

Research Article

Conversion of Phyto-Actives of JRK's 777 Oil Post-Sun Exposure Exhibit Calcipotriol like Activity – A Clinical Comparison at RML Hospital, New Delhi

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Keywords

• Dr. JRK's 777 oil, Psoriasis, Calcipotriol, *Wrightia tinctoria*, CCRAS

Abstract

Psoriasis is an auto immune disorder with the clinical symptoms of scaling, inflammation, itching and dryness. Drugs/medicines used for the psoriasis will be clinically evaluated based on the reduction in the symptoms and overall PASI score which include thickness, redness and itching.

In the present clinical evaluation, the efficacy of Dr. JRK's 777 oil and Calcipotriol was tested based on the reduction in the clinical symptoms and PASI score.

A total of 26 patients was taken for the study of each drug and given the instructions to use for 12 weeks. The results are monitored on basal PASI, 2nd week, 6th week and 12th week.

Results shows that in both the groups i.e., Dr. JRK's 777 oil and Calcipotriol ointment there is a great improvement in the clinical symptoms and PASI score by the end of the study where Dr. JRK's 777 oil had a higher edge without any side-effects.

Complete details are presented in the paper.

INTRODUCTION

Psoriasis is an incurable autoimmune disease with maximal manifestation in the skin where the skin cells, especially the keratinocytes enters into proliferation phase much before the completion their maturation and cell turnover cycle resulting in the formation of cells with absolute functional abnormalities of the daughter cells [1]. Such cells gather and accumulate over the skin causing hyperkeratotic patches with no benefit to the skin, leading to poor thermo balance and elicitation of various inflammatory reactions.

Siddha system of medicine is not only time tested but is also scientific where the ancient Siddhars through their divine power have evaluated the therapeutic effect of several herbal, mineral, metal and fecal materials of different animals on various diseases.

Dr. J.R. Krishnamoorthy, by continuing the legacy of Siddha system of medicine, discovered the usefulness of *Wrightia tinctoria* leaf oil extract for the treatment of Psoriasis which he later patented along with CCRAS and gifted to NRDC through CCRS to commercialize the technology for human welfare.

Several dermatologists in India were very optimistic about the discovery of Dr. J.R. Krishnamoorthy and forwarded voluntarily to evaluate the *Wrightia tinctoria* based oil which was named as

JRK's 777 oil in order to offer better, quicker and much needed relief to Psoriatic patients.

The *Wrightia tinctoria* based oil contains innumerable phytosterols and some even have exhibited structural analogue with calcipotriol [2]. On solar exposure the phytosterols turning to Vit D3 analogue and exhibiting calcipotriol like activity was the primary premise and which cannot be ruled out and that might be the reason for the therapeutic effect of JRK's 777 oil, initially the dermatologists presumed.

Before going to the mechanism of action and the possible reasons, the dermatologists at RML Hospital, New Delhi wanted to evaluate the clinical efficacy of JRK's 777 oil in comparison with calcipotriol in same patients as left-right comparison over 12 week of usage. The details of the clinical trial were presented by the dermatologists in 1997 in the National Conference of Dermatologists, Venereologists, Leprologists at Guwahati and the data we have presented in the paper.

The data was never covered in the proceedings of the conference nor has been published elsewhere. The complete data was not presented in the conference as the study was not completed then and hence only highlights alone were presented then and the details are given in the present paper.

MATERIALS AND METHODS

Twenty-six patients with comparable degree of plaque psoriasis both in clinical manifestation and also in duration (chronicity) were empaneled in the study.

All the patients required only topical medicament and the clinical condition of the Psoriasis was amenable to new investigational product of palliative nature.

All the patients were clearly instructed about the trial methodology, objectives, duration (12 week) and got the confirmation to participate in the trial and would follow the compliance.

Two distal anatomical sites with same extent of lesion in each patient were identified. The lesion that can be easily exposed to sunlight was chosen for JRK's 777 oil application and the other lesion was chosen for calcipotriol application.

Twice daily application of the treatment products was followed in all patients. The lesion that was treated with JRK's 777 oil was exposed to sunlight for 15 minutes. At the end of every 4th week, the patients were examined and the progress if any and or any adverse effect was recorded.

The statistical significance of the treatment response at different time points of treatment between Dr.JRK's 777 oil and calcipotriol were calculated using SPSS software and average and standard deviation were calculated for statistical importance.

RESULTS

Out of the 26 patients empaneled into the study, 16 were male and 10 were female patients. The age distribution of the patients was concerned, mostly were between 35- 45 years and small population were between 46-58 years of age. The duration of the disease in all patients ranged from minimum three years to maximum of 6 years (Table 1).

Four-week treatment with JRK's 777 oil has reduced the psoriatic symptom redness by 40% in 24 patients, thickening by 20% in all 26 patients, scaling by 50% in all 26 patients. In the case of calcipotriol treatment, close to 50% reduction in all the three parameters was observed in all 26 patients (Table 2).

Eight week treatment with JRK's 777 oil has reduced the psoriatic symptom redness by 50% in all 26 patients, thickening by 40% in all 26 patients, scaling by 60% in all 26 patients. In the case of calcipotriol treatment, close to 70% reduction in all the three parameters was observed in all 26 patients (Table 3).

Twelve-week treatment with JRK's 777 oil has reduced the psoriatic symptom redness by 80% in all 26 patients, thickening by 80% in all 26 patients, scaling by 80% in all 26 patients. In the case of calcipotriol treatment, close to 80% reduction in all the three parameters was observed in all 26 patients (Table 4).

Although all the 26 patients of both gender with plaque psoriasis responded to both JRK's 777 oil and calcipotriol by 12-week treatment, but the response was faster in male than female patients in relative terms (Table 5).

Irrespective of the duration of the disease, all the lesions responded to the treatment in a similar manner (Table 6).

The above data when compiled in terms of PASI score which includes redness (erythema), thickness (induration) and scaling (desquamation) in 12 weeks, marked decrease of 91.9 % in the PASI* score was observed in JRK's 777 oil treatment and 90.8% decrease in PASI* score in Calcipotriol treatment (Table 7).

DISCUSSION

The present clinical evaluation happened purely because of the care and welfare the psoriatic patients deserve the most as felt by the dermatologists at Ram Manohar Lohia Hospital, New Delhi where the consideration of Siddha drug did not appear suppress their enthusiasm.

Table 1: Age, gender and duration of the disease distribution.

Gender	No. of patients with 3-4 years duration of psoriasis	No. of patients with 5-6 years duration of psoriasis	Age in years	
			32-45	46-58
Male	8	8	10	6
Female	5	5	6	4

Table 2: clinical response after 4-week treatment.

Clinical parameters	% reduction and number patients	
	JRK's 777 oil treatment (n=26)/SD	Calcipotriol (n=26) /SDvv
Redness	40/24 ±0.5	50/26±0.4
Thickening	20/26 ± 0.7	40/26±0.2
Scaling	50/26 ± 0.2	50/26±0.5

Table 3: clinical response after 8-week treatment.

Clinical parameters	% reduction and number patients	
	JRK's 777 oil treatment (n=26) /SD	Calcipotriol (n=26) /SD
Redness	50/26 ±0.2	70/26 ± 0.2
Thickening	40/26 ±0.3	60/26 ± 0.3
Scaling	60/26 ± 0.5	70/26 ±0.5

Table 4: clinical response after 12-week treatment.

Clinical parameters	% reduction and number patients	
	JRK's 777 oil treatment (n=26) /SD	Calcipotriol (n=26) /SD
Redness	70/26± 1.5	80/26 ± 0.6
Thickening	70/26 ± 2.2	70/26 ±0.4
Scaling	80/26 ± 2.5	80/26 ±0.8

Table 5: overall clinical response versus gender.

Gender	No	Positive treatment response/% of patients		
		Week 4	Week 8	Week 12
Male	16	40	60	100
Female	10	20	40	100

Table 6: Treatment response versus duration of the disease.

Duration of disease (3-4 years) / no. patients shown positive response, n=12			Duration of disease (5-6 years) / no. patients shown positive response, n= 14		
Week 4	Week 8	Week 12	Week 4	Week 8	Week 12
5	12	12	13	13	14

Table 7: PASI score improvement in 12 weeks of treatment.

No. of weeks / mean values	Dr.JRK's 777 oil (26 cases) /SD	Calcipotriol ointment (26 cases) /SD
Basal PASI	19.9 ± 0.8	19.5 ± 0.7
2 weeks	8.9 ± 1.7	8.5 ± 0.2
6 weeks	4.5 ± 2.3	4.8 ± 0.3
12 weeks	1.6 ± 2.9	1.8 ±0.1

*PASI – Psoriasis area severity index

When Dr.J.R Krishnamoorthy discovered the usefulness of *Wrightia tinctoria* oil for the treatment of Psoriasis and gifted the same large-heartedly to CCRAS after sharing his invention in joint patent with CCRAS, purely for the benefit of mankind, the dermatologists at RML hospital moved by the gracious gesture of Dr.J.R Krishnamoorthy and has decided to evaluate the efficacy of JRK's 777 oil on psoriatic patients to reach the science of the same to the world.

As a part of their prior-art search, they found that some sterols present in *Wrightia tinctoria* have structural similarity with calcipotriol – Vit D3. Calcipotriol is a well-known drug for psoriasis. Therefore, they assumed that the above phytosterols may be exhibiting anti-psoriatic efficacy and hence JRK's 777 oil is effective. However, they deferred from exploring the cause-and effect mechanism and decided to evaluate the efficacy of JRK's 777 oil in 26 psoriatic patients by keeping calcipotriol as positive control treatment drug.

Further, to determine the clinical activity accurately, bi-side comparison was planned, meaning two distal end, comparable lesions were chosen and calcipotriol and JRK's 777 oil were applied separately over the selected lesion. The lesion where JRK's 777 oil was applied was further exposed to sunlight for 15 minutes for the conversion of phytosterols to calcipotriol.

Although a marginal difference in the clinical efficacy between JRK's 777 oil and calcipotriol was observed in the lesion, but by week 12, the lesions treated with either JRK's 777 oil or calcipotriol responded equally. All the key clinical features

of plaque psoriasis such as redness, thickening and scaling responded well.

JRK's 777 oil exhibited efficacy which was multi-sectionally comparable with that of calcipotriol proving the discovery of Dr JR Krishnamoorthy stupendous. There are also various other studies done on the Dr.JRK's 777 oil which proves its efficacy [3-9].

The compliance behavior of the patients recruited in the present study was very high as most the patients were in the middle age group and wants to achieve treatment success which was possible only through strict compliance of the medication. Irrespective of the duration of the disease, the treatment response was almost the same.

From the above clinical evaluation, we assume that JRK's 777 oil is very effective for the treatment of psoriasis and the same may be used especially during the early stage of the disease as soon as the disease was diagnosed. Such treatment adoption may help the patients to contain the disease early, prevent drug tolerance, tachyphylaxis and other drug induced problems. JRK's 777 oil is safe and can be used lifelong. Cost effective and therapeutically promising value also JRK's 777 oil will offer to the patients.

Findings as established in the clinical situation at RML assume great significance as it gives sufficient scientific evidence to the world that JRK's 777 oil is very effective for the treatment of psoriasis. The associated safety profile of JRK's 777 oil should

overweight the consideration of JRK's 777 oil in the treatment of psoriasis than any other medicaments due to the obvious side effects of all those preparations during their prolonged usage.

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