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An evaluation of tar liquid in the treatment of seborrhoeic dermatitis of the scalp : a controlled clinical trial.

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The efficacy of medicated tar in the treatment of seborrhoeic dermatitis of the scalp was evaluated in a double blind, randomised, placebo controlled study involving 64 patients. The patients used either one of the treatment twice weekly for 4 weeks. The clinical symptoms of pruritus, scaling, papulation/vesiculation and erythema were evaluated before and after therapy at the two week intervals. The overall results demonstrated medicated tar to be an effective treatment in improving and controlling seborrhoeic dermatitis. Ninety percent of patients using the tar preparation showed improvement after 4 weeks. There were significant differences between treatments, with the active group showing greater regression and improvement in pruritus and scaling. Tolerability and patient compliance were excellent, with 60 out of 64 patients completing the study. A very low incidence of side effects were reported. It is concluded that medicated tar provides a practical form of treating seborrhoeic dermatitis particularly in chronic cases.

Key words : *Tar, Seborrhoeic dermatitis.*

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ประสิทธิภาพของ *Tar liquid* ในการรักษา *seborrheic dermatitis* ของหนังศีรษะ ถูกประเมิน โดยการศึกษาแบบ *double blind randomized & placebo control* ในผู้ป่วย 64 ราย ให้ผู้ป่วยใช้ยาอย่างใด อย่างหนึ่งสัปดาห์ละ 2 ครั้งนาน 4 สัปดาห์ และดูอาการคัน อาการตกสะเก็ด อาการผื่น และอาการแดงของ ผิวหนังก่อนรักษาและทุก 2 สัปดาห์หลังเริ่มการรักษา ผลพบว่า *tar* มีประสิทธิภาพในการรักษาและควบคุม อาการของโรคได้ดี โดยร้อยละ 90 ของผู้ป่วยที่ใช้ *tar* มีอาการดีขึ้นใน 4 สัปดาห์ และยังมีผลต่ออาการคันและ การตกสะเก็ดอย่างมีนัยสำคัญเมื่อเทียบกับ *placebo* ผู้ป่วยทนต่อการใช้ยาได้ดี มีผลข้างเคียงน้อยมาก จึง เชื่อว่า *tar* เป็นยาที่เหมาะสมในการรักษา *seborrheic dermatitis* ตัวหนึ่ง

Seborrhoeic dermatitis is a persistent eczematous disorder occurring normally around the sebaceous areas. The cause of the disease is unknown, though some recent studies relate it to residual sebum,⁽¹⁾ infection with *Pityrosporum* yeasts,⁽²⁻⁴⁾ neurological abnormalities⁽⁵⁾ and manifestation of AIDS complex.⁽⁶⁾

Tar preparations have been used for many years in the treatment of various skin disorders, particularly psoriasis and various forms of eczema.⁽⁷⁾ The exact mechanism of action is still not fully understood. However, properties which have been observed include a) cytostatic action, which reduces the rate of epidermal cell turnover; b) antifungal action; c) anti-inflammatory effect; d) antipruritic effect and e) sebostatic effect.⁽⁸⁻¹³⁾

In this study, we evaluated the effectiveness of a medicated tar preparation* in the treatment of seborrhoeic dermatitis and eczema of the scalp. The active ingredients consisted of tar (0.3%), Juniper tar (0.3%), coal tar solution (0.1%), crude coal tar extract (0.3%) and oleyl alcohol (1%) in the vehicle of triethanolamine lauryl sulphate, cocunut diethanolamine, polysorbate 80 and hexylene glycol. The placebo is composed of the same inactive ingredients as in the medicated tar preparation.

Patients and Methods

The patients were male and female at the out patient clinic, Chulalongkorn hospital. All were suffering from seborrhoeic dermatitis of the scalp with the distinctive perifollicular redness and greasy scaling.

Patients who suffered from psoriasis of the scalp and those who has known sensitivity to any ingredient of the medication e.g. wood or coal tars were excluded from this study. Also excluded were those who were pregnant or lactating and those who had any serious or progressive medical disorders.

Each patient entered the double blind, randomised and placebo-controlled study after giving informed consent. The patients were instructed to wash their hair twice weekly during the 4 weeks of treatment period. On each occasion, approximately 5-10 ml of the liquid was applied, and the scalp was massaged vigorously with the fingertips for at least 5 minutes before rinsing. No other scalp treatments were permitted during the study.

The patients were examined by the same physicians at admission (Week 0), then after 2 and 4 weeks of treatment. At each examination, clinical assessment and global impression of the scalp condition were recorded.

The clinical assessment involved evaluation of the scalp condition in terms of erythema, scaling, pruritus and papulation/vesiculation. Each of these conditions were rated as "none", "mild", "moderate" or "severe". A global impression of the patients overall dermatological condition at each visit was determined as "normal", "borderline", "mild", "moderate", "severe" or "extreme". The global change in each patient's condition was compared from baseline, at weeks 2 and 4, on a 7 point scale ranging from "very much worse" to "very much improved".

Friedman 2-way ANOVA and Wilcoxon tests were used to compare the results of clinical assessments and global impression score. Chi-square test and Mann-Whitney U test were used to compare changes between treatments.

Results

The 64 patients included 33 men and 31 women whose age ranged from 16 to 76 years (median 33 years). Two patients in the active group failed to complete the study due to reasons unrelated to the study. In the placebo group, one patient withdrew after developing a mild pain on the scalp at day 6 and one patient refused to continue the treatment after 2 weeks because of lack of improvement. The characteristics of the patients are shown in table 1.

Table 1.

	Active gr.	Placebo gr.
Male	18	15
Female	14	17
Mean age	32.6 yr. (16-76)	33.3 yr. (16-76)

The results of the treatment are presented in Figures 1 and 2

Erythema

A decrease in severity of erythema was observed by 2 weeks in both groups, with no further significant change ($P < 0.01$). At the end of four weeks, 21 out of 30 patients in the active group were free of the symptoms, as compared to 14 out of 30 patients in the placebo group.

*POLYTAR, STIEFEL LABORATORIES LTD.

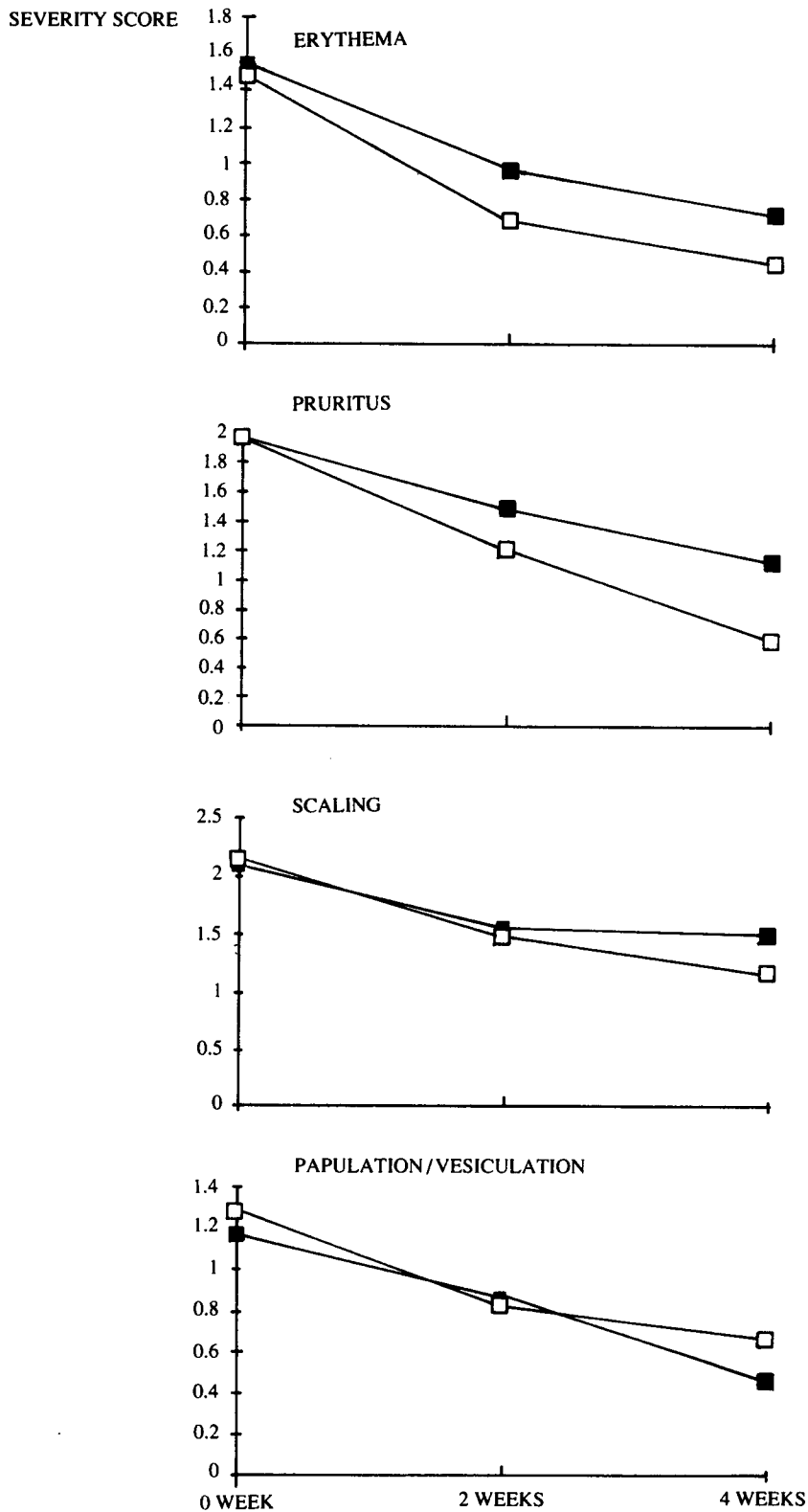


Figure 1. Effect of tar liquid on seborrheic dermatitis of the scalp. The symptoms were graded: none = 0, mild = 1, moderate = 2, severe = 3. Points are mean values for 32 patients in weeks 0, 2 and 30 patients in week 4. Tar liquid □ placebo ■ . The improvement in pruritus and scaling at week 4 are significant.

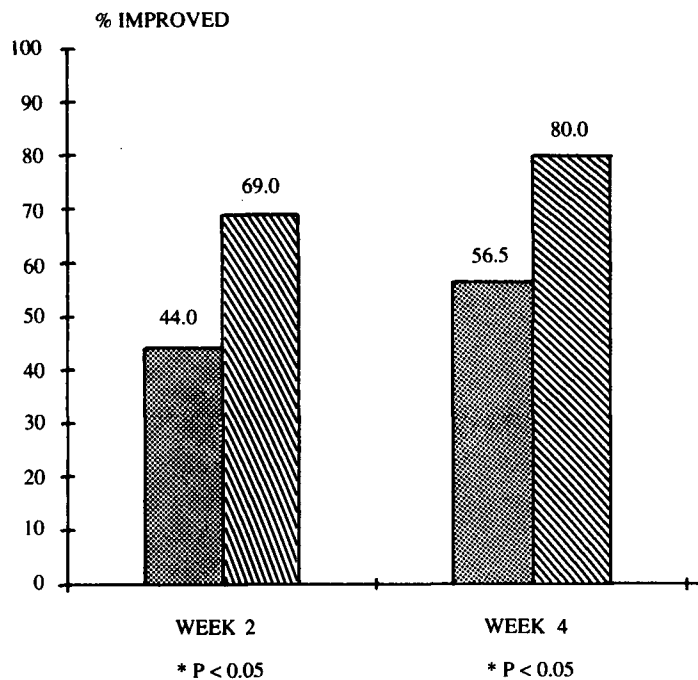


Figure 2. Global impression of overall dermatological condition. Tar liquid ■ placebo ▨
*Significant differences exists between treatments (mann-whitney u)

Scaling

Considerable reduction in scaling was seen in the majority of patients. There was a significant difference (Chi-square test, $P < 0.05$) between the two groups in change from baseline and at week 4.

Pruritus

This parameter demonstrated the most marked improvement in the study. At 4 weeks, patients in the active group showed a significantly greater improvement in pruritus than patients in the placebo group (Mann-whitney U test, $P < 0.05$).

Papulation/Vesiculation

Although there was substantial regression of this parameter in both groups at 2 weeks ($P < 0.01$ active; $P < 0.05$ placebo) and the active group showing a further significant decrease at 4 weeks (1% testing, Wilcoxon test), the differences between treatments were not significant.

Global Impression/Global Change

Overall the active group showed a significantly greater improvement rate than the placebo group at both weeks 2 and 4 ($P < 0.05$, Mann-Whitney U test).

Side Effects

Three patients in the placebo group and one patient in the active group reported adverse effects. These reactions were pruritus (active and placebo), scaling, mild pain and dryness of hair (all placebo).

Discussion

The results of the investigation showed that seborrhoeic dermatitis of the scalp responds favourably to the treatment of medicated tar throughout the study period. A very low incidence of adverse reactions were registered.

Where a significant difference was demonstrated between the groups, medicated tar was shown to be more effective than placebo. For the control of pruritus and scaling, medicated tar had a better effect which was significant. The improvement of seborrhoeic dermatitis in the placebo group, particularly in the second recruitment visit (week 2) is perhaps not surprising since merely washing of the scalp regularly could lead to an improved condition.^(14,15) However, the therapeutic response to non-medicated shampoo in dermatological conditions, such as dandruff, usually wanes after several days.⁽¹⁶⁾

Both global impression score of the patients overall dermatological condition and the global change over time showed a significantly greater improvement in the active group at both weeks 2 and 4, with 90% of the patients showing remission at 4 weeks.

These results correlate well with the work of other researchers, ^(10,11,17) who have demonstrated that medicated tar liquid are effective in the treatment of seborrhoeic dermatitis.

Given the mild but often chronic nature of the disease, and there being no known cure available, medicated tar should be considered as a practical therapy especially in sub-acute or non-acute cases.

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