

## Multicenter, open-label, non-comparative study of a combination of polytar and zinc pyrithione shampoo in the management of dandruff

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### ABSTRACT

**Background:** Dandruff is a common condition in clinical practice. We undertook a study to evaluate the efficacy and safety of a combination of zinc pyrithione and polytar in a shampoo base for the treatment of dandruff. **Methods:** A combination of polytar (1%) and zinc pyrithione (1%) was used for 4 weeks to treat 954 patients suffering from mild to severe dandruff. Scoring of dandruff was done on a 0-10 scale for each of the 6 regions of scalp at weeks 0, 2, 4 and 6. Follow up was for 2 weeks. **Results:** There was consistent improvement in dandruff scores over the treatment and the follow up period. There was significant improvement in signs and symptoms such as erythema and itching, with a negligible adverse event profile. The global assessment by investigators showed good-excellent results in the majority of patients and there was high acceptability for the treatment among the patients. **Conclusion:** A combination shampoo of polytar (1%) and zinc pyrithione (1%) offers a safe and effective option in the treatment of dandruff and its associated symptoms.

**KEY WORDS:** Dandruff, Zinc pyrithione, Polytar

### INTRODUCTION

Dandruff is a common condition encountered in clinical practice. The peak incidence and severity of dandruff occurs at approximately 20 years of age.<sup>1</sup> Since Malassez (1874) isolated yeast cells from human dandruff scales,<sup>2</sup> dandruff has been associated with the presence of yeast/fungi of the genus *Malassezia* or *Pityrosporum*. However, some investigators argue that the altered flora of the scalp is secondary to increased epidermal proliferation. Transmission electron microscopy of scalp tape strips indicates that dandruff affected scalp possesses abnormal stratum corneum ultrastructure.<sup>3</sup> Reversal of stratum corneum abnormalities would

require treatment of the cause of dandruff, not merely flake removal.

The common topical preparations used to treat dandruff include ketoconazole, zinc pyrithione, selenium sulfide, sulfur and coal tar. Zinc pyrithione (1%) has both cytostatic and anti-pityrosporal actions.<sup>4</sup> Polytar is a combination of different tars containing coal tar solution, pine tar, cade oil and arachis oil extract of coal tar.<sup>5</sup>

There are few studies reported from India in the management of dandruff.<sup>6</sup> The present study seeks to evaluate the efficacy and safety of a combination of

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zinc pyrithione and polytar in a shampoo base for the treatment of dandruff.

## METHODS

An open label, non-comparative study design was formulated. The study was conducted at 180 consultant led outpatient clinics. The number of patients studied at each clinic ranged between 5 to 10. Prior informed consent was taken from all subjects. Complete history was taken and general and systemic examinations were done to satisfy the inclusion and exclusion criteria. The exclusion criteria were psoriasis, atopic dermatitis, tinea capitis, Parkinson's disease, epilepsy, facial nerve palsy, spinal cord disease, pregnancy, lactation, immunodeficiency states, history of hypersensitivity to shampoos, and patients on oral antibiotics or antimycotics.

A preliminary dandruff assessment was performed on all those enrolled. Patients were told to use the shampoo twice a week, with an interval of at least 3 days between each application, for 4 weeks, and then once weekly for another two weeks. They were advised to wash their hair with warm water, followed by application of a capful of the shampoo to produce enough lather and gently massage for 1 minute. Each time they were asked to shampoo twice, first with one minute of contact, followed by three minutes of contact.

Clinical assessment was done at baseline and at 2, 4 and 6 weeks. Six scalp areas (right and left: frontal, temporal and occipital) were graded on the following scale to get dandruff scores: 0 = None, 1-2 = Almost none/slight, 3-4 = Mild, 5-6 = Moderate, 7-8 = Marked, 9-10 = Severe/heavy. Also, global improvement rating

(change in the clinical condition compared to baseline) was performed by the investigator and rated as follows: excellent (95-100% improvement), very good (75-95% improvement), good (50-75% improvement), and fair (<50% improvement). Patient acceptability of the prescribed treatment was graded as follows: Grade 4 = excellent, Grade 3 = very good, Grade 2 = good, and Grade 1 = fair. Other signs and symptoms were assessed such as itching and erythema and were graded as follows: 0 = Absent, 1 = Mild, 2 = Moderate, and 3 = Severe.

To find the significant difference for efficacy parameters like frontal, temporal and occipital scores, analysis of variance (Kruskal Wallis) was used and for categorical data, chi-square test was applied. A value of  $p < 0.05$  was considered as significant.

## RESULTS

A total of 954 patients were enrolled in the study. As 44 patients did not complete the required follow up of 6 week, only 910 were considered for the analysis. None of these patients dropped out due to reasons related to the study. The age of the patients ranged from 11 to 61 years with a mean age of 22.23 years. The male: female ratio was 46.4:53.6. The duration of the disease ranged from 2 weeks to 10 years.

Table 1 depicts the change in dandruff scores at six sites on week 0 (baseline), 2, 4 and 6 weeks. At each assessment visit (2, 4 and 6 weeks), the fall in mean dandruff score was statistically significant for all the six regions individually as well as collectively. The reduction in mean total dandruff scores at two weeks was 42.4%, at 4 weeks 71% and at 6 weeks 84.8%.

**Table 1: Dandruff scores at six sites on 0 (basal), 2, 4 and 6 weeks**

SCORE (Mean $\pm$ SD)	Basal	2 weeks	4 weeks	6 weeks
Right frontal	2.59 $\pm$ 1.25	*1.73 $\pm$ 1.25	*0.96 $\pm$ 0.95	*0.52 $\pm$ 0.83
Left frontal	2.52 $\pm$ 1.19	*1.60 $\pm$ 1.05	*0.84 $\pm$ 0.93	*0.43 $\pm$ 0.79
Right occipital	2.77 $\pm$ 1.18	*1.77 $\pm$ 1.10	*0.98 $\pm$ 0.98	*0.53 $\pm$ 0.83
Left occipital	2.69 $\pm$ 1.26	*1.70 $\pm$ 1.15	*0.90 $\pm$ 0.96	*0.49 $\pm$ 0.81
Right temporal	2.65 $\pm$ 1.10	*1.70 $\pm$ 1.04	*0.92 $\pm$ 0.99	*0.44 $\pm$ 0.78
Left temporal	2.60 $\pm$ 1.09	*1.61 $\pm$ 1.03	*0.85 $\pm$ 0.89	*0.42 $\pm$ 0.77
<b>Total</b>	<b>13.98 <math>\pm</math> 6.97</b>	<b>*8.05 <math>\pm</math> 6.09</b>	<b>*4.05 <math>\pm</math> 4.69</b>	<b>*2.13 <math>\pm</math> 2.98</b>

(By ANOVA) (Kruskal Wallis), \* $p < 0.05$  significant

Table 2 shows that the mean scores of itching and erythema fell significantly at weeks 4 and 6 from their baseline values ( $p < 0.05$ ). The symptom of itching showed an earlier improvement, with the mean score falling significantly in 2 weeks ( $p < 0.05$ ).

Table 3 shows that after the treatment, as early as the 2nd week, 72% cases showed good to excellent improvement. At the end of 4 weeks, 94.7% and at 6 weeks, 97% patients had good to excellent improvement.

Adverse events occurred in 9.7% of patients (Table 4), the most common one being hair loss (2.9%). Bad smell was reported by 2.3% of the patients.

## DISCUSSION

The association between seborrhoeic dermatitis and dandruff, and the yeast *Malassezia furfur* is well

recognized. Due to its anti-mycotic activity, zinc pyrithione is established as an effective treatment for these scalp conditions. It has an anti-biosynthesis effect in the epidermis and also probably suppresses the proliferative activity of epithelial cells, thus affording relief from dandruff. Many studies have established the efficacy and safety of zinc pyrithione 1% shampoo.<sup>4</sup>

Polytar has anti-mycotic, anti-inflammatory and antipruritic properties and aids in the control of scaling, erythema and itching. Coal tar has fungistatic, antipruritic and exfoliating properties. The fungistatic activities of ketoconazole and coal tar preparations may be comparable under clinical treatment conditions.<sup>5</sup>

The mean dandruff scores fell by 42.4% within two weeks indicating an early response to treatment with the combination of zinc pyrithione with polytar. On continued treatment, there was consistent reduction in mean dandruff scores to 84.8% at the end of six weeks (Figure 1). Adverse events were recorded in only 9.7% of patients.

Treatment with the combination of zinc pyrithione and polytar resulted in good to excellent improvement in dandruff in 72% of patients in just two weeks according to the physician's global assessment, and in 94.7% and 97% at the end of 4 weeks and 6 weeks respectively. The combination of zinc pyrithione (1%) and polytar (1%) is effective and safe option in the management of dandruff.

**Table 2: Changes in the mean score of itching and erythema after treatment**

Treatment duration (in weeks)	Mean itching scores $\pm$ SD	Mean erythema scores $\pm$ SD
Basal	2.04 $\pm$ 0.74	1.70 $\pm$ 0.71
2	*1.50 $\pm$ 0.58	1.40 $\pm$ 0.55
4	*1.20 $\pm$ 0.42	*1.09 $\pm$ 0.54
6	*0.78 $\pm$ 0.68	*0.81 $\pm$ 0.68

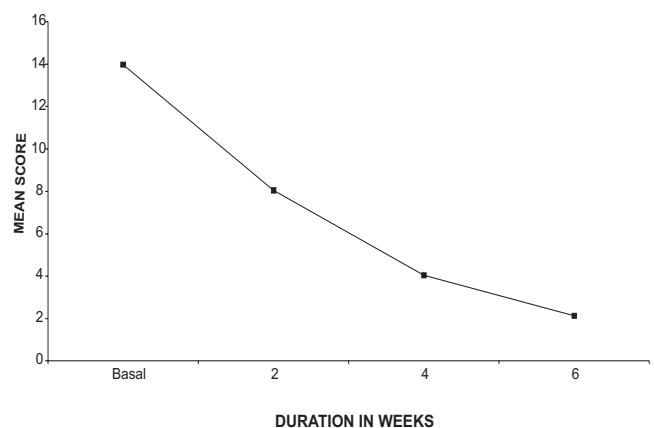
(By ANOVA) (Kruskal Wallis) \* $p < 0.05$  significant

**Table 3: Overall clinician's assessment of therapy**

Assessment	Week 2		Week 4		Week 6	
	No.	%	No.	%	No.	%
Excellent	101	11.1	228	25.0	485	53.3
Very good	248	27.3	395	43.4	309	33.9
Good	306	33.6	239	26.3	89	9.8
Fair	255	28.0	48	5.3	27	3.0
<b>Total</b>	<b>910</b>	<b>100.0</b>	<b>910</b>	<b>100.0</b>	<b>910</b>	<b>100.0</b>

**Table 4: Profile of untoward effects of the therapy**

Events	No. of patients (n = 954)	Percentage
Irritation	11	1.15
Burning	12	1.26
Loss of hair	28	2.93
Dryness of hair	14	1.47
Bad smell	22	2.30
Headache	03	0.31
Itching increased	03	0.31
Scaling increased	02	0.21
Erythema	02	0.21
<b>Total</b>	<b>88</b>	<b>9.67</b>



**Figure 1: Changes in average total score of dandruff after treatment**

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