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A RANDOMISED SINGLE BLIND PLACEBO CONTROLLED TRIAL TO ASSESS THE EFFECTIVENESS OF *AZADIRACHTA INDICA* 1X IN CASES OF PSORIASIS

***Dr. Annu Kanwar, Professor Dr. Aditya Sharma, M.D. Hom. and Prof. Dr. Aijaz Aziz Sulemani**

Mangilal Nirban Homoeopathic Medical College, Hospital & Research Institute, Bikaner, Rajasthan.

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***Corresponding Author**
Dr. Annu Kanwar
Mangilal Nirban Homoeopathic Medical College, Hospital & Research Institute, Bikaner, Rajasthan.

ABSTRACT

Background: Psoriasis is an autoimmune skin disease that causes skin cells to multiply up to 10 times faster than normal. This makes the build-up skin into bumpy red patches covered with white scales. Psoriasis most frequently affects the skin of the elbows, knees, scalp, lumbosacral areas, intergluteal cleft and genital organ. Psoriasis can't be passed from person to person. Psoriasis have devastating physical, mental, and psychosocial consequences. Because of the apparent cosmetic side effects, this disease in many cases influences how others affect patients and patients feelings about themselves. Among the worst complications of the disease are the phenomena of stigma and labeling from individuals and community. If psoriasis is not treated in initial stage than it spread into whole body In other systems of medicine the drug given are only to alleviate symptom at the cost of many side effects. Homeopathy can be of a great benefit for all those suffering from psoriasis.

AIM AND OBJECTIVES

- To assess the effect of *Azadirachta indica* 1X and Placebo in thecases of psoriasis.

OBJECTIVES

- To assess the effect of *Azadirachta indica* 1X and *Placebo* in the management of cases of psoriasis with the help of before and after scores in Psoriasis area and severity index (PASI) worksheet.

- To report new symptoms clinically verified during the study, if any.

STUDY DESIGN

Double Group Assignment, Random allocation, controlled trialsingle blind.

METHOD

In this study Patients presenting complaints of Psoriasis was taken upon the basis of their clinical symptoms and clinical findings.Patients complaints was noted with helping tool PASI score.

STUDY SETTING

The present study was undertaken at M.N. Homoeopathic Medical college, and Research Institute, Bikaner. The cases were taken fromthe OPD/IPD.

STUDY DURATION

First 2 month preparation of trial, then all 100 cases were randomised and divided into 2 group – group A & group B. Both the groups was given respective treatment i.e. group A- *Azadirachta indica* & group B- *Placebo* for aperiod of 7 month with each case follow up of 3 month atleast. Then research analysis for 3 month. All this was done in a period of 12 months.

INCLUSION CRITERIA

- Screening-Screening was done on the basis of presenting complaints.
- Cases with psoriasis with red / white patches skin and silvery scaly skin of any age group was included in the study irrespective of theirsex, caste, religion & duration of illness.
- Patients giving concent for the study.
- Patient with age group 20-40 years.

Exclusion Criteria

- Females who wanted to concieve, are pregnant or lactating.
- Cases with any other severe systemic disorder already diagnosed or diagnosed during screening if clinical features are suggestive of some systemic illness . To confirm, investigations regarding the same.
- Patient pursuing other treatment and were not willing to leave it.

- Patients with age group below 20 years and above 40 years.
- Patient suffering from severe & very severe(3 & 4) psoriasis inPASI scale.

InterventionGroup A

➢ *Azadirachta indica.*

- Potency- 1X
- Manufacturer- Medicine was obtained from a good manufacturer practice certified company.
- Repetition of doses- 1-2 tablets BD for 15 days.
- Route of administration- Oral.
- Dispensing- This was done by the college dispensary by aregistered pharmacist.

Group B

- *Placebo*

➢ Manufacturer- Medicine was obtained from a GMP certifiedcompany.

➢ Repetition of doses- 1-2 tablets BD for 15 days.

➢ Route of administration- Oral

➢ Dispensing- This was done by the college dispensary by aregistered pharmacist.

STATISTICAL TECHNIQUE AND DATA ANALYSIS

The statistical technique used was-'Paired t-test' and 'Independent t-test'.

Paired t-test was used to assess the before and after scores in each patient.

Independent t-test was used to compare effect between medicine *Azadirachta Indica* 1*X* & Placebo.

RESULTS

Levene's test for equality of variance calculated for independent "t" test shows equal variance assumed with means of group B9placebo)=84.79+/- 18.39(SD) as compared to mean =69.27+/-25.95(SD)in Group A *(Azadirachta indica* 1X) with significance of 0.05, which shows (*Azadirachta indica 1X*)significantly reduced PASI score as compared to placebo in cases suffering from psoriasis. Thus rejecting the null hypothesis and accepting alternative hypothesis(H2), *Azadirachta indica* 1X is more effective in reducing the red/white patches of skin and scaly silvery of skin in case of psoriasis in comparison of placebo.

Paired t-test calculated for group A (*Azadirachta indica 1X*) showedmean= 25.93±19.72(SD) as after score compared to mean=69.27±25.95(SD) as before score in PASI for patients suffering from Psoriasus with significance =0.00, which shows that *Azadirachta indica* 1X is effective in Reducing the PASI score in patients suffering from Psoriasis.

Paired t-test calculated for group B (Placebo) showed mean= 78.25±19.24(SD) as after score compared to mean=84.79±18.39(SD) as before score in PASI for patients suffering from Psoriasis with significance=0.00, which shows that placebo is effective in Reducing the PASI score in patients suffering from Psoriasis.

CONCLUSION

It is concluded that *Azadirachta indica 1X* is helpfull in casesesufeering from psoriasis. No adverse effect were recorded when homoeopathic medicine *Azadirachta indica* 1X was prescribed. It is concluded from the percentage of symptomatic relief that *Azadirachta indica 1X* much useful in treating the symptoms of psoriasis.

KEYWORDS: Psoriasis, PASI score, Randomized comparative trial.

INTRODUCTION

Psoriasis is an autoimmune skin disease that causes skin cells to multiply up to 10 times faster than normal.[1] This makes the build-up skin into bumpy red patches covered with white scales. Psoriasis most frequently affects the skin of the elbows, knees, scalp, lumbosacral areas, intergluteal cleft and genital organ. The extra skin cells form scales and red patches that are itchy and sometimes painful.[2] Psoriasis can't be passed from person to person. It does sometimes happen in members of the same family.[3]

Psoriasis usually appears in adulthood.[4] it mostly affects just a couple of areas mostyl. In severe cases, psoriasis can cover large parts of the body. The patches can heal then come throughout an individual's life.

Psoriasis have devastating physical[5], mental, and psychosocial consequences.[6] Because of the apparent cosmetic side effects, this disease in many cases influences how others affect patients and patients' feelings about themselves.[7] Among the worst complications of the disease are the phenomena of stigma and labeling from individuals and community. Individuals avoid having contact with the patients, which is very agonizing for the patients and leads them to develop an improper image of themselves. These attitudes, if repeated, may

cause anger, shame, or despair for the patients. Ultimately, this makes the patients concerned about encountering others, and that they refrain from social activities.[8] Stigma is defined as a mark of disgrace or discredit that forestalls the formation of normal relationships during a patient's life and can cause discrimination.[9] Stigma is known as a social process with personal experiences related to rejection, acceptance, blame, or devaluing the life of the patient[10], combined with unreasonable social judgments about the patient.[11] Skin diseases often cause rejection of the patients thanks to their aesthetic aspects and have negative impacts on their lives. Social rejection is an outcome variable and results of the buildup of objective and subjective deprivations of these who have a comparatively high level of deprivation, have experienced significant losses in their life, and feel that belonging to a specific group, different from normal people. Ghorbanibirgani A et al. the space of discrimination in the margins of public life in thecommunity. The skin plays a crucial role in interpersonal relationships; therefore, skin diseases have obvious effects on patients' appearance and alter people's attitudetoward them. Such skin changes may cause hatred, fear, and even intolerance, et al. may avoid contact with the patient thanks to fear of the possibly contagious nature of the disease.[12] Various studies report stigma and rejection as a consequence of psoriasis. For instance, in one study the rate of stigma and rejection among psoriasis patients was reported as 90.2%.[13] There is also research to suggest that 20 percent of patients with psoriasis have been rejected from the hairdressers, swimming pool, gym, or workplace due to this disease.[14] Moreover, stigma is likely to disturb the patients' social activities, general health status, and life quality.[13]

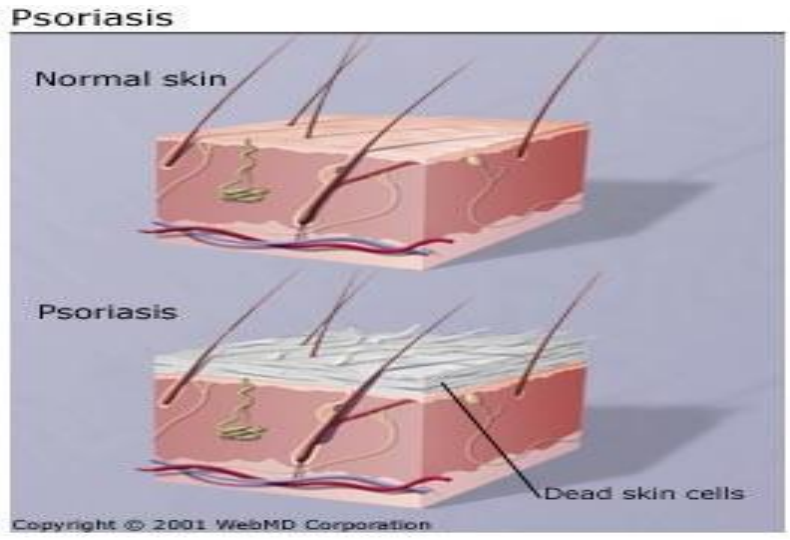

Figure 1: Diagram showing Normal and Psoriatic Skin[10]

If psoriasis is not treated in initial stage than it spread into whole body.[2] In other systems of medicine the drug given are only to alleviate symptom at the cost of many side effects. As our homeopathic drugs which can give better results at the lower cost for the patient, this clinical study is taken up to assess the effects of homeopathic drugs in psoriasis.

Homeopathy can be of a great benefit for all those suffering from psoriasis. As homeopathic prescription in based upon careful analysis of symptom of the patient it becomes a system of medicine that understands and treats the patient to ensure the complete elimination of the disease from the roots.[15]

BACKGROUND AND JUSTIFICATION

Psoriasis is a skin disorder in which patient suffers from red patches and scaly silvery skin, itching and also psychological symptoms affect the daily activities of a being. If psoriasis is not treated in initial stage then it can spread on whole body.[2]

Our homeopathic medicine *Azadirachta indica 1X* whose common name is NEEM is a kind of oil produced from the seed of ripe fruits and this oil is said to cure Itching of various part of the body, leprosy, eczema and some other obstinate skin disease. Homeopathic medicine give better result without any side effect and low cost for patient. The Neem tree is used for bacterial, viral, fungal infection.[16]

Neem has a remarkable effect on chronic skin conditions. Acne, psoriasis, eczema, ringworm and even stbborn warts are among conditions that can clear up easily when high quality, organic neem oil is used.[17]

Research Question

Do the patients suffering from psoriasis get beneficial results from *Azadirachta indica* 1X ?

Research Hypothesis

- **NULL HYPOTHESIS (H0)**

Azadirachta indica 1X and placebo have same effect in red / white patches of skin and scaly silvery skin in cases of psoriasis.

- **ALTERNATE HYPOTHESIS**

(H1)- *Azadirachta indica* 1X and placebo are not equally effective in red / white patches of skin and scaly silvery in cases of psoriasis.

(H2)- *Azadirachta indica 1X* is more effective in reducing red/white patches of skin and scaly silvery skin in cases of psoriasis as compared to placebo.

(H3)- Placebo is more effective in reducing red/white patches of skin and scalysilvery skin in cases of psoriasis as compared to *Azadirachta indica 1X*

AIM AND OBJECTIVES

AIM

- To assess the effect of *Azadirachta indica* 1X and Placebo in the cases of psoriasis.

OBJECTIVES

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- To report new symptoms clinically verified during the study, if any.

REVIVE OF LITERATURE

Historical View

This history of psoriasis begins in very old times when psoriasis, leprosy, and other inflammatory skin disorders were thought to be the same condition. Histopathology descriptions in the 1960s and 1970s shed some light on the patho- physiology of psoriasis, but many aspects of the disease remain unknown to this day. As Bechet expressed, "Psoriasis is an antidote for dermatologists' ego. Given the lack of understanding of its pathophysiology.[18] Chance observations by early clinicians of psoriatic improvement in patients prescribed medications for other conditions led to advancements in therapy. As our thoughtful grew, this karma evolved into detailed targeting of specific immunological processes. Newly directed therapies clarify aspects of the pathophysiology and treatment of psoriasis and other immune-mediated diseases.[19]

Ancient history: Lepra, psora, psoriasis

The roots be Ancient Greece. The Greeks, divided skin problem into the categories of psora, lepra and leichen. Psora cited itch, while lepra was derived from the Greek words lopos (the epidermis) and lepo (to scale). Hippocrates (460–377 BC) was one among the primary authors to put in writing descriptions of skin disorders. He utilized the word lopoi to explain the dry, scaly, disfiguring eruptions of psoriasis. kind of like Hippocrates' works,

the testament also lumped together many cutaneous disorders.[17]

TREATMENTS THROUGH THE YEARS

Theories about the pathogenesis of psoriasis continued to grow in the early 1900s, which helped to find various treatments that have been modified time to time and some are still used. A beneficial effect of sun on skin diseases has been known formore than 300 years, and it was recorded 100 years ago that psoriasis was better in the summer than in winter. William Goeckerman In 1925 investigated the effects of photosensitizers[20] and reported that prior application of crude coal tar enhanced the effects of UVR[21] on the skin. It is now known that narrowband UVB, which refers to a specific wavelength of radiation roughly between 311 to 313 nm, is a highly effective treatment option for generalized psoriasis. During the 1950s, psoriasis was thought to be primarily an epidermal reaction. For this reason, treatment modalities were mainly external application of drugs. Topical corticosteroids such as hydrocortisone were introduced during this time and were proven to be ineffective. Over the following 20 years, continued alterations to the steroid molecules lead to more potent steroid preparations, which proved to have a greater antipsoriatic effect.[22]

In 1953, consistent with Koebner's previous theory that certain environmental triggers could uncover psoriasis in susceptible individuals, John Ingram described psoriasis as a constitutional reaction. He defined a constitutional reaction as the expression of disturbed adjustment and adaptation between the patient and his environment. He viewed psoriasis as an individual disease based on a patient's unique personal history. After light treatment, a paste consisting of dithranol, salicylic acid, zinc oxide, starch, and soft paraffin was applied to the lesions. This regimen was repeated every 24 hours and was only able to clear psoriasis temporarily.[6] During the 1960s and 1970s, the principle force of research into the nature of psoriasis was directed at the increased proliferation of the keratinocytes. A study reported by Eugene van Scott in 1963, which involved carrying out mitotic counts of psoriatic skin compared with uninvolved skin led to the assumption that epidermal characteristics of psoriasis were secondary to the increased mitosis of keratinocytes. By this proposed that antimitotic drugs such as methotrexate[23] were bound to be helpful. As systemic methotrexate gained popularity in the treatment of severe psoriasis, Gerald Weinstein and Phillip in a study proposed that with increased mitosis, the cell cycle was likely to be altered and reported a reduced cell cycle of 37.5 hours compared with 457 hoursfor normal epidermis. They were

later able to use this information to optimize methotrexate dosing, which would help to selectively target psoriatic epidermis more than other more slowly proliferating tissues in the body. Although a great advancement, the theory that psoriasis was due to keratinocyte proliferation could not account for all of the histological features of the disease. The dermal cell infiltrate began to be investigated in the 1990s, mainly looking at the involvement of lymphocytes. Evidence of an immune mediated etiology for psoriasis was suggestedby the dramatic efficacy of cyclosporine, a drug whose.[24]

EPIDEMIOLOGY

The worldwide prevalence of psoriasis is estimated to be approximately 2–3%.[23] Although the disease is assumed to own higher prevalence within the polar regionsof the planet, its burden in an exceedingly very tropical/subtropical country like India can't be underestimated. India have vary different prevalence of psoriasis in different parts because of variable environmental and genetic factors. We found only six studies, mostly in an exceedingly very hospital setting, from North India estimating the prevalence of disease among adult dermatologic patients. the subsequent prevalence in males has been reported with a peak age at onset is within the third and fourth decade of life. In a study in Northern India, prevalence of paediatric psoriasis was estimated to be 0.0002%. the height age at onset among boys is within the 6–10 years people compared to women in 11–15 years people.[3] A positive account is additionally elicited in 9.8-28% of the kids. The age at onsetof rheumatoid arthritis varies from 35 to 50 years with no sex predilection. There is noarticular involvement in Nearly 70% of patients, onset of psoriasis by over 1 year in inanother 15%,, and within the remaining 15% of the cases, the 2 conditions occur within 12 months of every other. The yearly estimated incidence and prevalence of autoimmune disorder are, respectively, 3.0–23.1 cases/100,000 and 1–420 cases/100000 people[24], with similar winds up in Western countries and in China. Prey et al. in a systematic review concluded that arthritis affect upto 24% of patients with psoriasis. Such data is lacking among Indian patients. In children, arthritis may precede psoriasis in 50% of cases. The mean age of onset in children is 9–10 years with female predominance[25] Prevalence in several populations varies from 0% to 11.8%. for several of the information given, the range extends from around 0.5% to shut to 2.5%. Prevalence studies from India are mostly hospital-based.[2] There are comparative data from various epidemiological studies on psoriasis from India. Okhandiar et al. collected a comprehensive data from various medical colleges located in Dibrugarh, Calcutta, Patna, Darbhanga, Lucknow, urban center and Amritsar. It found that

the incidence of psoriasis among total skin patients is 0.44 and 2.2%, with total incidence of 1.02%. incidence in Amritsar (2.2%) was higher as compared to other parts in Eastern India and speculated that it should be associated with different environmental conditions (extremes of temperature), dietary habits, and genetic differences. The ratio of male to female (2.46:1) was very high which couldn't be clearly accounted for. Highest incidence was noted within the cohort of 20-39 years and also the mean age of onset in males and females was comparable.[1][25] The incidence of psoriasis is within the region (north-western rajasthan) of three cases within the population and within the Bikaner distric its about 2.1% case of psoriasis.[2] a more robust prevalence in males has been reported with a peak age at onset is within the third and fourth decade of life. Recently, it's been recognised that psoriasis may occur for the primary time within the seventh decade.[2]

DISEASE VIEW

Psoriasis is hyper proliferation of epidermal keratinocytes combined with inflammation of the skin. It affects about 1 to 5% of the population worldwide light- skinned people are at higher risk, and blacks are at lower risk. onset roughly bi- modal, at ages 16 to 22 and at ages 57 to 60, but the disease can occur at anyage.[15]

Etiology

Cause is not clear for psoriasis but involves stimulation of immune epidermal keratinocytes, vital role playedby T cells. Family history is common, and certain genes and human leukocyte antigens (Cw6, B13, B17) are associated with psoriasis. Genomewide linkage analysis has identified numerous psoriasis susceptibility loci; the *PSORS1* locus on chromosome 6p21 plays the greatest role in determining a patient's susceptibility of developing psoriasis. Trigger by environmental condition cause inflammatory response and hyperproliferation of keratinocytes. Well- identified triggers include Injury (Koebner phenomenon), Sunburn, HIV infection[25], Beta-hemolytic streptococcal infection (leading to guttate psoriasis), Drugs (especially beta-blockers, chloroquine, lithium, angiotensin-converting enzyme inhibitors, indomethacin, terbinafine, and interferon-alfa), Emotional stress, Alcohol consumption, Tobacco smoking and obesity.[26]

Symptoms and signs

Psoriasis Lesions are either pruritic or asymptomatic and are most often localized on the scalp, extensor surfaces of the sacrum, genitals, buttocks (commonly the gluteal cleft), elbows and knees. It may affected eyebrows, axillae, nails, umbilicus, and perianal region. It

can be involving confluent areas of skin extending these regions. Depending on type Lesions differ in appearance.

Manifestations of Psoriasis palpable lesions > 10 mm in diameter elevated Plaques. Psoriasis (pictured) typically manifests as plaques covered with thick, silvery, shiny scales.

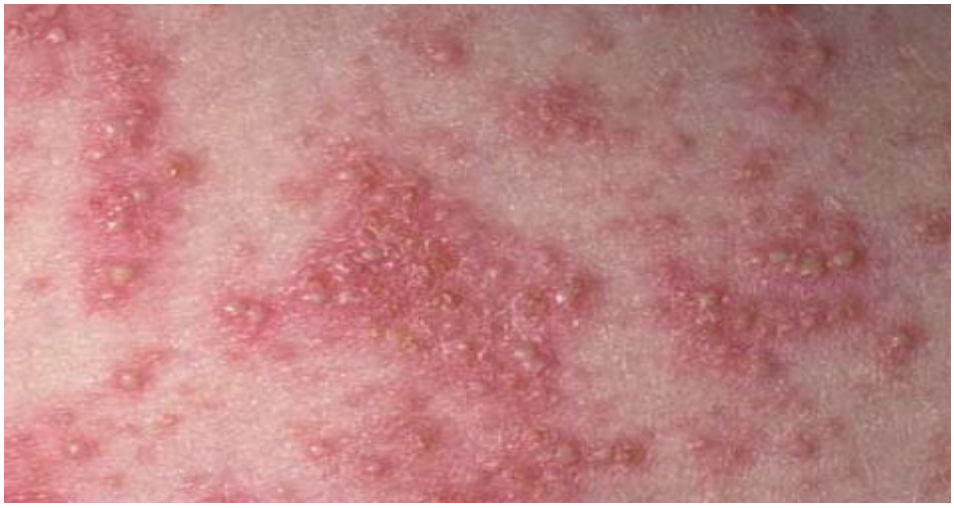

Figure: Image provided by Thomas Habif, MD[27]

Among the various psoriasis subtypes, about 90% is plaque psoriasis (psoriasis vulgaris or chronic plaque psoriasis) lesions are discrete, erythematous papules or plaques covered with thick, silvery, shiny scales. Lesions appear gradually and remit and recur spontaneously or with the appearance and resolution of triggers.

Arthritis develops in 5 to 30% of patients and can be disabling (psoriatic arthritis); joint destruction may ultimately occur.[28]

Psoriasis is rarely life-threatening but can affect a patient's self-image. Besides the patient's appearance, the sheer amount of time required to treat extensive skin orscalp lesions and to maintain clothing and bedding may adversely affect quality of life.

AYURVEDICVIEW

As per Ayurveda skin is a organ related to 'Fire', or Pitta. Skin therefore reacts very strongly to sunlight. One gets tanned, sun burnt or perhaps simply sensitive to an excessive amount of sun. All skin ailments are considered as "Pitta imbalances" - therefore one must reduce excess heat or Pitta from the body.[30] Psoriasis, as a skin condition, could be a Pitta ailment - the warmth has exceeded the body's limits for healthy containment, hence causing the

imbalance.[31]

Foods

- As per Ayurveda avoiding certain "faulty food combinations". the foremost common of those are fruit and dairy (therefore no fruit & yogurt or strawberries & cream), meat and dairy, fish and dairy. Combinations of these cause the accumulation of toxin in the body which attack the skin and cause psoriasis.
- Eating cooked foods helps to stimulate the digestive fire therefore help digesting all the food and helps to ensures that no food is converted into toxins.

Buttermilk is additionally specially recommended. For this blend one quarter yogurt and three quarters of water needed. to the present one can add spices like cumin powder, cinnamon, grated ginger, and cardamom. It has astringent qualities hich helps to eliminate excess heat. A glass 3-4 times every day.

- Regular intake of a cooling tea just like the Re Fresh – Pitta Tea will help to scale back the warmth within the body and improve the psoriasis. Massages.
- People tormented by dry flaky psoriasis should invest it slow in regular ayurvedicoil massages. Either a self massage with warm seasoning oil reception or visit your local ayurvedic therapist for a soothing calming Abhyanga[32] massage. confirm you have got a warm shower after your treatment as this helps to urge obviate any toxins that come up to skin level during the treatment.
- Ayurvedic foot massages helps for heat removing properties. For an enhancedbenefit, ask your therapist to use "Ghee", commonly called drawn butter.

YOGA VIEW

Yoga is one of the most metaphysical primordial sciences, yoga investigates the nature of soul and through that discipline and awakens the super-conscious mind. which unites the human being with the supreme spirit. Yoga leads to balance and also provides both the philosophy and the religion. Yoga help to unifty the nature with human being and human being to nature by the way help to reduce the stress. Yogacan serve both the individual and society.[15]

Yoga stimulates the parasympathetic nervous system (the calming influence) on physical level, which helps to reduces the body's stress response. It helps to improve the immune system of the body. Furthermore, new studies show that moderate exercise can quell

inflammation in the body, which is common with autoimmune disease. Therefore, by reducing the stress and by immunomodulation the Yoga therapy helps in the management of psoriasis.[26]

Figure: yoga & Pranayama A- Anulom Vilom Pranayam, B- BhastrikaPranayam[29]

UNANI VIEW

Psoriasis, termed as Taqashshure Jild, In classical literatures of unani. it is a common skin condition causes dryness of the skin and scale formation a bit like the size of fish. Psoriasis (Da-us–Sadaf) has been treated by eminent Unani physicians like Hippocrates, Galen, Avicenna, Razi, Ibn-e-Zohr and Majoosi through different modes of treatment like Ilaj BilGhiza (Dietotherapy), Ilaj Bit-Tadbeer (Regimenal Therapy) and Ilaj Bid-Dawa (Pharmacotherapy). Unani source of medicine used possess concoctive & purgative, anti-inflammatory, moisturizer, blood purifier, ciccative and demulcificant properties, these are the principles of treatment for this disease.[34] Worldwide various topical drugs, phototherapy and systemic medications are available for the treatment of Psoriasis with the variable outcome. In absence of satisfactory cure of the Psoriasis, it's imperative to look better options in other traditional system of medicine.[35] it's found mention of assorted descriptions of this disease within the various classical literature of Unani (Greek) Medicine in numerous languages, mainly in Arabic, Persian and Urdu. According to Unani Principles of Medicine(Greek) the oral drugs attending to normalize the humors of the patients by means

of Unani medicine required actions of purification (alleviationof acrid materials) of blood, relieving (normalization of hyper functioning) of skin cells together with correctives for immune functioning of the body.[36]

ALLOPATHIC VIEW

In the erlier 1960s and '70s, information about how the defense machnisum of immune system against germs plays a role in finding new treatment for psoriasis. Corticosteroids, methotrexate and cyclosporine became mainstays drugs for managing the psoriasis. For the next few decades, but advancement in treatment slowed down.[4]

Recent progress in research helps to find out new modalities of treatment like biologic therapies which work well to treat psoriasis, and other new treatments are close to FDA approval.

New Era of Psoriasis Treatment

Psoriasis Research most of time not make headlines and win funding like otherdisease in cancer or heart disease. And studies are hamstrung by the one-of-a-kind nature of your skin. Unlike many other diseases, experiments on mice and animals was not very helpful in find out the new treatments.

Research into other autoimmune diseases in recent years brought new insights about the immune system. which turns out that some of the problems in those conditions are active in psoriasis, as well.

The new info brought treatments that target specific areas of your immune system. Called biologics, these drugs launched a new era of psoriasis treatment.

Biologics

They're medicines made from substances found in living things. Doctors inject these lab-made proteins or antibodies into skin or bloodstream. Once inside the body, the drug blocks part of altered immune system that adds to psoriasis.[30]

In general, biologics work on psoriasis because they

- Curb T cells (a form of white blood cell)
- Block a substance called tumor necrosis factor-alpha (TNF-alpha), one of the main messenger chemicals in the immune system

- Stop a family of your immune system's chemical messengers called interleukins
- Bind to proteins that cause inflammation

Interaction between your skin cells and white blood cells causes patches and plaques of psoriasis. Biologics interfere with TNF-alpha or T cells, or they target IL(interleukin). This short-circuits that unhealthy link. This will ease your inflammation. You'll have less growth of thick, scaly skin, too.

Biologic medicines approved by the FDA to treat moderate to severe psoriasis include[31]

- Adalimumab (Humira), a TNF-alpha-blocking antibody
- Adalimumab-adbm (Cyltezo), a biosimilar to Humira
- Brodalumab (Siliq), a human antibody against interleukins
- Certolizumab pegol (Cimzia), a TNF-alpha blocker
- Etanercept (Enbrel), a TNF-alpha blocker
- Etanercept-szzs (Erelzi), a biosimilar like Enbrel
- Guselkumab (Tremfya), an antibody against interleukins
- Infliximab (Remicade), a TNF-alpha blocker
- Ixekizumab (Taltz), an antibody that binds to inflammation-causingproteins/interleukins
- Risankizumab-rzaa (SKYRIZI), an antibody against interleukins
- Secukinumab (Cosentyx), a human antibody against interleukins
- Ustekinumab (Stelara), a human antibody against interleukins

Biologics are good at treating psoriasis. In clinical trials, each of the drugs loweredpsoriasis activity by at least 75% in many people.[32]

HOMOEOPATHIC VIEW

Medicinal View

Azadirachta indica, normally referred to as neem, nimtree or Indian lilac, may bea tree within the rosid dicot family Meliaceae. it's one among two species within the rosid dicot genus, and is native to the Indian subcontinent.

Neem *(Azadirachta indica)* may be a member of the Meliaceae family and its role ashealth-promoting effect is attributed because it's rich source of antioxidant. Neem is widely utilized in various system of drugs worldwide like Chinese, Ayurvedic, and Unani medicines especially in Indian Subcontinent within the treatment and prevention of varied diseases.

previous result shows that neem and its constituent play role within the scavenging of atom generation and prevention of disease process. Some studies supported animal model established that neem and its chief constituents play pivotal role in treatment of cancer through the modulation ofassorted molecular pathways which including p53, pTEN, NF-κB, PI3K/Akt, Bcl-2, and VEGF. Previous studies shows is as a secure plant and modulate the many biological processes with none adverse effect. neem is beneficial for theprevention and treatment of diseases via the regulation of assorted biological and physiological ways[14]

Botanical description of Neem:- Neem belongs to the family Meliaceae which is found in abundance in tropical and semitropical regions like India, Bangladesh, Pakistan, and Nepal. it's a fast-growing tree with 20–23 m tall and trunk is straight and encompasses a diameter around 4-5 ft. The leaves are compound, imparipinnate, with each comprising 5–15 leaflets. Its fruits are green drupes which turn golden yellow on ripening within the months of June–August[16] Active Components of Neem:- nim tree L. (neem) have therapeutics role in health management due to its rich source of ingredients. azadirachtin, nimbolinin, nimbin, nimbidin, nimbidol, sodium nimbinate, gedunin, salannin, and quercetin Are the constituents of neem out of them azadirachtin may be a important one. Leaves of neem contain ingredients like nimbin, nimbanene, 6-desacetylnimbinene, nimbandiol, nimbolide, antioxidant, n-hexacosanol and aminoalkanoic acid, 7- desacetyl-7-benzoylazadiradione, 7-desacetyl-7-benzoylgedunin, 17- hydroxyazadiradione, and nimbiol. Quercetin and ß-sitosterol, polyphenolic flavonoids, were purified from neem fresh leaves and were known to own antibacterial and antifungal properties and seeds hold valuable constituentsincluding gedunin and azadirachtin.[16] Mechanism of action of Neem (Azadirachta indica) - a member of the Meliaceae family, has therapeutics implication within the diseases prevention and treatment. But the precise molecular mechanism ithin the prevention ofpathogenesis isn't understood entirely.[40] As neem tree contain rich source of antioxidant and other valuable active compounds like azadirachtin, nimbolinin, nimbin, nimbidin, nimbidol, salannin, and quercetin so it work well on th treatment of the diseases.[41]

Work machanisum of neem tree

Neem (Azadirachta indica) tree parts shows antimicrobial role by inhibiting the expansion of microbs by plasma membrane breakdown.[42] Azadirachtin, a fancy tetranortriterpenoid limonoid found in seeds, is that the key ingredient chargeable for both antifeedant and toxic effects on insects. Results of varied researches suggest that the ethanol extract of neem leaves

showed in vitro antibacterial activity against both Staphylococcus aureus and MRSA with greatest zones of inhibition noted at 100% concentration.[16]

1. Neem plays role as atom scavenging properties because of rich source of antioxidant. Azadirachtin and nimbolide
2. Neem ingredient shows effective role within the management of cancer through the regulation of cell signaling pathways. Neem modulates the activity of assorted tumour suppressor genes (e.g., p53, pTEN), angiogenesis (VEGF), transcription factors (e.g., NF-κB), and apoptosis (e.g., bcl2, bax).
3. it plays role as anti-inflammatory via regulation of proinflammatory enzyme activities including cyclooxygenase (COX), and lipoxygenase (LOX) enzyme.

Therapeutic uses of Neem helps diseases cure via activation of antioxidative enzyme, rupture the cytomembrane of bacteria and play role as chemopreventive through the regulation of cellular pathways. This medicine is formed from the bark of the Neem which have all the properties of Neem.[43]

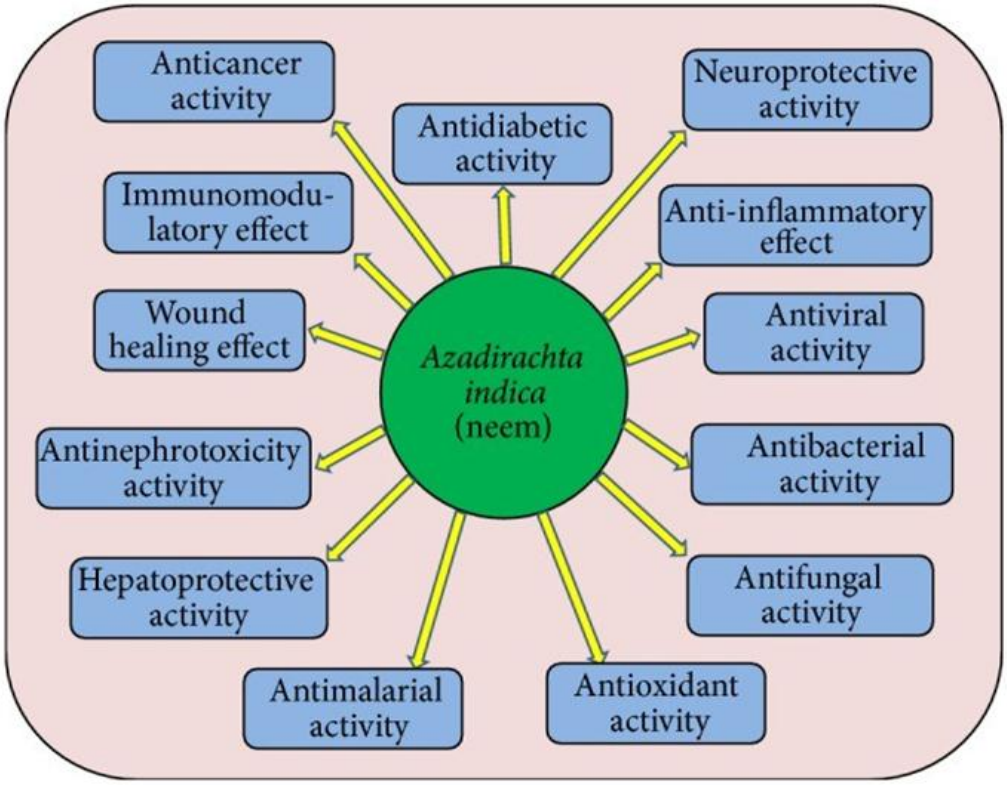

Figure 3: Pharmacological activities of Azadirachta indica L. neem in diseases management through the modulation of various.

Previous studies

Pandey et al. Reported in a only clinical trial assessing the use of neem for plaque psoriasis.22 it involved 50 participants with uncomplicated plaque psoriasis who were randomised and instructed to take either placebo or neem leaf extract capsules three times daily with the addition of a topical regimen that included 5% crude coal tar and 3% salicylic acid in a Vaseline base for 12 weeks. At the end of the study both groups showed decreased PASI scores indicative of response to the topical regimen at treatment endpoints, the mean PASI score was significantly better for the neem group compared with the placebo group at 8 weeks (9.7 vs. 12.24, respectively; $p < 0.05$) and after 12 weeks of intervention (4.74 vs. 9.47, respectively; $p < 0.001$). No adverseevents were reported.[24]

A doubled blind clinical study conducted by B.K.R. PillaP at all on the psoriasis inthis study the recruited 20 patients in each group one group was given nimbidin 200mg and other group given placebo. They asses the severity of the diseases and the area of body part affected and found that nimbidin have edge in the treatment of the psoriasis.[34]

A case report published by Rajasekharan S at all shows improvement in various symptoms of psoriasis by using neem extract. In this report they have taken a 72 year male with psoriatic lesion they prescribe nimbidin 100mg twice daily and his symptoms were recorded and blood investigations was done on the subsequent follow- ups it was found that patients red flat discoid disappears in 15 days, long axil papuls disappears in 66 days, white laminar scales in 45 days, erthymia in 45 days anditching in 15 days if we compaire the blood reports his ESR values also changed from18 to 8 mm/hr. so we can say by the report that nimbics is effective in the treatment ofpsoriasis.[35]

MATERIALS AND METHODOLOGY

Study Setting

The present study was undertaken at OPD /IPD of M.N. HomoeopathicMedical College & R.I. Bikaner, Rajasthan.

Study Duration

First 2 month preparation of trial, then all 100 cases were randomised and divided into 2 group – group A & group B. Both the groups was given respective treatment i.e. group A- *Azadirachta indica* 1X & group B- *Placebo* for a period of 7 month with each case follow up of 3 month atleast. Then research analysis for 3 month. All this was done in a period of 12

months.

Sample Size

To see the effect of *Azadirachta indica* 1Xand *Placebo* one in group A and other ingroup B.

The effective sample size for each group was 50. and total samples taken were 100cases.

- Group A- 50 cases- Azadirachta indica 1X
- Group B- 50cases- Placebo

Inclusion / Exclusion criteriaInclusion criteria

- Screening-Screening was done on the basis of presenting complaints.
- Cases with psoriasis with red / white patches skin and silvery scaly skin of 20-40 year age group was included in the study irrespective of their sex, caste, religion & duration of illness.
- Patients giving concent for the study.
- Patient with age group 20-40 years[1]

Exclusion Criteria

- Females who wanted to concieve, are pregnant or lactating.
- Cases with any other severe systemic disorder already diagnosed or diagnosed during screening if clinical features are suggestive of some systemic illness. To confirm, investigations regarding the same.
- Patient pursuing other treatment and were not willing to leave it.
- Patients with age group below 20 years and above 40 years.[1]
- Patient suffering from severe & very severe(3 & 4) psoriasis in PASI scale.

Drop Out

- Cases who discontinue treatment in between and cases without proper follow–up was excluded from the study.
- The cases requiring emergency treatment.

Study design

- Double Group Assignment, Random allocation, controlled trial single blind

Randomization was done using random number table. Patients were randomly allocated to two groups- group A (*Azadirachta Indica* 1X) and Group B (Placebo)

Selection of tools

- A detailed Case Report Form specially designed for the study and approved.
  These include the Case Report Forms (CRFs)that was contain information and documents the subject's ability to participate in the study (including a copy of a sign on consent form) and information from tests and examinations.

- **ASSESSMENT TOOLS:** A PASI SCORE is a tool used to measure the severity and extent of psoriasis. Psoriasis is characterized as mild, moderate, severe according to the amount of body surface area (BSA) affected and the severity of redness, thickness and scaling of the skin. An area and severity score for each region is calculated by multiplying the area score by the severity score (maximum 6×12=72). The amount each region contributes tothe final PASI is then weighted according to total amount of body surface area.[36]

- **DIAGNOSIS OF PSORIASIS:** The hallmark of classic plaque psoriasis is well-demarcated, symmetric, and erythematous plaques with silver scale. Plaques are typically located on the scalp, trunk, buttocks, and extremities but can occur anywhere on the body.[37]

Recording of data

- Data was recorded in approved Case Report Format
- Centralized data was collected in approved master chart in proper excel format.

Confidentiality

- All the evaluation forms, reports and other records was kept in locked filecabinet. Any information about the patient was not be leaked out until required.

Maintenance

Data collection

There are forms that are completed by for each subject recruited, including twoconsent form for the patient's information and his/her written consent for the enrolment in the study. Data was updated as per need.

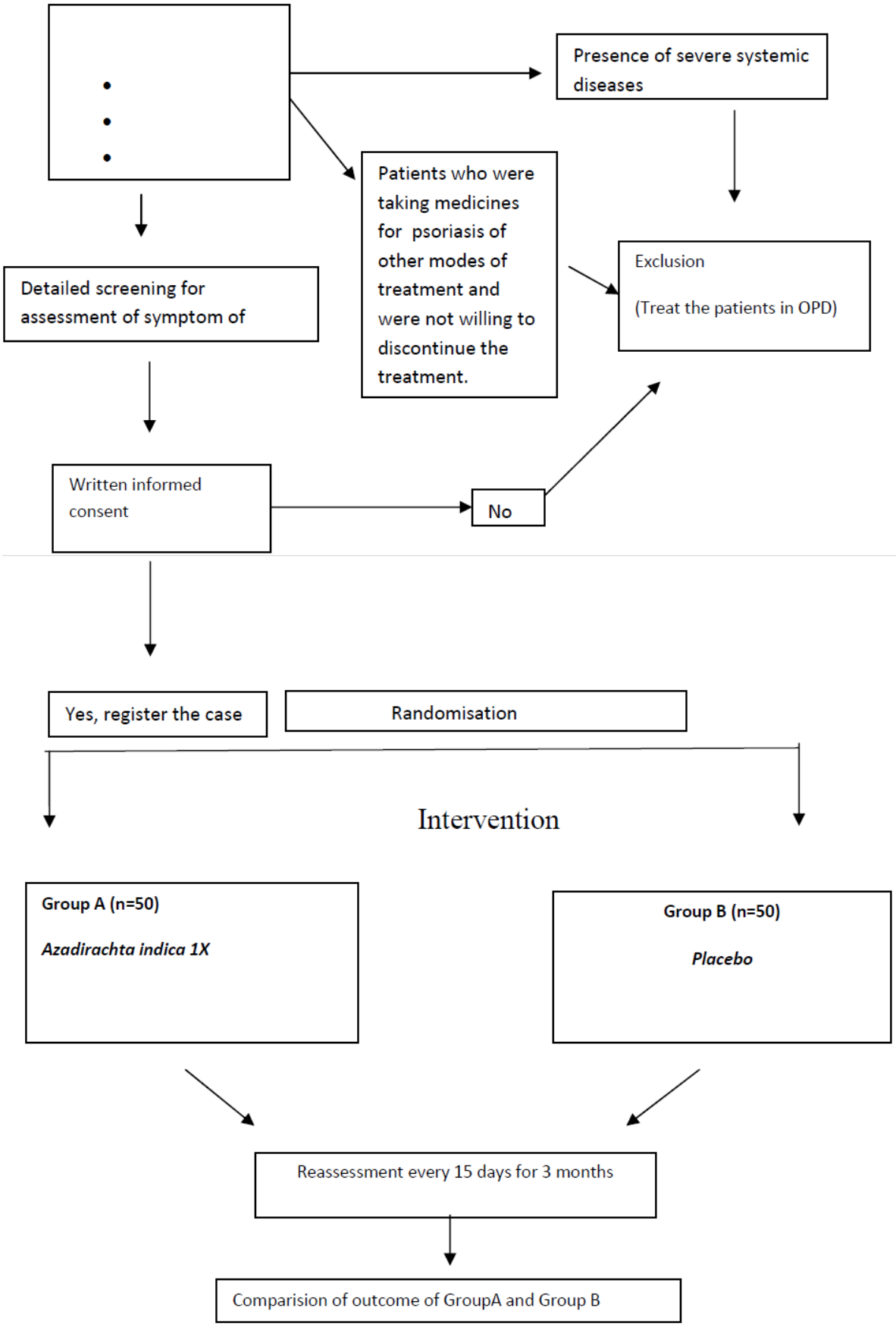

Figure 4: Flow Chart of Study Design.

Intervention

Group A

- *Azadirachta indica*
  - Potency- 1X.[38]
  - Manufacturer- Medicine was obtained from a good manufacturer practice certified company.
  - Repetition of doses- 1-2 tablets BD for 15 days.
  - Route of administration- Oral
  - Dispensing- This was done by the college dispensary by aregistered pharmacist.

Group B

- *Placebo*
- Manufacturer- Medicine was obtained from a GMP certifiedcompany.
- Repetition of doses- 1-2 tablets BD for 15 days.
- Route of administration- Oral
- Dispensing- This was done by the college dispensary by a registeredpharmacist.

Follow up

Patients enrolled in the study were visited every 15th day, as per the requirement, for follow up & assessment. In acute exacerbation state, frequency of visit were on alternate day. 6 follow ups of patient done for final assessessment.

General supportive care: Advice the patient as follows.

- Obstacle to cures such as diet, winter, stress, to frequent bath and use soap.
- A nutritious well-balanced, healthy diet, regular exercise and hygienemaintained
- Sun bath, bathing in hot water reduce scaling.
- Use mild soap.
- Protect against skin injuries and infection.
- Keep skin lubricated, Oils, creams and petroleum jelly preparations weresuggested.
- Wear comfortable cloth.
- Reduce stress.
- No smoking and alcohol.[9]

9.8 : Outcome Assessment

According to the before and after scores obtained from the PASI scoring method,Following parameters were fixed to diagnose the severity of psoriasis.

0 – None

1- Slight

2- ModerateFromula

$$\text{Results} = \frac{\text{Score before treatment} - \text{score after treatment}}{\text{Score before treatment}} \times 100$$

Table 1: Table to assess the improvement in psoriasis.

PSORIASIS AREA AND SEVERITY INDEX (PASI) WORKSHEET

HOSPITAL NO.:
PATIENT NAME:
DATE OF VISIT:

The Psoriasis Area and Severity Index (PASI) is a quantitative rating score for measuring the severity of psoriatic lesions based on area coverage and plaque appearance.

Plaque characteristic	Lesion score	Head	Upper Limbs	Trunk	Lower Limbs
Erythema	0 = None 1 = Slight 2 = Moderate 3 = Severe 4 = Very severe				
Induration/Thickness					
Scaling					
Add together each of the 3 scores for each body region to give 4 separate sums (A).					
Lesion Score Sum (A)					

Percentage area affected	Area score	Head	Upper Limbs	Trunk	Lower Limbs
Area Score (B) *Degree of involvement as a percentage for each body region affected (score each region with score between 0-6)*	0 = 0% 1 = 1% - 9% 2 = 10% - 29% 3 = 30% - 49% 4 = 50% - 69% 5 = 70% - 89% 6 = 90% - 100%				
Multiply Lesion Score Sum (A) by Area Score (B), for each body region, to give 4 individual subtotals (C).					
Subtotals (C)					
Multiply each of the Subtotals (C) by amount of body surface area represented by that region, i.e. x 0.1 for head, x 0.2 for upper body, x 0.3 for trunk, and x 0.4 for lower limbs.					
Body Surface Area		**x 0.1**	**x 0.2**	**x 0.3**	**x 0.4**
Totals (D)					
Add together each of the scores for each body region to give the final PASI Score.					

PASI Score = ☐

9.9 : **Statistical Technique** and **Data analysis**

Before treatment- [mean± SE_m]After treatment- [mean± SE_m]

Data was analysed by using STATA software and Excel.

The statistical technique used was–'Independent t-test' and'Paired t-test'.

- Independent t-test were used to compare two treatment groups.
- Paired t-test was used to assess the before and after scores in each patient.

9.10 : INVESTIGATION

- **Investigations:** As per the requirement & merit of the case followinginvestigations were carried out Intervention – Homoeopathic Medicines.

9.11 ETHICAL CLEARANCE

Ethical clearance was obtained from the Institutional Ethics Committee.

OBSERVATION AND RESULTS

Demographic Characteristics

01. Distribution of Population as per the Gender.

Table 2: Table showing distribution of Psoriasis 100 cases as per the gender.

Gender	Gender
Male	57
Female	43

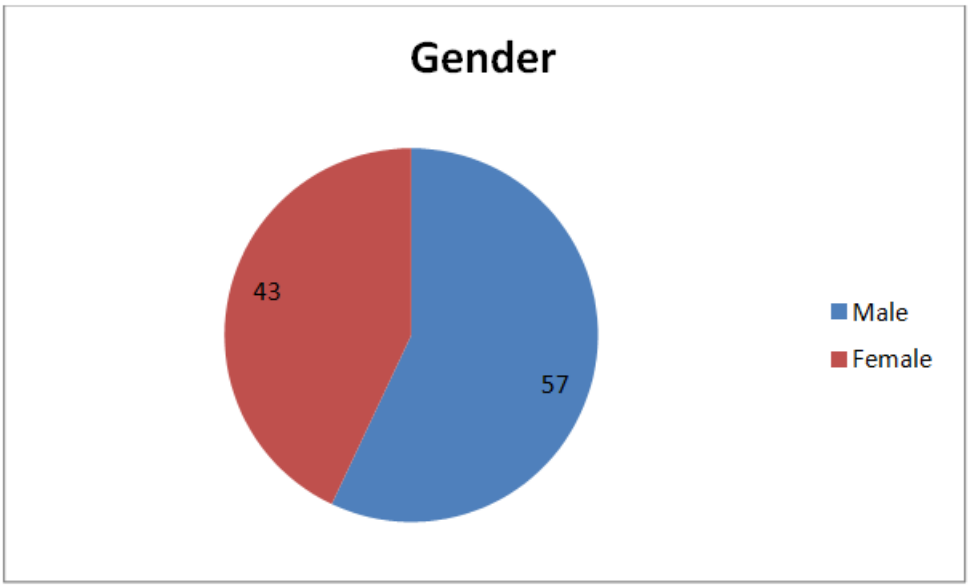

Fig 5: Figure showing distribution 100 cases of psoriasis according to Gender.

In the present study out of n=100 participants 57% (n =57) are male and 43% (n-43) are female. thus we can say males were more as compare to female.

2. Distribution of population as per Habitat

Table 3: Table showing distribution of Psoriasis 100 cases as per the habitat.

Habitat	Total	Group A	Group B
Rural	41(41%)	20(40%)	21(42%)
urban	59 (59%)	30 (60%)	29(58%)

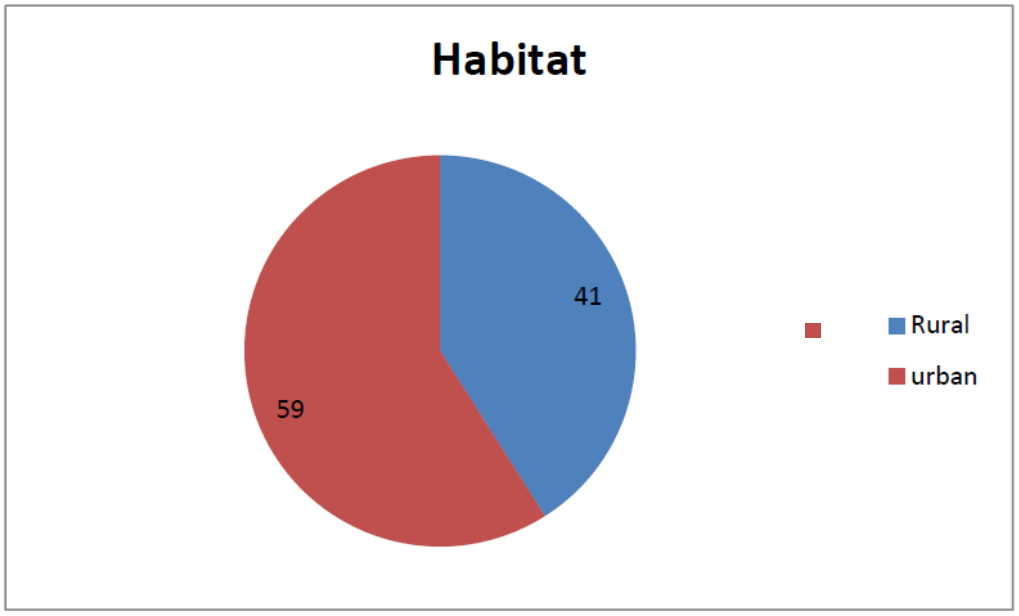

Figure 6: Diagram to show distribution of 100 cases of psoriasis according to Habitat.

In Total n=100 population, n= 41 (41%) were from rural and n=59(59%) were from Urban population. Thus patients of psoriasis were more from urban area as compare to rural are.

3.1 Distribution Of total population as per the religion in total population

Table 4: Table showing distribution of Psoriasis 100 cases as per the religion.

Religion	Religion
Hindu	88
Muslim	12

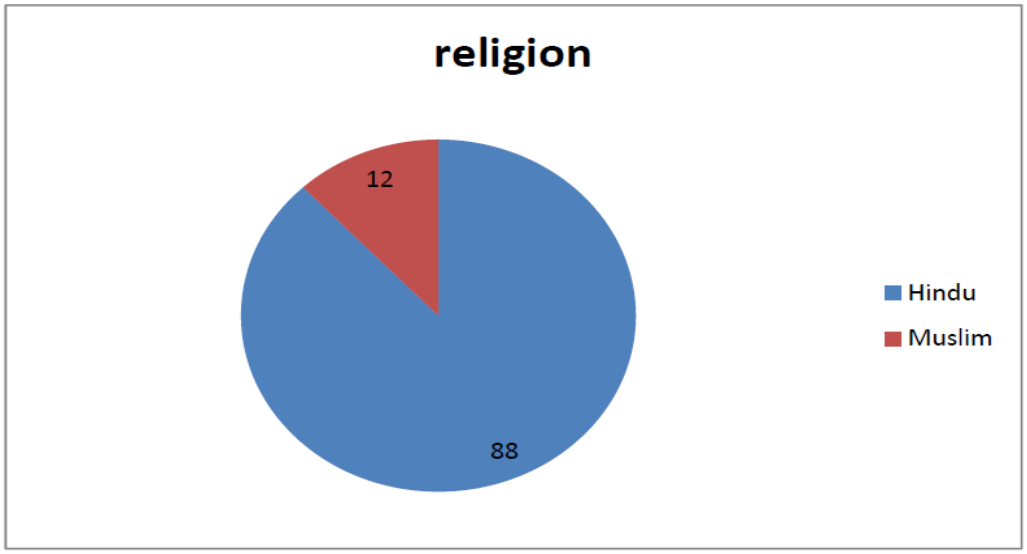

Figure 7: Diagram to show distribution of 100 cases of psoriasis as per the religion.

As per the religion our of total Population n=100, n= 88(88%) were Hindu and n=12(12%) thus, Hindu were more In the given population as comparing to Muslim.

4. Distribution of population as per the income Group

Table 5: Table showing distribution of Psoriasis 100 cases as per the socioeconomic status.

Socio EconomicStatus	Total	Group A	Group B
Low	19(19%)	11(22%)	8(16%)
Medium	63(63%)	31962%)	32(64%)
High	18(18%)	8(16%)	8(16%)

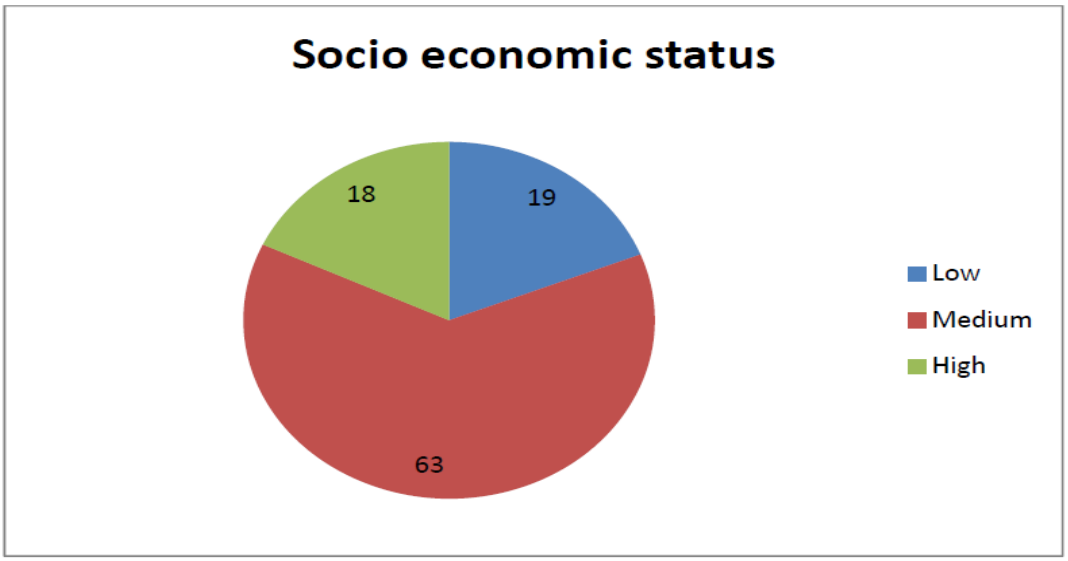

Figure 8: Distribution of 100 cases of psoriasis according to the socio economic status.

As per the income group n=19 (19%) were in low income group, n=63 (63%) were in middle income group and n=18(18%) were in high income group. Results shows majority of participants belongs to middle income group that is n=63 (63%).

5. Distribution of population according to Occupation.

Table 6: Table showing distribution of Psoriasis 100 cases as per the occupation.

Occupation	Total	Group A	Group B
Business	9(9%)	6(12%)	3(6%)
Farmer	7(7%)	5(10%)	2(4%)
Sitting job	45(45%)	19(38%)	26(52%)
Housewife	12(12%)	7(14%)	5(10%)
Student	23(23%)	10(20%)	13(26%)
Sweeper	4(4%)	3(6%)	1(2%)

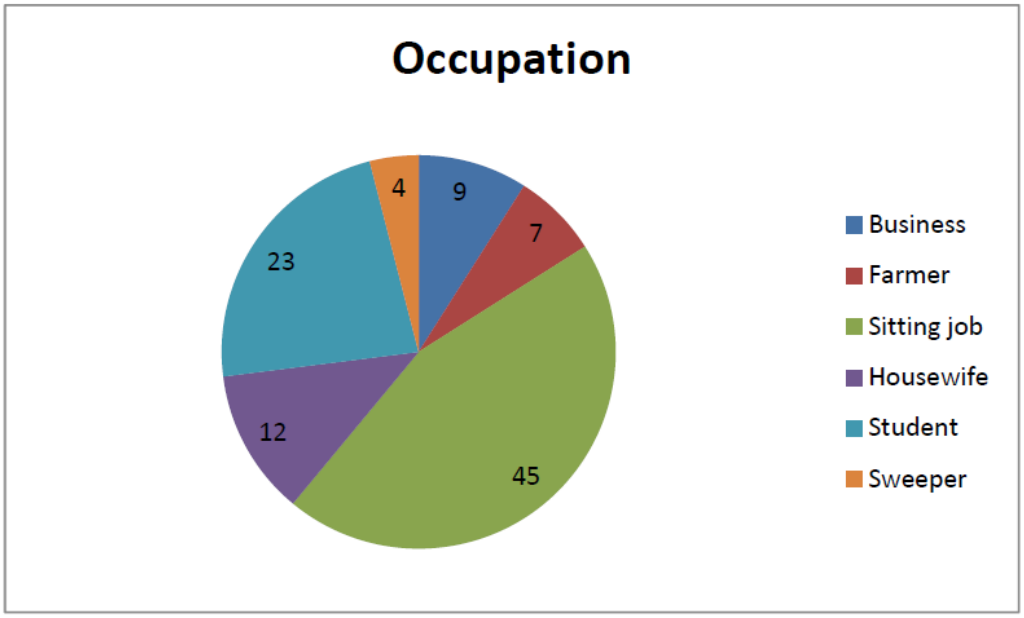

Figure 9: Diagram to show 100 cases of psoriasis according to occupation.

Distribution of the population as per the occupation were n=9 (9%) were in business, n=7(7%) were in farmer, n=45(45%) were in sitting job, n=12(12%) were house wives, n=23(23%) were students, n=4(4%) were sweeper out of n=100. This shows that majority of participants were in sitting job that is n=45(45%).

6. Comparison of clinical parameters on baseline and follow-up across the groups

Table 7: Table showing Before and after treatment Mean in both Groups.

Clinical Parameter	Azadirachta indica		placebo		p_1 (Between group Comparison)	p_2 (Within group Comparison)	
	Before Treatment (Mean+/- SD)	After Treatment (Mean+/ -SD)	Before Treatment (Mean+/- SD)	After Treatme nt (Mean+/ -SD)		Azadira chta indica	placeb o
PASI	69.27+/-	25.93 +/-	84.75+/-	78.25+/-	<0.01	<0.01	<0.01
	25.95	19.72	18.39	19.24			

If we see the Mean and SD of the pre treatment and post treatment it shows change in Mean and SD From 84.75±18.39 to 78.25±19.24 in placebo group and 69.25±25.95 to 25.93±19.72 in azadirachta indica.

Statically analysis: - categorical variables reported as frequency(percentage) where continuous variables were reported as Mean+/- SD. To assess the treatment effect across the two study groups, ANCOVA model was used. Baseline values were taken co-variants in ANCOVA model. P<0.05 was considered statistically significant throughout the statistical analysis.

STATISTICAL ANALYSIS

Paired T test *Azadirachta indica* 1X Group A.

	Mean	N	Std. Deviation	Std. Error Mean
before_treatment AZ	69.2700	50	25.95150	3.67010
after_treatmenta AZ	25.9300	50	19.72888	2.79008

Group A	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
before_treatmen tAZ after treatmenta AZ	4.33400E1	18.73109	2.64898	38.01668	48.66332	16.361	49	.000

Paired t-test calculated for group A (*Azadirachta indica* 1X) showed mean= 25.93±19.72(SD) as after score compared to mean=69.27±25.95(SD) as beforescore in PASI for patients suffering from Psoriasus with significance =0.00, which shows that *Azadirachta indica* 1X is effective in Reducing the PASI score in patients suffering from Psoriasis.

Paired T test Placebo Group B

	Mean	N	Std. Deviation	Std. Error Mean
Pair 1 Before_trtPlacebo	84.7920	50	18.39103	2.60088
after_trtPlacebo	78.2580	50	19.24721	2.72197

	Paired Differences					t	df	Sig. (2-Tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Before_trtPl acebo after_trtPlac ebo	6.53400	7.98204	1.12883	4.26553	8.80247	5.788	49	.000

Paired t-test calculated for group B (Placebo) showed mean= 78.25±19.24(SD) as after score compared to mean=84.79±18.39(SD) as before score in PASI for patients suffering from Psoriasus with significance =0.00, which shows that placebo is effective in Reducing the PASI score in patients suffering from Psoriasis.

Group Statistics

Table 9: Table showing after intervention Mean in both Groups.

Intervention	N	Mean	Std. Deviation	Std.ErrorMean
After Intervention placebo	50	78.25	19.24	2.72
Azadirachta indica	50	25.93	19.72	2.79

Table 10: Table showing "t" test in the groups.

	Levene's Test for Equality of Variances		t-test for Equality of Means						
	F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of theDifference	
								Lower	Upper
Before Equal Intervention variances assumed	3.916	.051	3.451	98	.001	15.52200	4.49825	6.59538	24.44862
Equal variancesnot assumed			3.451	88.304	.001	15.52200	4.49825	6.58311	24.46089

Levene's test for equality of variance calculated for independent "t" test shows equal variance assumed with means of group B9placebo)=84.79+/-18.39(SD) as compared to mean =69.27+/-25.95(SD)in Group A (*Azadirachta indica 1*X) with significance of 0.05, which shows (*Azadirachta indica* 1X) significantly reduced PASI score as compared to placebo in cases suffering from psoriasis. Thus rejecting the null hypothesis and accepting alternative

hypothesis(H2), *Azadirachta indica* 1Xis more effective in reducing the red/white patches of skin and scaly silvery of skin in case of psoriasis in comparison of placebo.

DISCUSSION

In our study 100 patients were enrolled and divided into two groups by randomization,where group A patients were prescribed *AZADIRACHTA INDICA* 1X and group B patients were prescribed Placebo. *AZADIRACHTA INDICA* 1X (group A) having a 50 cases, Placebo (group B) also having 50 cases.

Our study shows that Age group of 20-40 with mean age of 29.3 yrs. Which suggest that the majority of our population is at this age group. While we compare this with a study Joel M shows the average age of 42 years[39], in another study conducted by I.Y.K. Iskandar shows average age of 43.1[40], another study conducted by Nicolas Kluger shows means age of 29.4[41] study titled psoriasis: demographics, motivations and attitudes, complications, and impact on body image in a series of 90 Finnish patients.

In the present study the ratio of male and females are 43% were males and 57% were females in the present study, While we compared it with a study done by Joel M.shows 73% of males and 30% of females in another study done by Nicolas Kluger shows 90% of females and 10% of males[41] another study conducted by I.Y.K. Iskandar shows 81% male and 19% females.[40] In this study 88% were from hindu religion and 12% were Muslims in another study conducred by Ajith Vettuparambil at all shows 75.5% Hindus, 16.3 % Christians and 8.2% of Muslims.[42] In the present study if we see the socio economic status of the present study if shows 19% Low income group, 63% medium in come group and 18% high income group in a study conducted by Mercedes Freire at all shows 38% belongs to urban setting, 28.3 belongs to metropolitian setting and others were for the rural setting(43). While we see the occupation of the given study its shows 9% were in busniness, 7% were farmers, 45% were doing sitting job, 12 %house wife, 23% were students and 4% were sweepers. So it shows majority of study participants were from the sitting job while we compaire it with a study done by shristi laxmi at all it shows 15% farmers, 15% laboures, 12.5% housewives, 12.5% retired employes, 10% coocks, 5% construction workers 10% Others[44] another study done by L.NALDI at all shows 47% were doing manual work, 45% were doing the clerical work and 8% were professionals.

In this study change of PASI score Mean and SD of the pre treatment and post treatment it

shows change in Mean and SD From 84.75 ± 18.39 to 78.25 ±19.24 in *Azadirachta indica* 1X group and 69.25 ± 25.95 to 25.93 ± 19.72 in placebo group which shows significant in both the groups. While we do between group analysis By paired "t" test is shows significant difference at 95% CI.

At the end of the study while we compares the symptoms in the psoriasis patients according to PASI score before and after the treatment it shows -In the *Azadirachta indica* 1X group 30% of the participants shows marked improvement, 54% shows moderate improvement, 12% shows mild improvement and 4% shows non significant improvement while in the placebo Group 6% cases worse than previous, 20% cases no change in the status, 10% cases mild improvement 2% cases moderate improvement and 62% cases no significance. So we can say while comparing to the placebo *Azadirachta indica* 1X shows better results in the cases of Psoriasis while we evaluate the PASI score. So it is effective in the treatment of the Psoriasis symptoms.

CONCLUSION

This was a prospective, single blind, randomised, comparative trial with positive results and these results need further validations by conducting clinical trials.

From the above study it is concluded that *Azadirachta indica* 1X is helpfull in casese sufeering from psoriasis. No adverse effect were recorded when homoeopathic medicine *Azadirachta indica* 1X was prescribed. It is concluded from the percentage of symptomatic relief that *Azadirachta indica* 1X much useful in treating the symptoms of psoriasis. Thus, this study helps in improving clinical practice of homoeopathic physicians.

This study also has some limitations such as small sample size, comparison with another drug not present, single blinding, used only one scale for assessment.

No clinical verification studies could be found out. Hence, a clinical verification study and further researches should be planned accordingly.

A double blind, large sample size and a longer study duration can be planned for such studies. A better statistics can be applied for generalizations of the results.

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