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Research Article

Evaluation Of Therapeutic Efficacy Of Mitvana Anti-Dandruff Shampoo
And Mitvana Anti-Dandruff Hair Oil.

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ABSTRACT

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Dandruff is one of the most annoying disorders of scalp and if not treated well can lead to many complications. There are many chemical agents available that can eliminate dandruff but are also associated with a number of side effects, tolerance and recurrence. The present study was conducted to prove the safety and efficacy of combined application of Mitvana antidandruff shampoo and Mitvana Antidandruff hair oil. The result shows that the products were found to be highly effective, safe and caused significant reduction of dandruff in all the participants.

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INTRODUCTION:

Dandruff is actually caused by a microbe called *Malassezia* is a monophyletic genus of fungi and found in all warm-blooded mammals and humans and causes dandruff, atopic eczema/ dermatitis, pityriasis versicolor, seborrheic dermatitis and folliculitis etc. A microbe called *Malassezia globosa* is a single cell fungus and is known to be the main cause of dandruff. This fungus exists in every scalp and about 50% people react negatively to this fungus causing dandruff. Natural oils present in our scalp called sebum is a fuel/food for the dandruff-causing microbe. *Malassezia* feeds on these oils, breaking it down into many byproducts including oleic acid; formation of oleic acid is a starting point for the formation of dandruff¹. Approximately 50% people in the world are sensitive to oleic acid and affected by the dandruff. The body reacts to the presence of oleic acid by increasing the speed at which skin cells renew and due to this reaction of the body it starts shedding the irritant and that causes the formation of flakes. Dandruff causes the itchy scalp, dry scalp, inflammation, a red scalp etc².

One of the most frequently occurring disorder of scalp is Dandruff and it is also a very embarrassing disorder, which affects 5% of the global population. This disorder affects males more than females and is frequently seen in adults between 20-30 years of age³. Commonest symptoms of dandruff are seborrhea of the scalp followed by flaking. If it is not treated early may cause seborrheic dermatitis⁴. Fungus also releases toxic chemicals, which contribute to the development of a fungal infection⁵. There are many treatments available for dandruff that includes Salicylic acids, zinc pyrithione, Climbazole, etc. But all of them have severe limitations that includes poor efficacy and resistance, allergic reaction and long term toxicities. Also these chemical agents cannot prevent recurrence. Mitvana anti-dandruff shampoo and Mitvana anti-dandruff hair oil are two polyherbal formulations recommended for the treatment of dandruff and contains the extracts of *Ocimum sanctum*, *Eugenia caryophyllus*, oil of *Melaleuca leucodendron*. This study was planned to evaluate the clinical efficacy and safety of Mitvana Anti-Dandruff Shampoo and

Mitvana Anti-Dandruff Hair Oil in the management of dandruff.

Aim of the study

This study was planned to evaluate the clinical efficacy and safety (short- and long-term) of these two products in the management of dandruff.

Study design

The present study was a prospective, open, non-comparative, phase III clinical trial, as per the ethical guidelines of Declaration of Helsinki, from August 2018 to Nov 2018.

MATERIALS AND METHODS:***Inclusion criteria:***

A total of 30 patients between 18-55 years of age who were suffering from moderate to severe form of dandruff, and who were willing to give informed written consent were included in the study. Patients who committed not to use medicated/non medicated shampoos/soaps (including soaps containing antibacterial/antifungal agents) or any other antidandruff treatment/hair products (including prescription and nonprescription medications such as hair oil, conditioners) for the entire duration of the study.

Exclusion criteria:

- a. Any history of skin or systemic malignancy.
- b. Any skin lesions noticed recently
- c. Uncontrolled diabetes
- d. Any known hypersensitivity to ingredients of these products.
- e. Any hair procedures done within the past 2 weeks or during the study
- f. H/O Myocardial Infarction (MI) within 4 weeks prior to enrollment.
- g. Patients with immediate life threatening diseases
- h. Patients undergoing treatment for immunocompromised conditions/psychiatric illness.
- i. Any history of alcohol or drug abuse.
- j. Any H/O participating in any other clinical trial simultaneously.
- k. Pregnant or lactating females.
- l. If the investigator finds a person unsuitable for any other reason not specified in the exclusion criteria.

m. If the patient is not in a right frame of mind to give informed consent.

Study procedure:

At the start of the study, the patients were evaluated for their eligibility to participate in the study. All the patients were asked to give details of the baseline data that includes family history, personal history and past medical history and possible causes of exacerbation of symptoms. All the patients were advised to apply the Mitvana Anti-Dandruff Shampoo followed by Mitvana Anti-Dandruff Hair Oil daily for a period of 4 weeks.

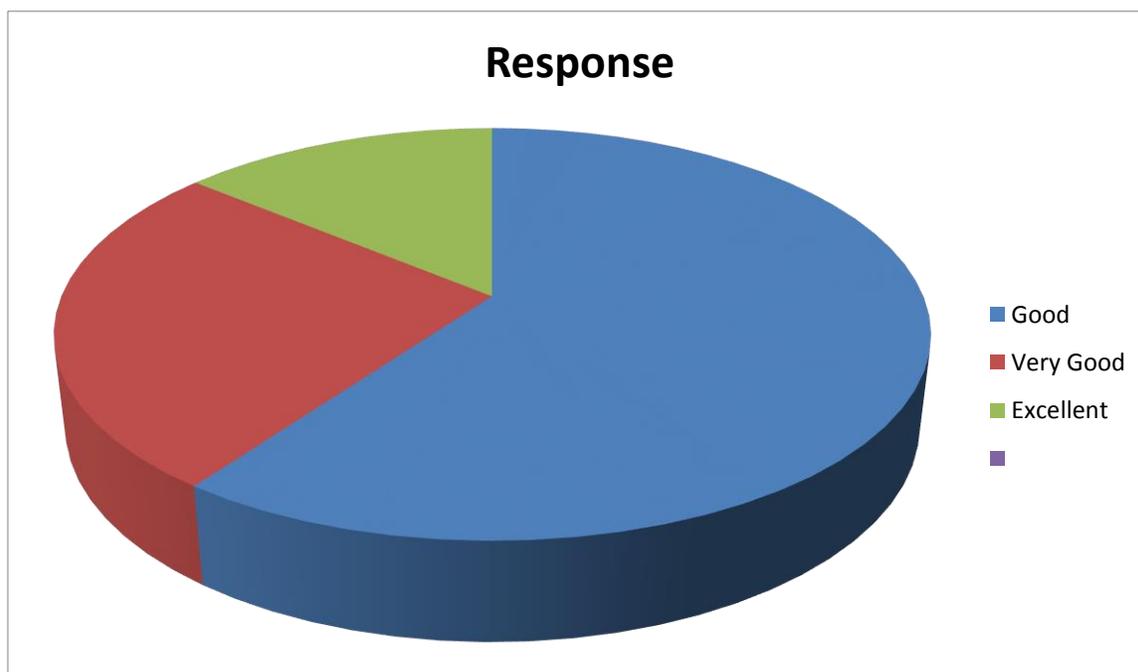
Follow-up and monitoring: All the patients were followed up for a period of 4 weeks and at each weekly follow-up visit, scalp skin examination was done to assess the improvement in the dandruff lesions. At the end of the 4th week, the overall performance of both the products were evaluated.

Primary and secondary end points: The efficacy of the product was evaluated on reduction of the inflammation on the scalp, reduction in scaling, reduction in dandruff lesions on the scalp and lastly, any incidence of adverse effect and then over all compliance to treatment.

Adverse events: Any adverse effect was recorded with all the information like date of onset, severity, duration of reaction and action taken.

RESULTS:

A total of 20 males and 10 females were enrolled in the study. There was a remarkable decrease in the scaling and itching of scalp after a week's treatment. Subsequently, there was remarkable improvement in the healing of the dandruff lesions from the second week onwards and there was complete control of dandruff in all the patients at the end of 4th week of treatment.



At the end of the 4th week, 12 patients (60%) graded the products as “good”, 5 subjects (26%) graded the products as “very good”, and 3 subjects (14%) graded the products as “excellent” (Figure). There were no clinically significant adverse reactions (either reported by patients or observed by the investigators) during the entire study period. There were no dropouts and

the overall compliance to the drug treatment was excellent.

DISCUSSION

Dandruff is the most annoying disorder of the scalp and may be caused by several factors but exact cause is still unknown. Dandruff can also be called a mildest

form of seborrheic dermatitis⁶. As the age of occurrence is during adolescence, it suggests an androgenic influence. Increase in androgenic activity during this phase also increases the chance of dandruff. High incidence of this disorder is usually seen during winter months and reduces during summer⁶. Diet, hormones, genetics and poor hygiene all contribute to the occurrence of dandruff. Dandruff can also occur in a person who uses excess hairsprays, hair colourants, tight fitting hair scarves, inadequate use of shampoo, excessive stress and anxiety. The main aim of the study was to first reduce the number of fungi on the scalp and reduce morbidity and complications⁷. No therapy can completely eradicate dandruff from the scalp but it can be controlled and managed efficiently through effective products. A large number of topical chemical antidandruff agents are available in the market like imidazoles, selenium, salicylic acid, but they cannot be used for a long time because of many side effects like drying of the scalp and tolerance and the major drawback is the frequent recurrence. While mild dandruff can be controlled by regularly shampooing the scalp with a mild, non-medicated shampoo, but when frequent shampooing alone does not control the dandruff, a medicated dandruff shampoo is needed^{8,9}. The present study showed reduction of white scales, irritation and itching and inflammation. Within 2 weeks of therapy, a significant symptomatic improvement was seen and by the 4th week, dandruff was completely controlled. The excellent antidandruff action of both Mitvana anti-Dandruff Shampoo and Mitvana Anti-Dandruff Hair Oil might have been due to the synergistic antifungal, anti-inflammatory and local immunostimulatory actions of its ingredients. *Melaleuca leucodendron* also called the Tea Tree Oil is well known for its anti-dandruff activity. There are many research papers on this plant which prove its activity against yeast, *Candida albicans* and other fungi and also *Malassezia furfur*. The principle ingredients of *Glycyrrhiza glabra* is Glycyrrhizic acid which is a potent antioxidant and has antifungal activity¹¹. *Juniperus communis* has antifungal activity¹², *Lawsonia inermis* leaves also have potent antifungal activity.

CONCLUSION

This study was planned to evaluate the clinical efficacy and safety of Mitvana Anti-Dandruff Shampoo and Mitvana Anti-dandruff Hair Oil in the management of dandruff. The study was conducted in 30 volunteers who had fulfilled the inclusion and exclusion criteria. Significant improvement at the end of 4 weeks of treatment. There was reduction in mean score of itching, inflammation, flakes of dandruff in the scalp. The anti-dandruff activity of these two products could be due to synergistic actions of the natural ingredients present in them.

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