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# A NONIMMUNOSUPPRESSANT APPROACH TO PSORIASIS SUBJECTS: FOLLOWUP AND DATA ANALYSIS

**Dermatology**

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## ABSTRACT

Mono- or combine immunosuppressants are commonly used for psoriasis; however the side effect caused by potent systemic immunosuppressants frequently incurred; moreover the inflammation flares up shortly after immunosuppressants are discon- tinued. An alternative nonimmunosuppressive therapy was introduced to psoriasis subjects. A retrospective observational study consisted of 1583 psoriasis patients who were treated with Herose Psoria capsule 1440 mg three times daily Psoriasis lesion evolution was photographed at monthly visit, and efficacy and safety were assessed using psoriasis area severity index PASI score grading, renal and liver function testing, and adverse event reporting and supplemented by information obtained during targeted telephone interviews. The effectiveness of Herose on psoriasis was inversely associated to prior immunosuppressants exposure , significant improvements occurred in non-immunosuppressants subjects, and complete clearance was achieved in 8 months (87.5%, 14 of 16); the wave like evolution of psoriatic lesion appeared in prior immunosuppressants subjects.

## KEYWORDS

Psoriasis, Nonimmunosuppressant Approach.

## INTRODUCTION

Psoriasis prevalence ranges from 0.6% to 4.8% and shows a wide variability among ethnic groups. As new research and clinical experience broaden our knowledge, changes in treatment and drug therapy are required, previously psoriasis had been viewed as primarily a disease of hyperproliferation, and more recently it has come to be regarded as an autoimmune-mediated disease; hence the conventional systemic immunosuppres-sive(Corticosteroids, PUVA, MTX, cyclosporine) therapy started shifting to immune system partial (T cell, cytokines, chemokines, proteases, integrins) suppressive therapy, and alefacept and efalizumab targeted anti-inflammatory strate- gies are being tested with T-cell inhibitors. Adalimumab, certolizumab, etanercept, infliximab, and golimumab tumor necrosis factor (TNF) antagonists are approved; ustek- inumab] and briakinumab are inhibiting inter- leukins (IL) 12 and 23; clinical trials are underway of a few drugs that inhibit IL-17 and/or L-17 receptor. Another trial is studying an IL-22 blocking agent; meanwhile resveratrol, vb-201, apremilast, and tasocitinib are being studied as oral inhibitors of inflammatory cytokines. The decision to implement therapy with immunosup- pressants must be derived from a precise understanding of these agents and the often formidable adverse reactions that accompany their use (efalizumab which inhibit CD11a has been associated with PML progressive multifocal leukoen-cephalopathy [10]), for inflammatory and autoimmune- related skin disorders as psoriasis which is not life-threat- ening; it is incumbent on the treating physicians to deter- mine that immunosuppressants are the appropriate form of treatment. Long-term remission and preventing recurrence were the priority in psoriasis management; this observational study was to describe the therapeutic response, tolerance, and safety of herose psoria capsule, a nonimmunosuppres-sive approach, in psoriasis patients.

## MATERIAL AND METHODS

A retrospective observational study we analysed 1583 consecutive psoriasis patients who were given Herose Psoria capsule. The medical records and photo documentation were reviewed. To complete mean 5 years of continuous follow up, we excluded patients who initialized heroes psoria therapy but the patients who were lost to follow up or dropped out for various reason were included; ultimately 1215 patients were included in this study. We collected the following information: age; psoriasis area severity index (PASI), prior psoriasis duration, dose and duration of prior treatment, comorbidities and concurrent treatments, thera- peutic benefit, adverse events, and duration of follow up. Patients were informed that herose psoria capsule was prescribed 1440 mg three times daily, and they gave written consent for its use. Herose psoria capsule is a botanical compound formulated to stimulate the yang com- ponent of the human body. Before starting herose, each patient underwent photograph taking, psoriasis area and severity index PASI grading; the blood test (liver function and renal function) was ordered for patients who were treated with systemic immunosuppressants previously. During the study period, no other antipsoriatic treatment modalities, apart from herose psoria, were given, patients were advised to use topical Johnson & Johnson lotion or Vaseline to relieve skin dryness, antihistamine for itchiness, and antibiotics if required for secondary infec- tion, psoriatic arthritis patiens were administrated with nonsteroid anti-inflammatory drugs (NSAIDs) by their rheumatologist, hypertension and hyperlipidaemia were given antihypertensive drugs and antihyperglycemic drugs by their cardioangiologist, diabetes and gastritis continued their antidiabetic medications and antigastritis or antiulcer agents, and asthma and eczema were advised non-steroids medications. Patients discontinued immunosuppressants therapy 7 days before initiating herose and were clinically monitored on a monthly basis, digital photographs were taken at each follow-up visit, and physicians reviewed photographs taken before and after treatment, when available. The efficacy parameters included PASI with photograph comparison and the Physician Global Assessment (PGA) of the therapeutic response. The main criteria assessed were as follows: time to receive PASI 75% improvements; time to reach full clearance after starting heroes. Adverse effects were assessed via clinical reporting, examination, lab studies. Descriptive statistics were calculated using numbers with means, percentages, and range. To identify potential predic- tors of a good clinical response, we evaluated correlation coefficient between time to reach PASI75 improvement to cumulated previous immunosuppressants treatments, and psoriasis duration before herose treatment, and initial PASI score at herose treatment, and patients' age. Time serial psoriasis lesion evolution curve of both prior non- immunosuppressive treatment group and prior immuno-suppressive treatment group was presented. Data were analysed and two-way graphs and matrix were produced by using STATA software (StataCorp, TX).

## RESULTS AND DISCUSSION

A total of 1583 consecutive psoriasis medical records were collectedTo complete mean 5 years of continuous follow up, ultimately 1215 patients were included in this study, of these patients with prior non-immunosuppressive therapy (n. 16), 14 patients (87.5%) reached complete clearance in 8 months thereafter with mean 30 months of subsequent follow up; of those patients with prior immunosuppressive therapy (n. 1199), 176 patients (14.7%) completed therapy and achieved PASI75 in 60 months treatment. We found that 141 (11.6%), 103 (8.5%), 47 (3.9%), 123 (10.1%), 19 (1.6%), 28 (2.3%), 19 (1.6%), 18 (1.5%), and 18 (1.5%) of patients with psoriasis had comorbidities of hypertension, hyperlipidaemia, asthma, arthritis, hepatitis B, diabetes, gas- tritis, eczema, and gout, respectively, in which some of pa- tients received more than one type of comorbidities. At the

baseline, the average of patients' age is at 42.4 years (range, 18 years to 71 years), the average of psoriasis duration is 9.7 years with range from 1 year to 39 years, and the mean PASI is 28.9 with range from 3.6 to 68. Of the 1215 pa- tients with psoriasis, only 16 (1.3%) received prior non- immunosuppressant therapy, and 1199 (98.7%) had previ- ous immunosuppressive treatment. 588 (48.4%) received less than 6 months of cumulated dose of prior immunosuppressants, and 332 (27.3%), 170 (14%), 33 (2.7%), and 76 (6.3%) received cumulated doses of prior immunosuppressants 6–12 months, 12–24 months, 24–36 months, and more than 36 months, respectively.we also found that almost all patients with psoriasis had used topical steroids therapy (98.7%), and 46.6% had received systemic steroid (orally P.O. or intravenously I.V.) therapy. Majority of Asia psoriasis subjects had taken traditional herbal immunosuppressive decoction/powder medication (71.5%), and the commonly used herbal immuno suppressant.

## CONCLUSION

The mechanism of action for clinical responses to herose, as well as its ability to modulate pathologic cellular and inflam- matory pathways in skin lesions, needs to be investigated further, and this retrospective uncontrolled clinical observational study and previous clinical findings suggest that non-immunosuppressive approach may play an important part in management of immune system cell (T cell) to avoid misfiring and inappropriately targeting the skin cells; it may also be that pharmacogenomics is an important variable: there may be groups of people who have a better response to one or the other of therapeutic agents, perhaps because of polymorphisms in genes that control the expression of the relevant molecules. In our opinion, clinically useful conclusions can be drawn despite the limitations of this study design, we suggest the non-immunosuppressive approach may be used as the first-line therapy to improve the thera- peutic outcome in patients with psoriasis, and further clinical investigation of controlled trial and mechanism of action is needed to be conducted for this indication.

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