Socio-Economic Status	No. Of Patients	Percentage
1	Upper	05	12.5
2	Upper Middle	20	50
3	Lower Middle	11	27.5
4	Upper Lower	03	7.5
5	Lower	01	2.5



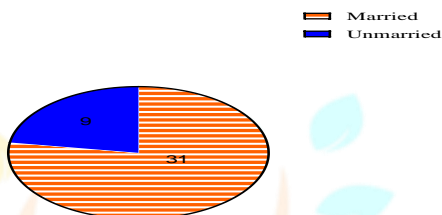
**Figure 5: Distribution of Patients According To Socio-Economic Status**

**Observation**

- Upper Group of Patient Is 5 I.E. 12.5%, Upper Middle Group Of Patients Is 20 I.E 50%, Lower Middle Group Of Patients Is 11 I.E. 26.5%, Upper Lower Group Of Patients Is 3 I.E. 7.5%, Lower Group Of Patients Is 1 I.E. 2.5%.

**Table 6: Distribution of Patients According To Marital Status**

S. No	Marital Status	No. Of Patients	Percentage
1	Married	31	77.5
2	Unmarried	09	22.5



**Figure 6: Distribution of Patients According To Marital Status**

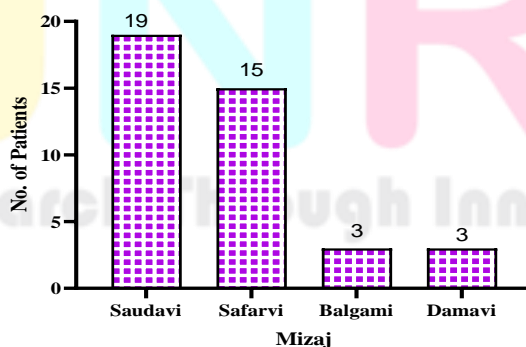
**Observation**

Total Number of Married Patients Is 31 I.E. 77.5%

Total Number of Unmarried Patients Is 9 I.E.22.5%

**Table 7: Distribution of Patients According To Mizaj**

S. No	Mizaj	No. Of Patients	Percentage
1	Saudavi	19	47.5
2	Safarvi	15	37.5
3	Balgami	03	7.5
4	Damavi	03	7.5



**Figure 7: Distribution of Patients According To Mizaj**

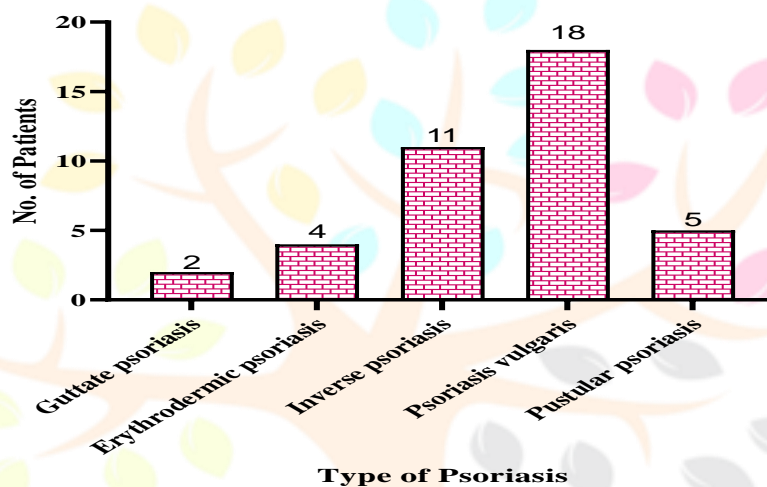
**Observation**

- Total Number Of Saudavi Patients Is 19 I.E. 47.5%
- Total Number Of Safarvi Patients Is 15 I.E. 37.5%
- Total Number Of Balgami Patients Is 3 I.E. 7.5%

- Total Number Of Damavi Patients Is 3 I.E. 7.5%

**Table 8: Distribution of Patients According To Type of Psoriasis**

S. No	Type Of Psoriasis	No. Of Patients	Percentage
1	Guttate Psoriasis	02	5
2	Erythrodermic Psoriasis	04	10
3	Inverse Psoriasis	11	27.5
4	Psoriasis Vulgaris	18	45
5	Pustular Psoriasis	05	12.5

**Figure 8: Distribution of Patients According To Type Of Psoriasis****Observation**

Total Number Of Guttate Psoriasis Patients Is 2 I.e. 5%, Erythrodermic Psoriasis Is 4 I.E. 10%, Inverse Psoriasis Is 11 I.E. 27.5%, Psoriasis Vulgaris Is 18 I.E. 45%, Pustular Psoriasis Is 5 I.E. 12.5%.

**Table 9: Distribution of Patients According To Severity Of Psoriasis**

S. No	Severity Of Psoriasis	No. Of Patients	Percentage
1	Mild	16	40
2	Moderate	24	60



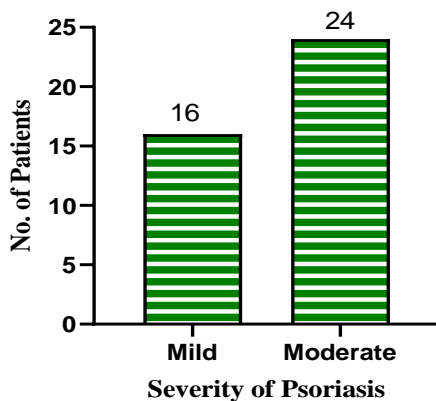


Figure 9: Distribution of Patients According To Severity Of Psoriasis

**Observation**

- Total Number Of Mild Cases Is 16 I.E. 40%
- Total Number Of Moderate Cases Id 24 I.E. 60%

Table 10: Pasi Before and After Treatment

Pasi	Minimum	Maximum	Mean ± Sd	P Value
Before	03	11.50	7.73±2.42	<0.0001*
After	01	10.50	3.78±2.43	

Significant Difference Was Found In PASI Before and After Treatment

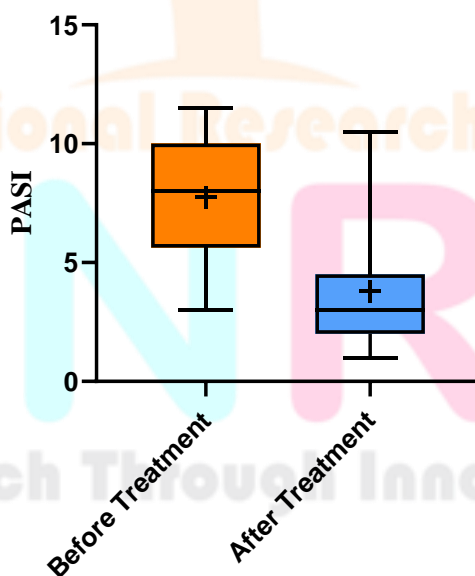
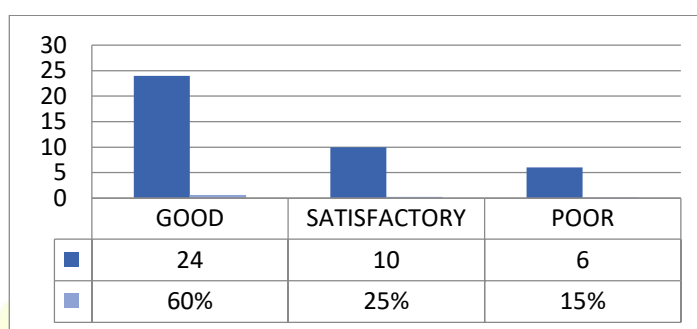


Figure 10: Pasi Before and After Treatment

Table 11: Therapeutic Response of Psoriasis:

Therapeutic Response	No. Of Patients	Percentage

<b>Good</b>	<b>24</b>	<b>60</b>
<b>Satisfactory</b>	<b>10</b>	<b>25</b>
<b>Poor</b>	<b>6</b>	<b>15</b>



**Figure 11: Therapeutic Response of Psoriasis:**

#### **Observation:**

60% Patients Got Good Response, The Satisfactory Patients Were (10) I.E. 25% And Poor Response Patients Were (6) I.E. 15%.

#### **Conclusion**

At The Outset I Would Like To Say That Very Keen Interest And Statement With Different Kinds Of Psoriasis And Their Informative, Informed, Principle Of Modern-Day And Unani Concept And Clinical Study Has Been Done.

The Aim Of Selection Of Topic Of Psoriasis To Evaluate The Safety And Efficacy Of Compound Unani Formulation And To Relief Nature Of The Disease Through Unani Medicine.

The **Daus'sadaf / Taqashur-E-Jild (Psoriasis)** Commonly Developed For Those Who Has Losed Their Body Immunity Or Quath-E-Muddabir-E-Badan (Defensive Mechanism) Due To Abnormal Maintenance Of "Sitta Zarooria" Many Caused Alternate The Tabiyath (Immunity) And Abnormal Changes Will Take Place In The Humorous And Temperament.

Aim And Objectives, The Tremendous Valuable Unani Concept And Pathogenesis Of Psoriatic Lesions, Material, Choice Of Drugs, Their Pharmaceutical Actions And Psoriasis Area And Severity Index (Pasi), Patient Informed Consent, Statical Data Analysis, Are Described In This Dissertation.

In This Present Clinical Study Of Psoriasis The Maximum Response Out Of (40) Cases, (24) Patients I.E. 60% Patients Got Good Response, The Satisfactory Patients Were (10) I.E. 25% And Poor Response Patients Were (6) I.E. 15%.

The Study Revealed That Usage Of This Unani Medicine Got Good Response In Decreasing The Sign And Symptoms Of Psoriasis Like Redness, Thickness, Itching, Scales. No Clinical Significant Side Effects Were Observed In This Study; These Results Conclude That The Drugs Used In This Study Are Easily Available, Safe And Effective.

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