

# Pentoxifylline as add-on therapy in the treatment of moderate to severe psoriasis

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**Background** Psoriasis is a common chronic inflammatory skin disease in Thailand. It is incurable and can cause physical and psychological morbidity. Pentoxifylline has the ability to inhibit TNF- $\alpha$  synthesis and interleukin-1, which play a significant role in the pathogenesis of psoriasis.

**Objective** To evaluate the efficacy and safety of pentoxifylline in patients with moderate to severe chronic plaque type psoriasis.

**Methods** Patients with moderate to severe chronic plaque type psoriasis were enrolled in this prospective, open trial group study. They received oral pentoxifylline at 800 mg/day for eight weeks as add-on therapy. The primary end point was improvement of PASI 50 (defined as improvement of the psoriasis area and severity index  $\geq 50\%$  from baseline) at eight weeks post pentoxifylline treatment. Changes in itching score, global clinical status, and adverse effects also were evaluated.

**Results** A total of 28 patients were studied, of which three were excluded, due to side effects and failure to follow-up. The mean PASI score of 25 patients, at week eight, showed significant improvement when compared to the baseline (7.08( $\pm 5.53$ ) vs. 18.63( $\pm 9.33$ )) ( $p < 0.001$ ). The PASI 50 was achieved in 72.7% of the patients at week eight. The itching score was decreased significantly from the baseline ( $p = 0.033$ ). The global clinical status also was improved from the baseline. No serious or life threatening events were reported.

**Conclusion** Pentoxifylline was shown to be an effective add-on therapy in the treatment of moderate to severe plaque type psoriasis. Larger and randomized controlled studies are needed to validate these results. **Chiang Mai Medical Journal 2013;52(3-4):43-50.**

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**Keywords:** pentoxifylline, treatment, psoriasis, anti-TNF

## Introduction

Psoriasis is a common inflammatory skin disease. Although it is rarely life threatening, it is not curable and is frequently associated with stigmatizing chronic lesions that can cause considerable physical and psychological morbidity.

Standard systemic therapies for moderate to severe psoriasis such as methotrexate, cyclosporine, and etretinate are highly effective.<sup>[1]</sup> However, these agents have risks of major organ toxicities such as hepatotoxicity, nephrotoxicity, teratogenicity, and bone marrow suppression.

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Psoriasis is now recognized as an immune mediated disease that consists predominantly of activated CD4-positive, CD8-positive T-cells<sup>[2,3]</sup> and cytokines-interferon- $\gamma$ , interleukin-2, interleukin-12. Additionally, the activity of TNF- $\alpha$ , a key pro-inflammatory cytokine of the innate immune response which is substantially increased in psoriasis, strongly promotes expression of intercellular adhesion molecule-1 on keratinocytes and dermal endothelial cells and produces overexpression of VEGF/VPF, which causes vascular hyperpermeability and angiogenesis.<sup>[4-6]</sup>

The role of TNF- $\alpha$  in psoriasis came to light through observations of the efficacy of anti-TNF biological therapies, such as Etanercept and Infliximab. Although these biological treatments have great advantages in the management of psoriasis, their utilization may be limited due to the very high cost of the medications and their safety profiles.<sup>[7-9]</sup>

Pentoxifylline is a methylxanthine derivative. This medication has similar properties to theobromine, caffeine and theophylline but has fewer adverse effects on the cardiovascular system. The pharmacokinetic feature of pentoxifylline is that it is well absorbed in the small bowel, where the active ingredient is continuously released. The time required for maximum concentration is 2-4 hours. Its half-life time is 0.4-0.8 hours.

The drug is metabolized by the liver and red blood cells and 90% of metabolites are excreted by the kidneys. These metabolites are more potent than pentoxifylline itself. This medication improves blood flow by influencing pathologically altered red blood cell deformability, inhibiting platelet aggregation, and reducing blood viscosity. It enhances microcirculation in areas with impaired blood flow. In addition, pentoxifylline has several molecular effects on the immune process that can modulate neutrophil migration and enhance protective mechanisms against infection. It was shown to inhibit TNF- $\alpha$  synthesis and interleukin-1 from white blood cells, which play an important role in the pathogenesis of psoriasis. Pentoxifylline also inhibits activation of T and B lymphocytes, natu-

ral killer cell activity and promotes wound healing resulting from decreased fibroblast activity.

For two decades, pentoxifylline has been used for treatment of peripheral arterial occlusive diseases and circulatory disturbances with a safety profile and is not expensive. Adverse effects of pentoxifylline are not common, but /include nausea and vomiting, drowsiness, palpitations, myalgia, tremor and, rarely serious events, such as confusion, chest pain, and hypotension. Contraindications include hypotension, unstable ischemic heart disease and allergy to caffeine or xanthine derivatives such as theophylline.<sup>[10-16]</sup>

Pentoxifylline has been reported in the treatment of many skin diseases such as, venous leg ulcers, vasculopathies and vasculitides, leprosy, pigmented purpuric dermatosis.<sup>[14]</sup> However, there have not been many studies of the efficacy of pentoxifylline in the treatment of psoriasis.<sup>[14-18]</sup> Some studies showed the beneficial effect of pentoxifylline in psoriasis.<sup>[15-17]</sup> However, one study showed no statistically significant difference between the clinical and histological improvement of the treatment groups with pentoxifylline and with placebo.<sup>[18]</sup> This study was designed to evaluate the efficacy and safety of pentoxifylline as add-on therapy in patients with moderate to severe chronic plaque type psoriasis.

## Methods

### Patient population

This prospective, open trial group study design enrolled Thai patients with psoriasis. This study was performed at the Dermatologic Clinic of Maharaj Nakorn Chiang Mai Hospital, Chiang Mai University from March 2007 to March 2008. All participants provided written consent to be included in the study. The study protocol was approved by the hospital ethics committee.

The following inclusion criteria were applied: age  $\geq 15$  years old, moderate to severe chronic plaque type (body surface area involved  $\geq 10\%$ ), clinically stable  $\geq 1$  month and regular follow-up visits.

The following exclusion criteria were applied: patients with hypotension, severe ischemic heart disease, and history of allergy to caffeine or xanthine derivatives such as theophylline, pregnancy, lactation, active infection and underlying systemic disease.

The following discontinuation criteria were applied:

severe clinical deterioration after pentoxifylline started, allergy to pentoxifylline, inability to tolerate adverse effects, or desire to use other treatments.

### Study Protocol

After enrollment, at the baseline visit the following data were recorded: history of illness, concomitant medications, and complete physical examination including PASI (psoriasis area and severity index) score.

Eligible patients were treated with add-on oral pentoxifylline (Trental®, Aventis) 400 mg twice daily for eight weeks. Patients were reassessed using the PASI score at the visits week two, four, and eight of therapy together with adverse effects from pentoxifylline. The concomitant medications were maintained in the same dosage and regimens. In each visit the global clinical status and itching symptoms were rated by patients and recorded (Table 1 and 2). For all patients who refused this study, failed to follow up, or withdrew in the first two weeks of the study, the data were not used to evaluate drug efficacy. All adverse events, including nausea and vomiting, headache, dizziness, stomach ache, palpitations and skin rash were monitored and rated on a scale ranging from 1 (mild) to 3 (severe) until the end of the study.

### Statistical methods

**Sample size:** The sample was calculated based on the primary end point, estimating that at least 24 patients were required for the study to have a statistical power of 50% to detect an absolute clinical response of pentoxifylline.

$$N = \frac{Z^2 pq}{e^2}$$

N : sample size

Z : Standard score at confidence interval 95%=1.96

p : Clinical response rate, assume as 50%\*

q : Clinical failure rate, assume as 50%\*

e : Error from test, assume as 20%\*

Remark \* assume as reference at 50%

**Study end points:** In the study, the primary end point was drug efficacy which was defined as an improvement of PASI score  $\geq$  50% from baseline (PASI 50) at eight weeks after the start of pentoxifylline.<sup>[19]</sup>

**Null hypothesis:** No difference was found in clinical signs and symptoms of psoriasis before and after pentoxifylline administration between baseline and eight weeks.

### Statistical analysis

Based on this assumption, a sample size of at least 24 patients was required to detect differences in PASI score  $\geq$  50% from baseline (PASI 50). Data distribution as analyzed by Kolmogorov-Smirnov and Shapiro-wilk tests showed an abnormal distribution. The primary endpoint was assessed by a non-parametric test, Friedman test, at 5% level of sig-

nificant ( $\alpha=0.05$ ). Change in itching score, global clinical status, and adverse effects were also evaluated.

The difference in treatment outcomes of pentoxifylline, including PASI Score, itching, and global status, were analyzed by Wilcoxon match-pairs sign-ranks test to reject null hypothesis. For patients with missing values, the analysis was performed with the last observation carried forward. However, such a method would not capture data for patients discontinuing the trial in the first two weeks. Safety descriptive analyses included all patients who received pentoxifylline.

All data were captured and stored in database reports. Data management and statistic analyses were performed using SPSS statistical software (version 15.0).

## Results

### Baseline characteristics and patient disposition

A total of 28 patients (40% male), aged 18 to 67 years (mean 41.68 years), were enrolled in the study (Table 3). Average duration of psoriasis was 10.44 years. Seventeen patients (68%) had been receiving methotrexate, 32% had nail involvement and no psoriatic arthritis. In the first two weeks after the start of the therapy, three patients of the 28 enrolled patients discontinued the study due to palpitations (n=1), development of generalized erythematous maculopapular rash and refusal of further study (n=1) or failure to follow up (n=1).

A total of 25 patients who received pentoxifylline for at least four weeks were included in

**Table 1.** Patient's Itching Symptom Score

0	= no symptom
1	= mild itching
2	= moderate itching
3	= severe itching

**Table 2.** Patient's global assessment

5	= markedly improved
4	= improved
3	= no change
2	= worse
1	= markedly worse

**Table 3.** Baseline characteristics of the 28 patients.

Characteristic at baseline	
Male, n (%)	10 (40)
Age, yr, mean ( $\pm$ SD)	41.68 ( $\pm$ 13.62)
Duration of psoriasis, yr, mean ( $\pm$ SD)	10.44 ( $\pm$ 6.22)
Psoriatic nail, n (%)	8 (32)
Psoriatic arthritis, n (%)	0
Concomitant treatments, n (%)	
Methotrexate	17 (68)
UV therapy	2 (8)

the drug efficacy analysis. Baseline concomitant medications and clinical characteristics are listed in Table 4. Three patients discontinued pentoxifylline before week eight due to clinical worsening (n=1) and failure to follow-up (n=2).

### Efficacy

**PASI score:** There was, overall, statistically significant improvement in PASI score ( $p < 0.001$ ). The means of PASI scores at baseline, week two, week four and week eight were 18.63, 12.93, 9.82, and 7.08, respectively. Mean absolute changes from baseline up to week two, week four and week eight were -5.70, -8.87 and -11.77, respectively ( $p < 0.001$ ). At week eight, there was at least a 50 percent improvement in the psoriasis area and severity index (PASI 50) in 72.7% of the patients (Table 5).

### Itching score

The patients' perceptions of itching gradually declined during the study period. The mean itching scores at baseline, week two, week four and week eight were 2, 1.5, 1.36 and 1.3, respectively. The overall itching significantly improved in patients ( $p = 0.033$ ). The mean itching score at week eight was significantly decreased from the baseline (1.3( $\pm$ 0.48) vs. 2( $\pm$ 0.72)) ( $p = 0.015$ ).

### Global clinical status

The global clinical status was evaluated dur-

ing the study period by comparison to the baseline using a five-point scale. Overall, patients treated with pentoxifylline showed improvement in global clinical status.

The mean scores of the five-point scale were 4.08 ( $\pm$ 0.27), 3.92 ( $\pm$ 0.77), and 3.95 ( $\pm$ 0.78), at week two, week four and week eight, respectively, showing improvement in global clinical status.

### Drug safety

Reported adverse events were nausea and vomiting, drowsiness, palpitations, myalgia, circumoral paresthesia, dizziness and rash (Table 6). The most frequent events were nausea and drowsiness, especially in the first few days of the treatment, which spontaneously resolved without discontinuing of the medication. Only two patients of the 28 enrolled patients were withdrawn from the study because of adverse events; one patient developed palpitations that resolved after cessation of pentoxifylline; the other patient developed generalized erythematous maculopapular rash which could have been either allergic rash or viral exanthems. No serious or life threatening events were reported during the trial.

### Discussion

This study was a prospective open trial and was designed to investigate the efficacy of pentoxifylline, a TNF- $\alpha$  antagonist, as add-on therapy in the treatment of moderate to severe chronic plaque type psoriasis vulgaris. This study showed better clinical outcome at week two with gradual improvement until the end of week eight. Overall there was a statistically significant improvement of the PASI Score ( $p < 0.001$ ); the PASI 50 was achieved in 72.7% of the patients at week eight. The mean PASI score at week eight showed significant improvement when compared to the baseline (7.08( $\pm$ 5.53) vs. 18.63( $\pm$ 9.33)) ( $p < 0.001$ ). These results are similar to Anastazy Omulecki and colleagues that conducted the study using pentoxifylline 1,200 mg/day. The mean PASI score significantly decreased from 24.2 (baseline) to 15.2 (at eight weeks) ( $p < 0.05$ ).

**Table 4.** Baseline characteristics and PASI scores of the 25 patients

No	Age	Duration of disease (yrs)	Current medications	PASI score			
				Wk0	Wk2	Wk4	Wk8
1	55	5	MTX 7.5mg/wk, 5% LCD in TA cr, 2% SA oit	18	13.5	17.6	Discon.
2	56	13	MTX 5mg/wk, 5% LCD in TA cr, kanolone lotion, tar shampoo	18.8	15.7	11.1	2.1
3	42	9	MTX 7.5mg/wk, 5% LCD in TA cr, betnovate cr, dermovate cr, tar shampoo	8.5	5.6	6.2	3.6
4	33	4	MTX 10mg/wk, dermovate cr, topicort, tar shampoo	41.8	32.7	18.2	22.4
5	31	1.5	MTX 5mg/wk, dermovate cr, diprosalic, tar shampoo, urea cr	17.4	10.6	-	4.4
6	50	15	PUVA, LCD oit, dermovate cr, tar shampoo, urea cr	17.6	15.6	14.8	6.4
7	41	10	MTX 2.5mg/wk, 5% LCD in TA cr, tar shampoo	27.1	12.6	7	6.6
8	52	20	MTX 2.5mg/wk, 5% LCD in TA cr, dermovate cr	25	14.4	5.5	5.4
9	42	10	MTX 7.5mg/wk, 5% LCD in TA cr, coal tar solution	13.3	8	7.6	3
10	53	20	5% LCD in TA cr, coal tar solution, coal tar oit, 0.1% TA cr	20.5	14.7	9.4	5.6
11	49	20	PUVA, MTX 5mg/wk, coal tar solution, 0.1% TA cr	15.9	7.5	5.9	8.4
12	51	20	5% LCD in TA cr, coal tar oit	39.6	31.4	21.6	18.5
13	49	20	coal tar solution, 0.1% TA cr	10.2	5.5	4	3.4
14	43	10	MTX 7.5mg/wk, 5% LCD in TA cr, coal tar oit, dermovate cr	26.3	19	16	15.5
15	56	4	MTX 5mg/wk, coal tar oit, 0.1% TA cr, tar shampoo	10.4	9.7	7	5.6
16	60	10	MTX 10mg/wk, dermovate cr, topicort cr	9.2	3.1	2.3	1.3
17	26	10	MTX 2.5mg/wk, 5% LCD in TA cr, diprosone cr	13.2	8.6	5.2	Lost to FU
18	20	0.5	MTX 7.5mg/wk, 5% LCD in TA cr, topicort, 0.02% TA cr	11.7	5.8	4.8	5
19	25	10	LCD oit, Esperson, topicort, urea cr	7.1	2.6	2.3	0.8
20	67	10	LCD oit, Esperson cr, kanolone lotion, tar shampoo, urea cr	33.5	24.9	18	9.5
21	40	5	MTX 7.5mg/wk, coal tar oit, diprosone cr, kanolone lotion, tar shampoo	18.4	10.2	9.2	10.2
22	18	7	5% LCD in TA cr, diprosone cr	11.4	7.9	4.6	2.0
23	32	17	MTX 5mg/wk, 5% LCD in TA cr	21.4	17.7	12.5	8.7
24	29	7	MTX 12.5mg/wk, coal tar oit, topicort, betnovate cr, dermovate cr, urea cr	9.7	8	6.1	7.4
25	22	3	5% LCD in TA CR, esperson, diprosone cr	19.8	17.9	18.7	Lost to FU

Discon: discontinue, MTX: methotrexate, TA: triamcinolone acetonide, cr: cream, oit: ointment, FU: follow up



**Table 5.** PASI score, PASI 50 during 8-week treatment

Week	N	Mean PASI score ( $\pm$ SD)	Mean absolute changes from baseline	$p^*$	PASI 50** N(%)
0	25	18.63 ( $\pm$ 9.33)	-		-
2	25	12.93 ( $\pm$ 7.88)	-5.70	< 0.001	5 (20)
4	24	9.82 ( $\pm$ 5.86)	-8.87		12 (50)
8	22	7.08 ( $\pm$ 5.53)	-11.77		16 (72.7)

\* Analyzed by Friedman test, \*\*; PASI 50 defined as improvement of PASI score  $\geq$  50% from baseline, N = Number of patients

**Table 6.** Reported adverse events

Events	n (%)
Nausea and Vomiting	8 (32)
Somnolence or decreased ability to concentrate	5 (20)
Palpitations	1 (4)
Myalgia	1 (4)
Circumoral paresthesia	1 (4)
Dizziness	1 (4)
Rash	1 (4)

[17] However, these results could not be compared to our result directly because of the different dosage of pentoxifylline. The study of Medhat el-Mofty and colleagues using combination of sulfasalazine 2 g/day and pentoxifylline 1,200 mg/day for eight weeks also showed a significant improvement from the baseline (28.52 ( $\pm$ 12.4) vs. 14.92( $\pm$ 12.2)) ( $p = 0.043$ ) when compared to sulfasalazine or pentoxifylline alone, which showed no significant improvement.<sup>[20]</sup> Another study did not show any significant improvement when using pentoxifylline for psoriasis treatment.<sup>[18]</sup> In our study, the mean itching score at week eight was significantly decreased from the baseline. The global clinical status was also better than the baseline.

The most common side effect of pentoxifylline was nausea and vomiting that occurred in 32% of our patients compared with 20% in Medhat el-Mofty's study.<sup>[20]</sup> However, these side

effects were not limited the pentoxifylline usage. No serious or life threatening events were reported. Two patients discontinued the treatment because of palpitations and generalized erythematous maculopapular rash respectively that resolved without clinical sequelae after cessation of pentoxifylline. One patient discontinued pentoxifylline before week eight due to clinical worsening.

In conclusion, this preliminary study showed pentoxifylline was effective as an add-on therapy in the short term treatment of moderate to severe chronic plaque type psoriasis. Pentoxifylline may be useful when standard systemic therapies are contraindicated. However this was an open prospective and short term study with a limited number of patients. Further study is warranted to determine efficacy and adverse events of long term treatment using blind design or randomized placebo-controlled trial and larger sample sizes.

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## การใช้ยาเพนทอกซิฟิลลินเสริมการรักษาเดิมในผู้ป่วยโรคสะเก็ดเงินรุนแรงปานกลางและมาก

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**บทนำ** โรคสะเก็ดเงินเป็นโรคผิวหนังเรื้อรังที่พบได้บ่อยในประเทศไทย ยาเพนทอกซิฟิลลินออกฤทธิ์ยับยั้งการสร้างทีเอ็นเอฟ-อัลฟาและอินเตอร์ลูคิน-1 ซึ่งมีบทบาทสำคัญในการเกิดโรคสะเก็ดเงิน

**วัตถุประสงค์** เพื่อศึกษาประสิทธิภาพและความปลอดภัยของการรักษาผู้ป่วยโรคสะเก็ดเงินที่มีความรุนแรงปานกลางถึงและมากด้วยยาเพนทอกซิฟิลลิน

**วิธีการศึกษา** ผู้ป่วยโรคสะเก็ดเงินที่มีความรุนแรงปานกลางถึงมากที่ได้รับคัดเลือกจะได้รับยาเพนทอกซิฟิลลินขนาด 800 มิลลิกรัมต่อวัน เสริมเข้าไปกับการรักษาเดิมเป็นระยะเวลา 8 สัปดาห์ และประเมินประสิทธิภาพที่สิ้นสุดการรักษาโดยเปรียบเทียบคะแนน psoriasis area and severity index (PASI), จำนวนผู้ป่วยที่มีคะแนน PASI ลดลงมากกว่าร้อยละ 50 วัดคะแนนอาการคัน อาการทางคลินิกโดยรวมและภาวะแทรกซ้อนที่เกิดขึ้น

**ผลการศึกษา** ผู้ป่วยเข้าร่วมการศึกษาทั้งหมด 28 ราย มี 3 รายถูกคัดออกจากการศึกษาเนื่องจากเกิดผลข้างเคียงและไม่ได้มาติดตามการรักษา คะแนน PASI เฉลี่ยของผู้ป่วย 25 รายลดลงอย่างมีนัยสำคัญเมื่อเทียบกับก่อนรักษา (7.08 ( $\pm$ 5.53) เปรียบเทียบกับ 18.63 ( $\pm$ 9.33) ( $p < 0.001$ ) โดยมีผู้ป่วยร้อยละ 72.70 มีคะแนน PASI ลดลงมากกว่าร้อยละ 50 คะแนนอาการคันลดลงอย่างมีนัยสำคัญเมื่อเทียบกับก่อนรักษา ( $p = 0.033$ ) และอาการทางคลินิกโดยรวมดีขึ้น ไม่มีรายงานการเกิดผลข้างเคียงที่ร้ายแรง

**สรุป** ยาเพนทอกซิฟิลลินสามารถใช้ในการรักษาโรคสะเก็ดเงินที่มีความรุนแรงระดับปานกลางถึงรุนแรงมากได้อย่างมีประสิทธิภาพโดยไม่พบอาการแทรกซ้อนที่ร้ายแรง ควรมีการศึกษาแบบสุ่มและมีกลุ่มควบคุมในผู้ป่วยกลุ่มใหญ่ขึ้นเพื่อยืนยันประสิทธิภาพของการรักษา **เชียงใหม่เวชสาร 2556;52(3-4):43-50.**

**คำสำคัญ:** โรคสะเก็ดเงิน ยาเพนทอกซิฟิลลิน ยาค่านทีเอ็นเอฟ การรักษา