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## · 药物与临床 ·

## 吡硫翁锌气雾剂治疗寻常性银屑病

罗绍森 苏禧 范敏 苏敬泽

为评价吡硫翁锌气雾剂治疗寻常性银屑病的疗效及安全性,我们于 2006 年 1 月至 2007 年 6 月,对吡硫翁锌气雾剂治疗寻常性银屑病进行临床观察。

## 一、病例与方法

1. 病例:105 例寻常性银屑病患者均来自本门诊部,男 54 例,女 51 例,年龄 16~68 岁,平均(38±1.5)岁,病程 5 个月至 28 年,平均(10±1.2)年。按就诊顺序分为吡硫翁锌组和他扎罗汀组。两组患者的性别构成、年龄、病程及治疗前病情比较,差异均无统计学意义。有下列情况之一者均不作为观察对象:3 个月内接受过全身糖皮质激素、维 A 酸类药物、免疫抑制剂、NB-UVB 或 PUVA 治疗;1 个月内接受过局部糖皮质激素或其他抗银屑病治疗;消退期患者;对治疗药物或相关成分过敏者;皮损面积占体表面积 20% 以上者。孕妇、哺乳期妇女或近年有生育愿望的妇女;有严重性心、肝、肾、血液系统疾病的患者。

2. 方法:吡硫翁锌组患者在皮损区应用西班牙原装进口的吡硫翁锌气雾剂(西班牙国际新化学药厂生产),喷洒量以薄层药物覆盖皮损面为度,每日 3 次。他扎罗汀组患者每天晚上临睡前在皮损区用他扎罗汀凝胶涂抹 1 次,并轻轻揉擦,以促使药物吸收。两组均停用其他内服药及外用药,每周随访 1 次,治疗时间为 4 周。

3. 观察指标:选皮损典型、面积较大、便于观察的皮损部位为靶皮损,根据靶皮损红斑、鳞屑、肥厚浸润及靶皮损缩小程度进行评分。评分标准:0 分为无红斑、鳞屑、肥厚斑块,>90% 皮损消退;1 分为淡红色斑,少许鳞屑,肥厚斑块<1 mm,皮损消退 60%~90%;2 分为红斑,较多鳞屑,肥厚斑块 1~2 mm,皮损消退 30%~59%;3 分为暗红色斑,鳞屑厚,肥厚斑块>2 mm,皮损消退<30%。

4. 疗效评定标准:疗效指数=(疗前积分-疗后积分)/疗前积分×100%。基本痊愈为疗效指数≥90%;显效为疗效指数 60%~<90%;进步为疗效指数 30%~<60%;无效为疗效指数<30% 或无变化或加重。以显效和基本痊愈例数计算有效率。

5. 安全性评价:治疗过程中观察药物的不良反应。按与药物有关、可能有关、无法判定、可能无关和无关 5 级,评价临床反应与所观察药物之间的关系。以前 4 者之和计算不良反应发生率。

6. 统计学方法:采用  $t$  检验与  $\chi^2$  检验。

## 二、结果

1. 疗效分析:吡硫翁锌组及他扎罗汀组治疗前后的症状体征积分比较,差异均有统计学意义。治疗前两组症状体征

表 1 吡硫翁锌气雾剂治疗寻常性银屑病前后  
症状体征积分比较( $\bar{x} \pm s$ )

组别	例数	治疗前	治疗后	$t_1$ 值	P 值
吡硫翁锌组	53	63.72 ± 26.15	8.31 ± 5.39	2.86	< 0.01
他扎罗汀组	52	62.25 ± 27.43	15.63 ± 5.21	2.77	< 0.01
$t_1$ 值		1.85	2.16		
P 值		> 0.05	< 0.05		

注: $t_1$  值为治疗前后比较, $t_2$  值为两组比较

表 2 吡硫翁锌气雾剂治疗寻常性银屑病的疗效[例(%)]

组别	例数	基愈	显效	进步	无效	有效率
吡硫翁锌组	53	20(37.7)	27(50.9)	5(9.4)	1(1.9)	88.7%
他扎罗汀组	52	12(23.1)	23(44.2)	14(26.9)	3(5.8)	67.3%

积分比较,差异无统计学意义;治疗后两组比较,差异有统计学意义。见表 1。吡硫翁锌组有效率为 88.7%,他扎罗汀组有效率为 67.3%,两组比较, $\chi^2=8.31$ , $P<0.05$ ,见表 2。

2. 安全性分析:吡硫翁锌组瘙痒 2 例,红斑和破裂各 1 例,不良反应发生率为 7.5%。他扎罗汀组瘙痒 5 例,灼热 4 例,红斑 3 例,刺痛、破裂各 2 例,不良反应发生率为 28.8%,两组比较, $\chi^2=8.03$ , $P<0.05$ 。

## 三、讨论

吡硫翁锌气雾剂的主要成分吡硫翁锌具有抑制表皮细胞增殖过速、角质促成、角质分离和抗过度角化作用,并能抑制糠秕马拉色菌等表皮真菌与细菌生长,调节皮脂分泌,缓解与鳞屑性皮肤病有关的瘙痒等作用<sup>[1]</sup>。吡硫翁锌气雾剂在国外常用于治疗鳞屑性皮肤病如银屑病、脂溢性皮炎等,经多年临床应用,证实其疗效确切,起效迅速,通常用药数日即可显效<sup>[2]</sup>。我们在本次观察中发现,吡硫翁锌组患者在用药 1 周后即有 26 例(49.1%)已达到显效水平。4 周后统计最终疗效,吡硫翁锌组有效率达 88.7%,明显优于他扎罗汀组。说明吡硫翁锌气雾剂治疗寻常性银屑病的疗效确切,起效迅速。吡硫翁锌气雾剂不良反应轻微,表现为轻度瘙痒、破裂,无须停药,不影响治疗。所有病例均未见到全身不良反应。由于该药剂型为气雾剂,使用方便,不污染衣物、毛发,不留有色素沉着及皮肤萎缩等副作用,可使用于头面部等特殊部位,患者依从性好。

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**Drug and Clinic**

**Therapeutic effects of pyrithione zinc aerosol on psoriasis vulgaris**

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In order to evaluate the therapeutic efficacy of pyrithione zinc aerosol against psoriasis vulgaris and its safety, we carried out clinical observations of zinc pyrithione aerosol in treating psoriasis vulgaris from January, 2006 to June, 2007.

**I. Cases and methods**

**1. Cases**

105 cases with psoriasis vulgaris were all from our dermatological specialist clinic. There were 54 men and 51 women, aged from 16 to 68 years, mean age  $38\pm1.5$  years. The disease course was 5 months to 28 years, averaged  $10\pm1.2$  years. They were divided into two groups according to visit sequence, zinc pyrithione group and tazarotene group. No differences in gender, age, disease course and preexisting symptoms were found between the two groups. Cases with any one of following conditions should be excluded from clinical observation: patients had general treatment with glucocorticoids, tretinoins, immunosuppressive agents, NB-UVB or PUVA within previous three months; topical glucocorticoid or other anti-psoriasis therapies within previous one month; in regression period; known to be allergic to any of study drugs or components; psoriasis area of over 20% of surface area; pregnant women, lactating mothers or women of childbearing

potential may become pregnant in next years; patients with severe heart, liver, kidney or hematological diseases.

## 2. Methods

Patients in zinc pyrithione group were applied with pyrithione zinc aerosol at psoriasis area (manufactured by Cheminova Internacional S.A., Spain), which was imported in original package from Spain. The drug should be used enough to cover the affected area, three times each day. Patients in tazarotene group were applied with tazarotene gel at psoriasis area at bedtime once per day followed by slight rubbing to promote drug absorption. Other medicines for oral or external use should be withdrawn for both the two groups. Follow-up visit was carried out once per week. The treatment duration lasted 4 weeks.

## 3. Observation indexes

Typical large affected areas that were convenient for observation were chosen as target areas, which were scored based on red spot, squama, hypertrophy, infiltration and degree of lesion reduction on target areas. The criteria were: 0 score, no red spot, squama or hypertrophic plaque, and degree of reduction >90%; 1 score, reddish spot, few squamae, hypertrophic plaque<1mm, degree of reduction 60-90%; 2 scores, red spot, major squamae, hypertrophic plaque 1-2 mm, degree of reduction 30-59%; 3 scores, dark red spot, thick squama, hypertrophic plaque>2 mm, degree of reduction <30%.

## 4. Criteria for therapeutic efficacy assessment

Therapeutic index = (pre-treatment score-post-treatment score)/pre-treatment score×100%. General healing, therapeutic index≥90%;

marked efficacy, therapeutic index 60 %-< 90%; improvement, therapeutic index 30%-<60%; inefficacy, therapeutic index <30%, no change or aggravation. Efficacy ratio was calculated using the cases with marked efficacy and general healing.

## 5. Safety evaluation

Adverse reactions should be monitored during the treatment period. The relationship between adverse reaction and drug was classified into 5 grades: definite, probable, doubtful, possible, and impossible. Rate of adverse reaction was a sum of the former four grades.

## 6. Statistical analysis

T test and  $\chi^2$  test were used.

## II. Results

### 1. Analysis of therapeutic efficacy

There was statistical significance in symptom-syndrome scores between before and after treatment in zinc pyrithione and tazarotene groups. No statistical difference was observed in symptom-syndrome scores before treatment between the two groups; however there was statistical significance after treatment (table 1). Efficacy rates in zinc pyrithione and tazarotene groups were 88.7% and 67.3% respectively ( $\chi^2=8.31$ ,  $P<0.05$ ) (table 2).

**Table 1:** comparison of symptom-syndrome scores between before and after treatment of psoriasis vulgaris with zinc pyrithione aerosol

(mean $\pm$ SD)

Group	Number of cases	Before treatment	After treatment	t <sub>1</sub> value	P value
pyrithione zinc	53	63.72 $\pm$ 26.15	8.31 $\pm$ 5.39	2.86	<0.01
tazarotene	52	62.25 $\pm$ 27.43	15.63 $\pm$ 5.21	2.77	<0.01
t <sub>2</sub> value		1.85	2.16		

P value	> 0.05	<0.05
<b>Note:</b> t <sub>1</sub> , comparison between before and after treatment; t <sub>2</sub> , comparison between the two groups.		

**Table 2:** therapeutic efficacy of pyrithione zinc aerosol against psoriasis vulgaris [case (%)]

Group	Number of cases	General recovery	Significant efficacy	Improvement	Inefficacy	Efficacy rate
pyrithione zinc	53	20(37.7)	27(50.9)	5(9.4)	1(1.9)	88.7%
tazarotene	52	12(23.1)	23(44.2)	14(26.9)	3(5.8)	67.3%

## 2. Safety analysis

There were 2 cases with itching, 1 case with red spot and 1 case with rhagades in zinc pyrithione group. The rate of adverse reaction was 7.5%. In tazarotene group, 5 cases with itching, 4 cases with burning sensation, 3 cases with red spot, 2 cases with stabbing pain and 2 cases with rhagades were found. The rate of adverse reaction was 28.8%. There was significant difference between the two groups ( $\chi^2=8.03$ , P<0.05).

## III. Discussion

The major component of pyrithione zinc aerosol is zinc pyrithione, which can inhibit epidermal cell overproliferation, has keratoplastic, keratolytic, and anti-hyperkeratotic activities, as well as can inhibit growth of epidermal fungi and bacteria including *Malassezia furfur*, regulate sebum secretion and relieve itching associated with scalded skin syndromes [1]. In foreign countries, pyrithione zinc aerosol is often used to treat scalded skin syndromes, such as psoriasis vulgaris, seborrheic dermatitis, etc. Many years' clinical application confirms its definite and rapid therapeutic efficacy. Generally, application of

pyrithione zinc aerosol for several days can achieve satisfied efficacy [2]. In this study, we showed significant efficacy was observed in 26 cases (49.1%) after one-week treatment in zinc pyrithione group. The efficacy rate of pyrithione zinc aerosol was 88.7% after 4-week treatment, which was obviously better than tazarotene. The results indicated pyrithione zinc aerosol has definite and rapid therapeutic efficacy against psoriasis vulgaris. In zinc pyrithione group, only slight adverse reactions including mild itching and rhagades were found, which did not affect the therapy. No systemic adverse reaction was observed in any cases. Since this product is an aerosol which is convenient and does not cause clothes or hair pollution, pigmentation or dermatophobia, it can be used at special parts such as head and faces with good patients' compliance.

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- [1] Rowlands CG, Danby FW. Histopathology of psoriasis treated with zinc pyrithione. Am J Dermatopathol, 2000, 22(3):272-276.
- [2] Crutchfield CE 3rd, Lewis EJ, Zelickson BD. The highly effective use of topical zinc pyrithione in the treatment of psoriasis: a case report. Dermatol Online J, 1997, 3(1):3.