

CLINICAL TRIAL OF "PSORA V"
Evaluation of the efficacy of "PSORA V" in the management of
SYMPTOMS and other complications of PSORIASIS"

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Reason: (HETU)

Ayurved is a science that considers any disease from its origin to its treatment. It is to prevent disease from its recurrence. This is the need of today's mankind suffering from various psychological and physical problems to get treated by natural way of healing. So is our step further to use modern technology, knowledge available, diagnostic help combine with Non Toxic, Non Narcotics, Non Metallic, Non Animal ingredient, purely Herbal Ayurvedic formulations to achieve this goal.

Vivechan (Introduction):

Psoriasis is a non-infectious, inflammatory disease of the skin. It is characterized by well-defined erythematous (reddish) plaques with large adherent silvery scales. The main abnormality in psoriasis is an increased proliferation of the skin layers due to excessive division of the cell in the basal layers of the skin. Severe itching may associate with the plaques. Dryness of the skin and silvery scaling are characteristics of this condition.

1% to 3% of the most population has Psoriasis. It is very common among Europeans and North Americans. It is often seen between 15 to 40 yrs of age.

The exact reason behind Psoriasis is unknown. There is frequently a genetic predisposition. A child with one affected parent has a 15% chance of developing the disease and this rises to 50% if both the parents are affected. Upper respiratory tract may exacerbate the condition. Deprivation of sunlight influences this condition and mental stress plays an important role in aggravating the condition. Certain drugs may aggravate this condition.

Size may vary from a few millimetres to several centimetres in diameter. Common sites are scalp elbows knees and lower back. Pitting of the nails is very common. Involvements of palm are not uncommon. Many may develop Sero-negative inflammatory arthritis.

Utpatti: (Metabolic transformation):

Psoriasis is an inflammatory disease that manifests most commonly as well-circumscribed, erythematous papules and plaques covered with silvery scales. Multiple factors contribute, including genetics. Common triggers include trauma, infection, and certain drugs. Symptoms are usually minimal, but mild to severe itching may occur. Cosmetic implications may be major. Some people develop severe disease with painful arthritis. Diagnosis is based on appearance and distribution of lesions.

Psoriasis vulgarise is a common skin disorder characterised by focal formation of inflamed, raised plaques that constantly shed scales derived from excessive growth of skin epithelial cells. The disease is defined by a series of linked cellular changes in the skin: hyperplasia of epidermal keratinocytes, vascular hyperplasia and ectasia, and infiltration of T lymphocytes, neutrophils, and other types of leukocyte in affected skin. In

a relatively short period, psoriasis vulgaris has been conceptualised as a T lymphocyte mediated autoimmune disease and new biological therapies that target T cells have just entered routine clinical practice. Similarly, rapid progress has been made towards dissecting cellular and molecular pathways of inflammation that contribute to disease pathogenesis. This short review presents current pathogenic concepts that have emerged from genetic, genomic, and cellular information obtained in basic studies and from clinical studies of selective immune targeting drugs.

Symptoms of Psoriasis: (Lakshan)

- Loose silvery scales
- Itching or burning skin
- Raised pus-filled skin bumps
- Skin redness around pustules
- Restricted joint motion
- Emotional distress
- Skin pain and inflammation
- Skin blisters
- Dry skin patches
- Bleeding skin patches
- Red patches of skin covered with silvery scales
- Small scaling spots (commonly seen in children)
- Dry, cracked skin that may bleed
- Itching, burning or soreness
- Thickened, pitted or ridged nails
- Swollen and stiff joints

Psoriasis patches can range from a few spots of dandruff-like scaling to major eruptions that cover large areas.

Most types of psoriasis go through cycles, flaring for a few weeks or months, then subsiding for a time or even going into complete remission.

Types of Psoriasis: (Prakar):

- **Plaque psoriasis.** The most common form, plaque psoriasis causes dry, raised, red skin lesions (plaques) covered with silvery scales. The plaques itch or may be painful and can occur anywhere on your body, including your genitals and the soft tissue inside your mouth. You may have just a few plaques or many.
- **Nail psoriasis.** Psoriasis can affect fingernails and toenails, causing pitting, abnormal nail growth and discoloration. Psoriatic nails may become loose and separate from the nail bed (onycholysis). Severe cases may cause the nail to crumble.
- **Scalp psoriasis.** Psoriasis on the scalp appears as red, itchy areas with silvery-white scales. The red or scaly areas often extend beyond the hairline. You may notice flakes of dead skin in your hair or on your shoulders, especially after scratching your scalp.
- **Guttate psoriasis.** This primarily affects young adults and children. It's usually triggered by a bacterial infection such as strep throat. It's marked by small, water-drop-shaped sores on your trunk, arms, legs and scalp. The sores are covered by a fine scale and aren't as thick as typical plaques are. You may have a single outbreak that goes away on its own, or you may have repeated episodes.

- **Inverse psoriasis.** Mainly affecting the skin in the armpits, in the groin, under the breasts and around the genitals, inverse psoriasis causes smooth patches of red, inflamed skin. It's worsened by friction and sweating. Fungal infections may trigger this type of psoriasis.
- **Pustular psoriasis.** This uncommon form of psoriasis can occur in widespread patches or in smaller areas on hands, feet or fingertips. It generally develops quickly, with pus-filled blisters appearing just hours after your skin becomes red and tender. The blisters may come and go frequently. It can also cause fever, chills, severe itching and diarrhea.
- **Erythrodermic psoriasis.** The least common type of psoriasis can cover entire body with a red, peeling rash that can itch or burn intensely.
- **Psoriatic arthritis.** In addition to inflamed, scaly skin, psoriatic arthritis causes pitted, discoloured nails and the swollen, painful joints that are typical of arthritis. Symptoms range from mild to severe and can affect any joint. It can cause stiffness and progressive joint damage. May lead to permanent deformity.

Pathogenesis: (SAMPRAPTI)

The cause of psoriasis isn't fully known, but it's thought to be related to an immune system problem with cells in your body. More specifically, one key cell is a type of white blood cell called a T lymphocyte or T cell. Normally, T cells travel throughout the body to detect and fight off foreign substances, such as viruses or bacteria. If you have psoriasis, however, the T cells attack healthy skin cells by mistake, as if to heal a wound or to fight an infection.

Overactive T cells trigger other immune responses. The effects include dilation of blood vessels in the skin around the plaques and an increase in other white blood cells that can enter the outer layer of skin. These changes result in an increased production of both healthy skin cells and more T cells and other white blood cells. This causes an ongoing cycle in which new skin cells move to the outermost layer of skin too quickly – in days rather than weeks. Dead skin and white blood cells can't slough off quickly enough and build up in thick, scaly patches on the skin's surface. This usually doesn't stop unless treatment interrupts the cycle.

Just what causes T cells to malfunction in people with psoriasis isn't entirely clear. Researchers have found genes that are linked to the development of psoriasis, but environmental factors also play a role.

Causes of Psoriasis: (Karan)

Psoriasis typically starts or worsens because of a trigger that may be able to identify and avoid.

- Infections, such as strep throat or skin infections
- Injury to the skin, such as a cut or scrape, bug bite, or a severe sunburn
- Stress
- Cold weather
- Smoking
- Heavy alcohol consumption
- Certain medications
- Heredity can be crucial.
- Consumption of opposite foods – Viruddh Ahar- (such as fish and milk together)
- Trauma on skin, cuts, bruises or burns
- Skin irritants
- Excessive smoking
- Alcohol consumption
- Mental stress or psychological trauma

Differential Symptoms with psoriasis (Vyadhi Vinischay):

Other conditions that may look like psoriasis or may occur at the same time as psoriasis:

- **Seborrheic dermatitis.** This type of dermatitis is characterized by greasy, scaly, itchy, red skin. It's often found on oily areas of the body, such as the face, upper chest and back. Seborrheic dermatitis can also appear on the scalp as stubborn, itchy dandruff.
- **Lichen planus.** This is an inflammatory, itchy skin condition that appears as rows of itchy, flat-topped bumps (lesions) on the arms and legs.
- **Ringworm of the body (tinea corporis).** Ringworm is caused by a fungal infection on the top layer of your skin. The infection often causes a red, scaly ring or circle of rash.
- **Pityriasis rosea.** This common skin condition usually begins as one large spot (herald patch) on your chest, abdomen or back, which then spreads. The rash of pityriasis rosea often extends from the middle of the body, and its shape resembles drooping pine tree branches.

Investigations: (PARIKSHAN)

In most cases, diagnosis of psoriasis is fairly straightforward.

- **Physical exam and medical history.** Diagnose psoriasis by taking medical history and examining skin, scalp and nails.
- **Skin biopsy.** A small sample of skin (biopsy) that's examined under a microscope to determine the exact type of psoriasis and to rule out other disorders.
- **Pathological Investigations.** There is no any specific Blood test to diagnose it.
- **Family History.**

NIDAN: (Predisposing factors)

Many basic Ayurvedic texts have explained skin diseases, which resembles Psoriasis. According these references, Psoriasis can be considered as the vitiation of Vata and Kapha. (Two of the basic energies which maintains our body equilibrium)

Accumulation of low potency vikars (Dooshi vishas), are the basic pathological changes taking place in the system. Irregular food habits, consumption of foodstuffs that cannot be eaten together (Eg: dairy products with fish), excessive intake of yogurt, black gram, seafood, sour and salted items etc can activate the pathogenesis.

Alcohol and tobacco consumption will act as a catalyst here. Ayurveda do emphasize on the effect of stress in the pathogenesis of Psoriasis.

According to Ayurveda, Psoriasis appears due to imbalance of two doshas - Vata (Air) and Pitta (Fire). Vata and Pitta doshas manifest in the skin and cause accumulation of toxins. These toxins accumulate in deep tissues like rasa (nutrient plasma), rakta (blood), mansa (muscles), and lasika (lymphatic). These toxins cause contamination of deeper tissues, leading to Psoriasis.

Purification of blood and tissues is the primary aim of Ayurvedic treatment in cases of Psoriasis. Toxins are cleansed from the body and the digestion restored to prevent further accumulation. Nourishing herbs are then administered to strengthen and tone the tissues to promote complete healing of the skin.

- Atap ati sevan : excessive exposure to sun, heat
- Dhoom sevan : excessive exposure to dust, fumes
- Ati vyavay : excessive physical indulgence
- Ati amla guru ahar : excessive Acidic and heavy diet
- Manasthap : Mental stress
- Vega avrodha : suppression of natural urges, urine, stool.
- Snigdhaalpata : Lack of protein.
- Ras dhatu kshaya : Lack of Vitamines

Rakta dhatu kshaya : Anemia

Prevention: (NIDAN PARIVARJAN)

Ways to Prevent Psoriasis Flare-Ups

- Use moisturizing lotions. Symptoms get worse when your skin is dry, so keep it moist with creams and lotions. Thick and oily ones, like petroleum jelly, are usually best.
- Take care of skin and scalp. Be careful with the skin. Never pick at patches or scales, as it may make psoriasis worse.
- Use caution when trimming nails.
- Avoid dry, cold weather
- Use a humidifier. It's important to keep skin moist. Turn on the humidifier when it's dry.
- Avoid medications that cause flare-ups.
- Avoid scrapes, cuts, bumps, and infections
- Get some sun, but not too much. The ultraviolet rays in sunlight slow the growth of skin cells
- Use Sunscreen. Sunburn can trigger psoriasis
- Zap Stress.
- Try to Relieve Anxiety.
- Meditation or Yoga.
- Not to Alcohol.
- Exercise.
- Eat right.
- Maintain Healthy Weight.

Diet & Lifestyle Advice: (Ahar Vihar):

- Avoid consuming opposite foods.
- Do not control natural urges like vomiting, urination, bowels, etc.
- Do not take cold water bath immediately after a heavy workout, travelling, a long walk, etc.
- Take care not to consume foods which cause indigestion.
- Absolutely do not eat too much of salty, sour or acidic foods.
- Avoid sleeping in afternoons.
- Say no to radish, sesame, jaggery (gur), curds, fish
- Avoid sour foods.

GENERAL TREATMENT: CHIKITSA

Purification of blood and tissues is the primary aim of Ayurvedic treatment in cases of Psoriasis. Toxins are cleansed from the body and the digestion restored to prevent further accumulation. Nourishing herbs are then administered to strengthen and tone the tissues to promote complete healing of the skin.

Coming to the treatment aspects of Psoriasis according to Ayurveda, it aims at the detoxification of the body or elimination of toxins from the body fluids. It can be achieved by "*Panchakarma*" treatments

Internal and external medications purely of plant origin.

- ✓ Rough out line of this schedule is as follows.
 - (i) Consumption of medicated ghee, considering the Dosha type of the Psoriasis and the person, for 5 to 7 days.
 - (ii) Detoxification
 - (iii) Vomiting (Vamana)
 - (iv) Purgation (Virechana).
 - (v) Massage (Snehan)
 - (vi) Steam (Swedan)
- ✓ Cover the affected part with a fresh thin banana leaf.
- ✓ Take 15-20 sesame seeds and soak in a glass of water. Keep it overnight and drink on an empty stomach early in the morning.
- ✓ Take 1-2 cup of bitter gourd juice on empty stomach in the morning. Continue this for 5-6 months
- ✓ Moisture Everywhere
- ✓ No Dyes or Perfumes
- ✓ Diet may play a role in managing psoriasis.
- ✓ The National Psoriasis Foundation lists soy, nuts, chocolate, and cranberries as a few "functional foods" for treatment
- ✓ As healthy as olive oil is inside the body, it can have extra benefits for the skin. Applying olive or vegetable oil to scales and patches of psoriasis can lock moisture and nutrients in.
- ✓ Try massaging a few tablespoons on the scalp to help loosen troublesome plaques during your next shower.
- ✓ In the Bathtub. A lukewarm bath with Epsom salt, mineral oil, milk, or olive oil can soothe the itching and infiltrate scales and plaques.
- ✓ Moisturize immediately after the bath for double benefits

Treatment types : (Chikitsa prakar)

- ✓ 1.Daiva vyaprashraya Chikitsa
(Chanting of Mantras, Homas, Spiritual healing,Religious rites etc.)
- ✓ 2.Yukti vyaprashraya Chikitsa
(Medicines {Shodhana & Shamana } & Diet)
- ✓ 3.Satwaavajaya Chikitsa
(Psychotherapy)

Yukti Vyapashraya:

(A) Antah Parimarjana-

- ✓ Shodhana: Cleansing (Panchkarma as per the predominance of Doshas like Ghrita Pana & Mild purgation in Vataja type,
- ✓ Therapeutic Emesis & Purgation in Pitta & Kaphja type
- ✓ (b)Shamana:Palliative (Medhya Rasayanas,Diet etc.)

(B) Bahir Parimarjnana

- ✓ Murdha Taila, Ahyanga, Shirodhara etc.
- ✓ Shashtra Pranidhana-Use of Instruments & Surgical interventions.

Daivavyaprashya Chikitsa:

- ✓ Mantra- Chanting of Hymns.
- ✓ Aushadha- Sacred Herbs.
- ✓ Gems- Auspicious Stones.
- ✓ Mangala- Auspicious offerings.
- ✓ Homa- Yajna
- ✓ Niyama - Regulations.
- ✓ Prayaschita-Atonement.
- ✓ Upavasa-Fasting etc.

3. Satwaavajaya (Psychotherapy)

- ✓ When the underlying condition is treated the symptoms do not returns
 - ✓ Aachara Rasayana Physical & Mental Conduct should be followed.
 - ✓ No involvement of Drugs.
 - ✓ Maintains total life process.
 - ✓ To speaks truth, free from anger, abstains from alcohol & Over indulgence.
 - ✓ Maintains Hygiene,
 - ✓ Regular Sleep,
 - ✓ Wholesome Diet.
 - ✓ Controls over his Sense organs etc for Physical,Mental & Spiritual Wellbeing. (Cha.Chi 1/30)
- **Medication:**
 - Stop or reduce consumption of products that contain caffeine, such as coffee, tea, cola, energy drinks, and chocolate.

Ayurvedic treatment: (CHIKITSA)

Apart from various drugs available in Ayurved we have selected a patented Ayurvedic herbal medicine named "PSORA V", manufactured by "Veer Health Care", Ahmedabad, India.

Drug review: (AUSHADHI VIVECHAN)

Contains of PSORA V TABLET

Hindi Name	Weight	Botanical Name	Properties
Manjishtha	60.60MG	Rubia Cordifolia	Alterative, anti-tumor, astringent, diuretic, emmenagogue, hemostatic, lithotriptic, it is a blood purifying herb. It is used as an immune regulator. (its role in supporting heart health is evidenced by studies that show that it regulates blood pressure, blood vessel constriction and the tendency of blood to form Clots). Its evaluation as an anticancer compound in the laboratory has been extensive, the extract showing weak activity in vitro and in vivo against standard tumor cell lines. The plant extract shows significant anti-inflammatory activity.
Patol Patra	113.63MG	Trichosanthes dioica	Patol Patra is blood purifier and anti-inflammatory, so it is useful in blood disorders and inflammation. Working of the digestive system and the skin health are directly related with the working of liver. So Patola Patra also benefits in these conditions also. Patola Patra is a soft laxative thus helps in proper evacuation of feces. It also detoxifies the body, cleanses the blood.
Gorakhmundi	113.63MG	Sphaeranthus indicus	The major components of Gorakhmundi are a-ionone, methyl chavicol, d-cadinene, p-methoxy cinnamaldehyde. The minor components are geraniol, a-terpinene, citral, sphaerene, sphaeranthine, b-ionene and geranyl acetate. It also has tannins, glucoside, volatile oil, reducing sugar and mineral matter. It helps to reduce the level of creatinine, Uric Acid and urea in the blood stream of the individuals. It provides solution to skin disorders, relief from haemorrhoids, treatment for the Syphilis, gonorrhoea and other Venereal diseases.
Anantmul	30.30MG	Hermidesmus indicus	It ensures proper nutrition to every part of the body, benefits in bleeding disorders and detoxifies the body, a good blood purifier, improves skin complex.

Kishor Guggul	30.30MG		It is a aging skin health promoter, joint health, natural blood cleanser, useful in skin diseases, Blood Purifier, Supports healthy skin. Helps with elimination of toxins.
Katha	30.30MG	Acacia Catechu	It is an effective herb that helps in purifying blood. It prevents skin dryness, wrinkles and maintains healthy skin. Cures acne, pimples and other skin ailments. protects skin from infections and environmental factors Effectively used for Eczema, It acts as a spasmolytic agent It is effective in treating skin allergies Beneficial in treating various skin related ailments It works as an anti-age agent Anti-microbial
Babulchaal	121.24 MG	Acacia arabica	It is a blood purifier, haemostatic, vasoconstriction and healing property, Babul powder is sprinkled on burnt injuries and bleeds. It works well in skin diseases. It possesses astringent property.

Method:

The clinical study was planned by VAIDYA VINOD C MEHTA, BAMS (MUMBAI UNI) and DR MANAN V MEHTA, MBBS (MUMBAI UNI), in and around Mumbai and Ahmadabad.

Plan of Study:

The study was planned by the doctors and volunteers to evaluate the clinical efficacy of “PSORA V” Tablet in the management of neurological ailments.

Inclusion criteria:

Patients suffering from at least one of the following neurological symptoms of forgetfulness, Stress, Depression, Aggravation, fear, lack of concentration, Insomnia, At least from 6 or more months.

Exclusion criteria:

Patients with Skin Cancer, Whole Body Psoriasis, infection, Cellulites, Severe dehydration, Toxic symptoms, renal failure, sever Hyper or hypoglycaemia.

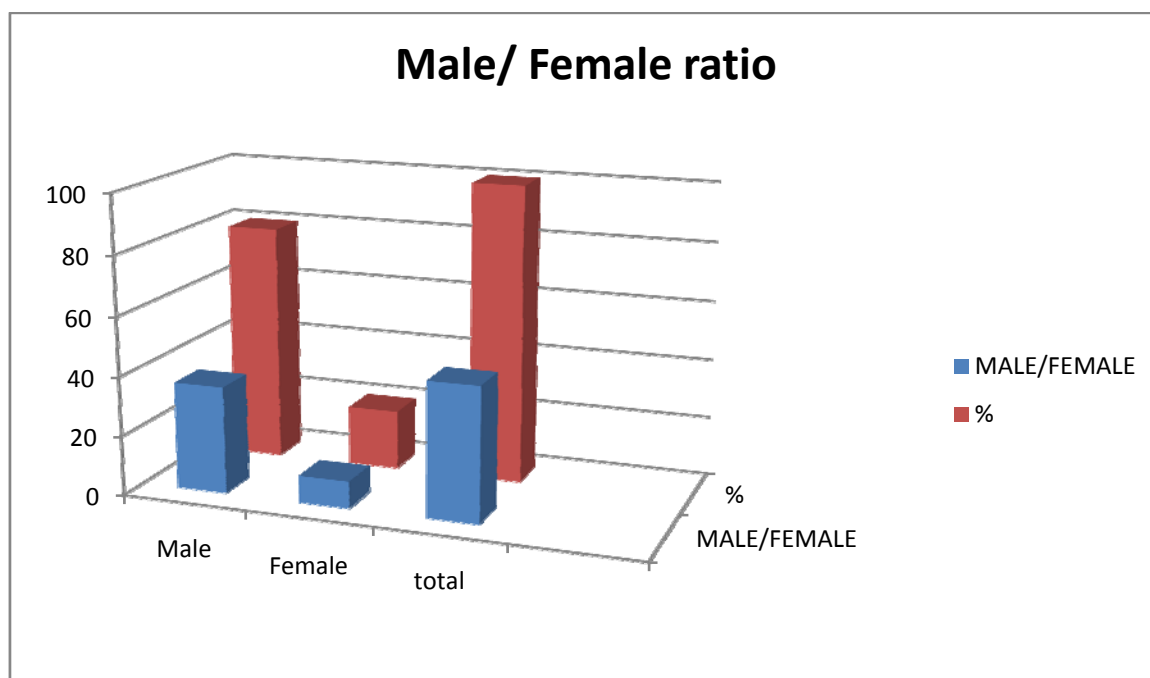
Study procedure:

Total 45 patients were selected for the study.

Each patient's complete medical history including personal data, a description of symptoms was taken. All the patients underwent a thorough clinical and pathological examination.

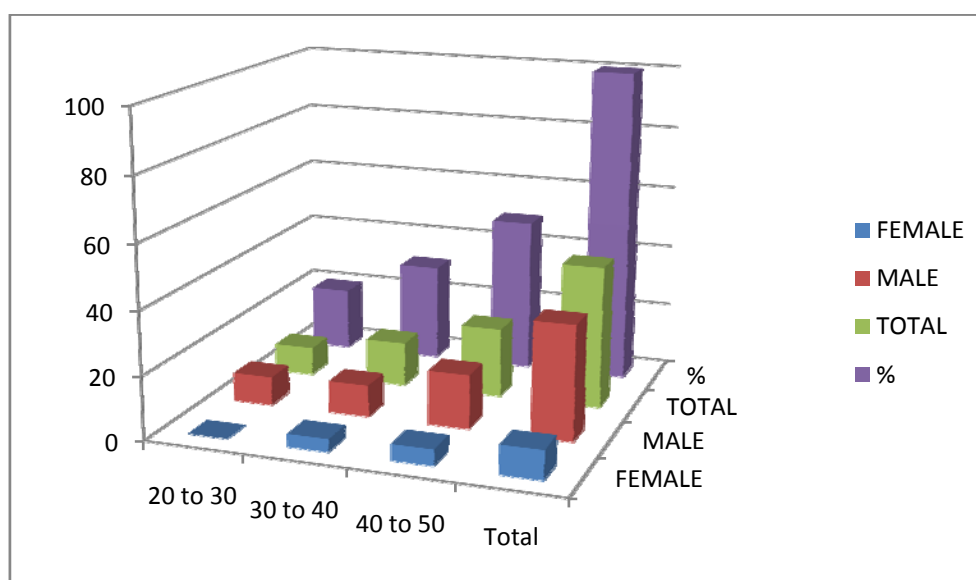
Gender:

Male	36
Female	9
Total	45



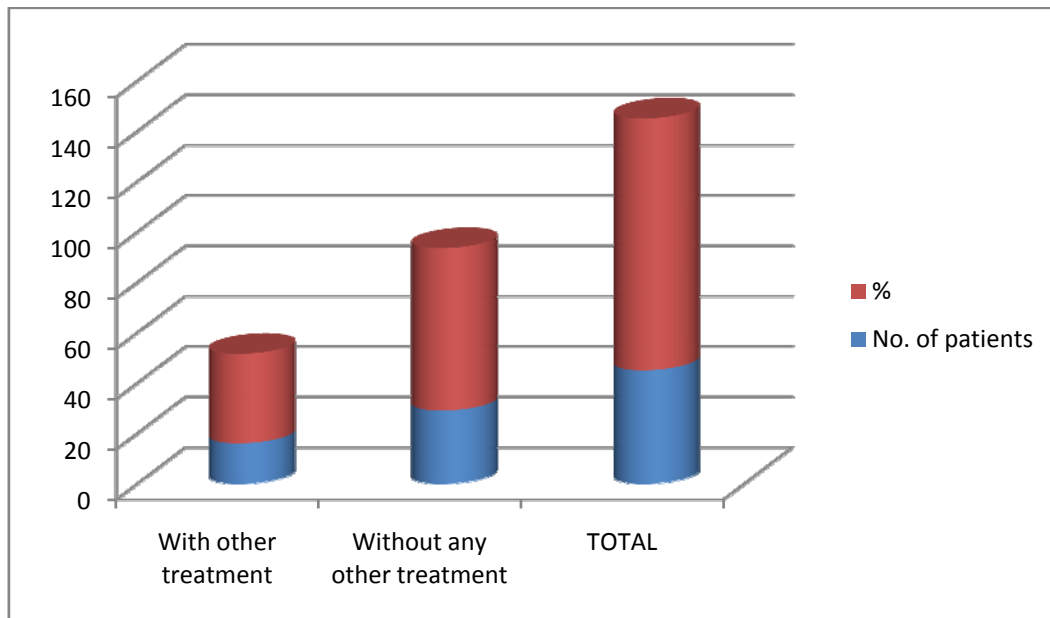
Age Ratio:

AGE	FEMALE		MALE	TOTAL
20 to 30	0		9	9
30 to 40	4		10	14
40 to 50	5		17	22
Total	9		36	45



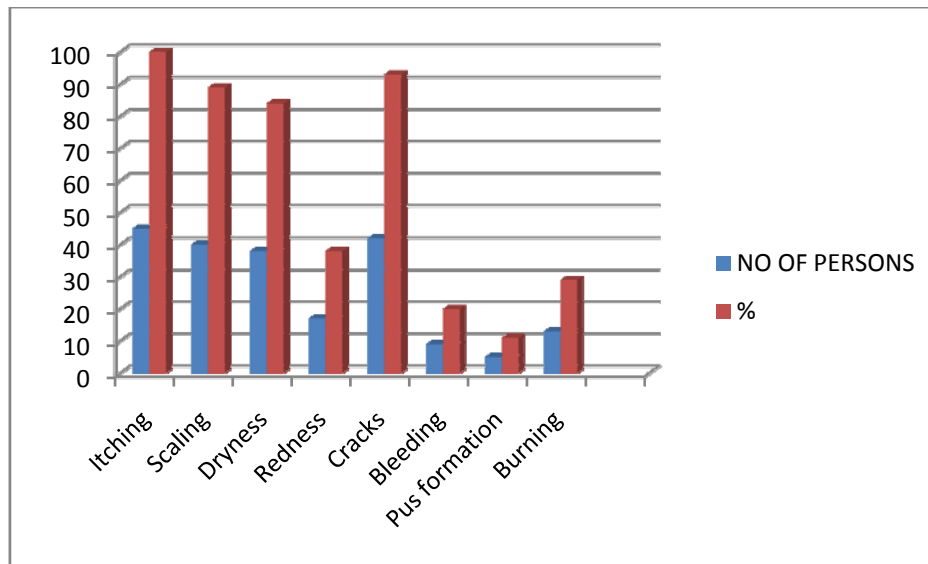
Other Treatment along with PSORA V Tablets

With other treatment	16
Without any other treatment	29
TOTAL	45



SYMPTOMS :

SYMPTOMS	NO OF PERSONS	%
Itching	45	100
Scaling	40	89
Dryness	38	84
Redness	17	38
Cracks	42	93
Bleeding	9	20
Pus formation	5	11
Burning	13	29



Dosage:

2 tablets of "PSORA V" were given to every one 3 times a day

With water

After Breakfast, Lunch and After Dinner

PSORA V CREAM was given to apply 3 times a day.

Health Plan: (VIHAR)

- Regular light exercise
- Increased water intake
- Proper meal timings
- Not to sleep in day time
- Proper counselling
- Panchkarma

(AHAR): To have: (PATHYA)

Three things were explained to patients.

- What they eat
- How much they eat
- When they eat
- A diet plan was tailored according to patients diet habit, working condition, daily routine, weight, age and gender.
- At the base there are foods rich in carbohydrates, such as grains, fruit and vegetables, Fibre, Dark green leafy vegetables was suggested.
- Amla, Dadimb, Resin, Black sesame seeds advised
- Milk, Curd, Butter milk, coconut water was increased
- Coconut, Banana, Water Melon was added to everyday diet
- Salt intake was restricted to small quantity

Diet not to have: (APATHYA)

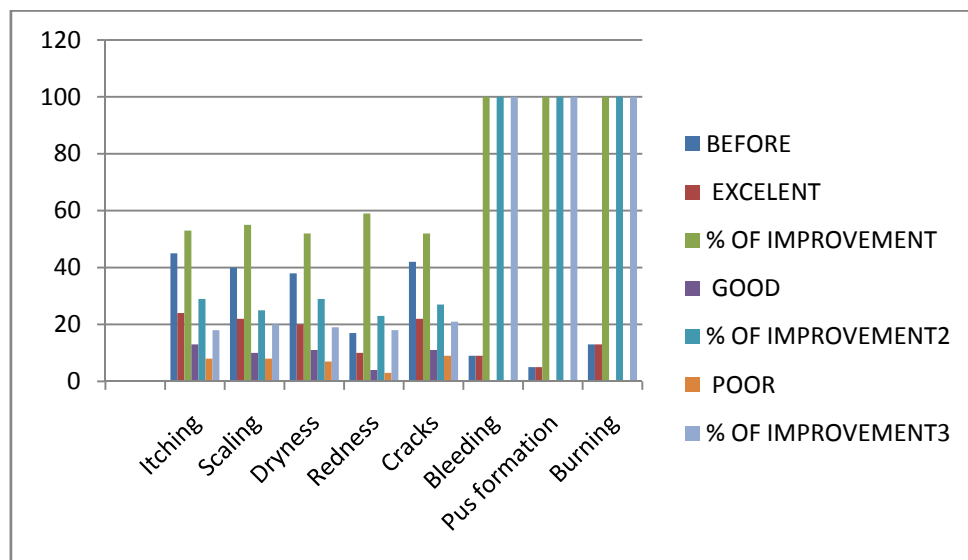
- × Fried food
- × All sour, pungent, spicy food was stopped
- × Excess chillies
- × No onion , garlic, green chillies

- × No Chutney, papad, Pickles
- × Eggs, Fish, Mutton, Chicken
- × Stalled food
- × Outside eatables
- × Late night diner

Assessment of result: (UPSHAY) After administration of PSORA V for 60 days, the following result was achieved.

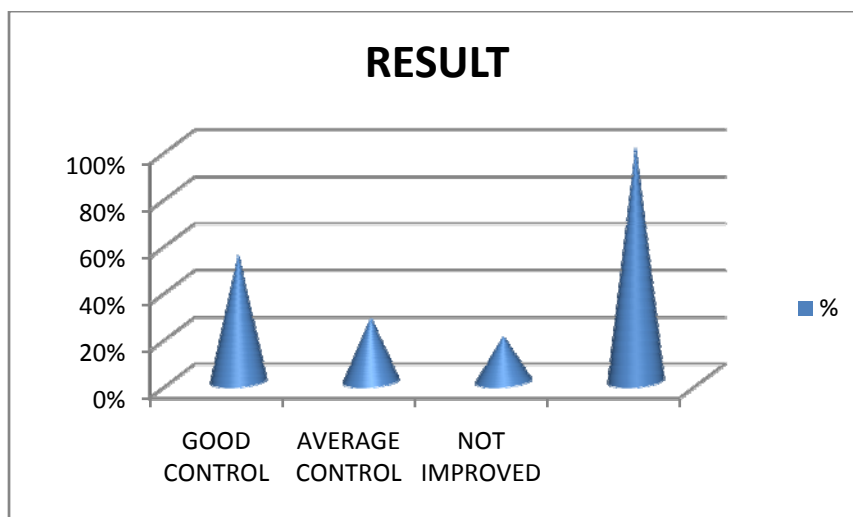
RESPONSE OF THE TREATMENT

SYMPTOMS	BEFORE TREAT	EXCELENT	% OF IMPROVEMENT	GOOD	% OF IMPROVEMENT	POOR	% OF IMPROVEMENT
Itching	45	24	53	13	29	8	18
Scaling	40	22	55	10	25	8	20
Dryness	38	20	52	11	29	7	19
Redness	17	10	59	4	23	3	18
Cracks	42	22	52	11	27	9	21
Bleeding	9	9	100	0	100	0	100
Pus formation	5	5	100	0	100	0	100
Burning	13	13	100	0	100	0	100



RESULT

GOOD CONTROL	54 %
AVERAGE CONTROL	27 %
NOT IMPROVED	19 %
Total	100 %



Conclusion:

Principles of Sadvritta & Achara Rasayana laid down in Ayurveda highlights the importance of Socio Cultural factors in the maintenance of Social health. By Ayurvedic line of treatment with Medicinal therapy, proper Ahara and Vihara, one can be able to treat any diseases effectively.

According to result data it is established that "PSORA V" is effective in curing Psoriasis and its major symptoms like Itching, Scaling, Dryness, Redness, Cracks in 54 % of patients, shown average control in 27% and was not found effective in 19 % Whereas some of the symptoms like, Bleeding, Pus formation, Burning were cured absolutely 100 %.

Reference:

Text Reference :

Charaka Samhita-Sutra, Nidana, Chikitsa sthan.

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Charak Chikitsa sthan. 1/30

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Vanoaushadhi Gunadarsh. Purvardh

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