

ZHONGGUO
PIFU—XINGBINGXUE ZAZHI

ISSN 1001-7089
CN 61-1197/R



中国皮肤性病学杂志

THE CHINESE
JOURNAL OF
DERMATOVENEREOLOGY



美国化学文摘来源期刊

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中国生物医学核心期刊

临床医学类中文核心期刊

中国学术期刊综合评价数据库来源期刊

6

第22卷 2008年6月

Vol. 22 No. 6 June 2008

ISSN 1001-7089



9 771001 708042

中华人民共和国教育部 主管
西安交通大学 主办

表 1 两组患者治疗前后皮损 PASI 评分比较 ($\bar{x} \pm s$)

组别	例数(例)	皮损面积	红斑	浸润	鳞屑
治疗组	34				
治疗前	34	3.5 ± 1.3	2.0 ± 0.6	2.2 ± 0.6	32.8 ± 1.0
治疗 6 周末	34	1.2 ± 0.8	0.5 ± 0.3	0.4 ± 0.8	0.5 ± 0.6
t*		2.354	1.985	2.065	2.364
P		<0.025	>0.05	<0.05	<0.025
对照组	34				
治疗前	21	3.3 ± 1.2	1.9 ± 0.6	2.0 ± 10.5	2.7 ± 0.9
治疗 6 周末	21	1.7 ± 0.6	0.9 ± 0.4	0.8 ± 0.8	1.1 ± 0.7
t*		2.078	2.032	2.057	2.248
P		>0.05	>0.05	>0.05	<0.05
t▲		0.57	0.60	1.27	0.37
P 值		>0.05	>0.05	>0.05	>0.05

▲两样本比较 t 检验: * 配对 t 检验

表 2 两组头皮银屑病患者临床疗效比较 例(%)

组别	例数	治愈	显效	好转	无效	有效率(%)
治疗组	34	13(38.24)	16(47.06)	3(8.82)	2(5.88)	85.29
对照组	21	4(19.05)	7(33.33)	7(33.33)	3(14.28)	52.38

提高了疗效(有效率达 84.38%, 明显高于对照组), 说明钙泊三醇与丙酸倍氯米松合用可产生相加或协同效应。此法治疗费用较低, 同时减轻了患者对长期外用激素的恐惧心理, 易于为患者接受。总之, 达力士搽剂联合丙酸倍氯米松霜治疗头皮银屑病不失为一种安全、有效、值得临床推广使用的方法。

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- [收稿日期] 2007-10-31
[修回日期] 2008-01-18

吡硫翁锌气雾剂联合迪银片治疗寻常性银屑病疗效观察

The Therapeutic Effects of Pyrithione Zinc Aerosol Combined with Diyin Tablet on Treating Psoriasis Vulgaris

陈国生

CHEN Guo-sheng

[摘要] 目的 观察吡硫翁锌气雾剂联合迪银片治疗寻常性银屑病的临床疗效。方法 采用随机(1:1)单盲法将 92 例寻常性进行期银屑病患者随机分为治疗组、对照组各 46 例, 治疗组给予迪银片口服, 5 片/次, 3 次/d; 同时外用吡硫翁锌气雾剂 2 次/d。对照组单服迪银片, 用法同上。两组疗程均为 4 周。治疗前后分别评定 PASI 积分, 观察两组患者临床疗效及不良反应。结果 ① 两组治疗后 PASI 积分均降低, 治疗前后积分差异有显著性($P < 0.001$)。② 治疗组治愈率 69.57%, 有效率 86.96%。对照组分别为 15.22% 和 50.00%。两组治愈率及有效率差异均具有显著性($P < 0.005$)。两组均无明显不良反应。结论 吡硫翁锌气雾剂联合迪银片治疗寻常型银屑病, 疗效优于单用迪银片组。

[关键词] 吡硫翁锌气雾剂; 迪银片; 寻常型银屑病

[中图分类号] R 758.63 [文献标识码] B [文章编号] 1001-7089(2008)06-加页 1-02

银屑病在自然人群中的发生率为 0.1%~0.3%^[1]。笔者 2005 年 1 月~2007 年 8 月采用吡硫翁锌气雾剂(商品名: 适今可, 西班牙国际新化学药厂)与

迪银片(重庆华邦制药厂生产)联合治疗寻常性银屑病 46 例, 疗效满意, 结果报告如下。

1 资料和方法

1.1 病例入选及排除标准 入选标准: ① 本科门诊患者; ② 进行期寻常性银屑病患者; ③ 皮损面积 < 体表面积的 20%; ④ 年龄 18~65 岁者; ⑤ 常规检查除外其他器质性病变者。排除标准: ① 1 个月内未用皮质类固醇激素、免疫抑制剂、维甲酸治疗者; ② 妊娠、哺乳期妇女; ③ 严

重器质性疾病、肝肾功能异常者; ④ 对治疗组药所列成分及对照药物过敏者。

1.2 一般资料 共入选 92 例, 采用随机(1:1)单盲试验, 按患者就诊的先后顺序将其分为两组: 治疗组 46 例, 男 30 例, 女 16 例, 年龄 27~58 (41.59 ± 14.06) 岁; 病程 6 个月~21 年, 平均 (7.71 ± 7.57) 年。对照组 46 例, 男 32 例, 女 14 例, 年龄 23~54 (41.01 ± 14.91) 岁, 病程 6 个月~18 年, 平均 (6.91 ± 7.60) 年。两组患者的性别、年龄、病程及皮损面积差异

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无统计学意义 ($P > 0.05$)。

1.3 治疗方法 治疗组: 迪银片 5 片口服, 3 次/d, 同时外用吡硫翁锌气雾剂 2 次/d, 喷洒量以薄层药液覆盖皮损区为度。对照组: 单服迪银片, 用法同上。两组疗程均为 4 周, 治疗前、后分别复查血、尿常规、肝、肾功能, 用药期间每周复诊 1 次, 观察并记录症状和体征, 若出现不良反应, 进行酌情处理。

1.4 观察方法 治疗前、后记录以下项目: 皮损部位与范围; 红斑、鳞屑与皮疹浸润的严重程度; 用药后的变化以及各种副作用; 并以 PASI 评分标准^[2] 评定治疗结果, 计算全身各个部位皮损面积积分及相应皮损严重程度积分得到 PASI 总分。综合比较治疗前、后 PASI 总分以判定疗效。

1.5 疗效判定标准 根据卫生部推荐临床疗效评分标准^[2]。

1.6 统计学方法 两组治疗前、后 PASI 评分采用配对 t 检验, 治愈率采用 χ^2 检验。

2 结果

2.1 治疗结果 见表 1, 2。两组患者治

服药次数后不适症状自行缓解; 治疗组 5 例喷雾用药后皮肤出现潮红、有轻微刺痛感, 减少喷药次数后症状自行缓解, 不影响继续治疗。两组治疗结束后复查血、尿常规、肝、肾功能均正常。

3 讨论

吡硫翁锌气雾剂主要成分是吡硫翁锌及甲基乙基硫酸钠, 其治疗银屑病的机理是: ① 有效抑制表皮细胞的过度增殖, 防止表皮角化不全和过度, 恢复表皮细胞的更新周期; ② 抗炎作用, 减轻银屑病皮损处的炎性反应, 缓解皮损处的瘙痒和疼痛; 且甲基乙基硫酸钠能增强吡硫翁锌的上述作用^[4,5]。它对红斑及红丘疹的消退作用最强, 对慢性期皮损如苔藓化的肥厚性斑块及坚实的丘疹也有效, 同时起效快, 喷雾式给药, 避免涂抹药物对皮损的机械性刺激, 使用方便, 布药均匀, 尤适合多毛发部位, 不沾染衣物, 患者更乐于接受^[6]。其对大部分银屑病患者皮损的控制有效, 起效甚快, 推测其可能有较强的非特异性抗炎作用, 且不会产生耐药性。皮损复发, 再次使用该药物治疗仍然有效。国内外多个权

利的多种代谢及生化过程, 能提高人体免疫力, 维持正常人体蛋白代谢及微量元素平衡, 有效调节人体表皮角质形成细胞增殖与分化, 从而消除症状^[8], 疗效较好。但迪银片起效相对慢, 疗程长, 将吡硫翁锌气雾剂与迪银片联合应用, 明显地提高了治疗效果。少数患者出现轻度口干、皮肤干燥、脱屑、瘙痒, 皮肤出现潮红、有轻微刺痛感, 减少服药及喷药次数后症状自行缓解, 不影响继续治疗。但二者联用的远期疗效尚需进一步观察。

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[收稿日期] 2007-11-27

[修回日期] 2007-12-24

表 1 治疗前、后 PASI 积分比较 ($\bar{x} \pm s$)

组别	例数(例)	治疗前	治疗后	t	P
治疗组	46	18.83 ± 5.40	3.12 ± 2.88	16.89	<0.001
对照组	46	18.78 ± 7.74	8.93 ± 5.80	8.26	<0.001
t		0.95	8.65		
P		>0.05	<0.001		

表 2 两组患者临床疗效比较 例(%)

组别	例数	痊愈	显效	进步	无效	有效率(%)
治疗组	46	32(69.57)	8(17.398)	4(8.70)	2(4.35)	86.96
对照组	46	7(15.22)	16(34.78)	17(36.93)	6(13.04)	50.00

疗前 PASI 积分比较差异无统计学意义。两组治疗后 PASI 积分均降低, 治疗前、后积分差异有显著性意义 ($t = 8.65$, $P < 0.001$)。两组临床疗效有效率比较差异有显著性意义 ($\chi^2 = 16.20$, $P < 0.005$), 治疗组临床疗效优于对照组。

2.2 不良反应 两组患者各有 3 例出现轻度的口干、皮肤干燥、脱屑、瘙痒, 减少

威机构的检测结果也证实其不含激素^[1], 因此, 长期使用可避免血管改变、皮肤萎缩等副作用。

研究表明细胞免疫参与银屑病的发病转归过程, 银屑病患者存在体液免疫功能下降, 循环 T 淋巴细胞机能缺陷等^[7]。迪银片为生物制剂, 含多种活性多肽、氨基酸及微量元素, 直接参与人体

The Therapeutic Effects of Pyrithione Zinc Aerosol Combined with Diyin Tablet on Treating Psoriasis Vulgaris

Chen Guo Sheng

[Abstract]

Purpose: to observe the clinical therapeutic effects of pyrithione zinc aerosol combined with Diyin tablet in the treatment of psoriasis vulgaris.

Methods: A total of 92 cases with progressive psoriasis vulgaris was randomly divided into treatment and control groups using single blind method, 46 each group. In the treatment group, patients had oral Diyin tablet (5 tables once, three times per day) in combination with external application of topical pyrithione zinc aerosol (twice per day). In the control group, patients orally took Diyin table alone with the same dose regime. The treatment lasted for 4 weeks. PSAI scoring was carried out before and after treatment respectively for observation of clinical efficacy and adverse reactions of study agents in the two groups.

Results: 1. PASI scores of the two groups both decreased after treatment. There was significant difference between before and after treatment in PASI scores ($P<0.001$) in the two groups. 2. Healing rate was 69.57% and efficacy rate was 86.96% in treatment group, whereas they were 15.22% and 50.00% respectively in control group. There were significant differences both in healing rate and efficacy rate between the two groups ($P<0.005$). No obvious adverse reactions were observed in either the treatment group or the control group.

Conclusion: combined therapy of pyrithione zinc aerosol and Diyin tablet had better therapeutic effect in treatment of psoriasis vulgaris than Diyin table alone.

Key words: pyrithione zinc aerosol; Diyin tablet; psoriasis vulgaris

[Chinese Library Classification] R 758. 63 **[Document code]** B **[Manuscript ID]** 1001- 7089 (2008) 06-additional page 1-02

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Psoriasis has an incidence rate of 0.1%-0.3% in natural populations [1]. Here, we showed that pyrithione zinc aerosol (trade name: Skin-Cap, manufactured by Cheminova Internacional S.A., Spain) had satisfied therapeutic efficacy in treatment of 46 cases with psoriasis vulgaris and the report was shown as follows.

1 Data and Methods

1.1 Criteria of case inclusion and exclusion

Inclusion criteria: 1, cases from our dermatological department; 2, cases with progressive psoriasis vulgaris; 3, psoriasis area less than 20% of body surface; 4, aged from 18 to 65 years; 5, no other organic diseases as revealed by routine examinations. Exclusion criteria:

1, cases who received therapy of glucocorticoids, tretinoins or immunosuppressive agents within one month; 2, pregnant women or lactating mothers; 3, cases with severe organic diseases, or abnormal liver or renal functions; 4, patients who were allergic to any of study drugs

1.2 General data

A total of 92 patients were included. In this single-blind randomized controlled trial, the cases were equally divided into two groups according to visit sequence: the treatment group (46 cases: 30 men, 16 women; aged from 27 to 58 years, averaged 41.59 ± 14.06 years; disease course, 6 months to 21 years, averaged 7.71 ± 7.57 years) and the control group (43 cases: 32 men, 14 women; aged from 23 to 54 years, averaged 41.01 ± 14.91 years; disease course: 6 months to 18 years, averaged 6.91 ± 7.60 years). There was no difference in gender, age, disease course, area of psoriasis parts between the two groups ($P > 0.05$)

1.3 Treatment methods

In the treatment group, patients received oral administration of Diyin tablets (five tablets once, three times per day) and external application of topical pyrithione zinc aerosol (twice per day, the drug should be used enough to cover affected area). In the control group, cases orally took Diyin tablets with the same regime to that for treatment group. The treatment course was four weeks. Blood and urine routines, liver and renal function examinations were carried out before and after treatment respectively. Clinical symptoms and signs were observed every week within the treatment course. Adverse reactions should be managed at physician's discretion.

1.4 Observation methods

Following indexes should be recorded both before and after treatment: psoriasis part and scope; severities of red spot, squama and rash infiltration; changes before and after treatment and side effects; PASI scoring [2] criteria were adopted to evaluate therapeutic efficacy. Total PASI score was a sum of the area score of a certain psoriasis part and the severity score of the corresponding affected part. The therapeutic efficacies were assessed by comparing the total PASI scores between before and after treatment.

1.5 Therapeutic effect evaluation criteria

Clinical efficacy evaluation criteria recommended by the Ministry of Health were employed [2].

1.6 Statistical analysis

Paired *t* test was used to compare PASI scores between before and after treatment, and χ^2 test was used to compare healing rate.

2 Results

2.1 The therapeutic efficacy was shown in tables 1 and 2. There was no difference in PASI

scores before treatment between the two groups. However, PASI scores after treatment were found decreased both in the two groups. There was significant differences in PASI scores between before and after treatment for the treatment group and the control group respectively ($t=8.65$, $P<0.001$). The therapeutic effect in the treatment group was significantly better than that in the control group ($\chi^2=16.20$, $P<0.005$)

Table 1 Comparison of PASI scores between before and after treatment ($\bar{x}\pm s$)

Group	Number (case)	Before treatment	After treatment	<i>t</i>	P value
Treatment group	46	18.83±5.40	3.12±2.88	16.89	<0.001
Control group	46	18.78±7.74	8.93±5.80	8.26	<0.001
<i>t</i>		0.95	8.65		
<i>P</i>		>0.05	<0.001		

Table 2 Comparison of clinical efficacies between the two groups case (%)

Group	Number of cases	Healing	Significant efficacy	Improvement	Inefficacy	Effective rate (%)
Treatment group	46	32 (69.57)	8 (17.398)	4 (8.70)	2 (4.35)	86.96
Control group	46	7 (15.22)	16 (34.78)	17 (36.93)	6 (13.04)	50.00

2.2 Adverse reaction

Three cases with mild adverse reactions including slight dry mouth, skin dryness and itching were found in the treatment group and the control group respectively. Decreasing dosing frequency could alleviate these uncomfortable symptoms. In the treatment group, 5 cases had skin flushing and slight prickling sensation after external application of pyrithione zinc aerosol. However, these symptoms were relieved after spraying frequency was decreased, which did not affect subsequent therapy. Blood and urine routines, liver and renal function examinations that were carried out after treatment showed normal indexes.

3. Discussion

The major components of pyrithione zinc aerosol include zinc pyrithione molecule and methyl ethyl sodium sulfate. The mechanisms of pyrithione zinc aerosol in the treatment of psoriasis were: 1, effective inhibition of over proliferation of epidermal cells, prevention of parakeratosis and hyperkeratosis and recovery of renewal cycle of epidermal cells; 2, anti-inflammatory activity, alleviation of inflammatory reaction around psoriasis parts and relief of itching and pain at psoriasis parts. In addition, methyl ethyl sodium sulfate could enhance the above-mentioned activities of zinc pyrithione [4, 5]. Pyrithione zinc aerosol had the most potent effect against red spots and papule. Also, it could manage chronic psoriasis such as lichenified hypertrophic plaques and solid papules. Moreover, this agent has immediate effects and is used by spraying. Therefore, it is convenient, produces good drug distribution, prevents mechanic irritation to psoriasis part, and does not cause cloth

pollution, which is welcomed by the patients [6]. Application of this drug at multi-hair parts is preferred. Pyrithione zinc aerosol showed rapid and effectively inhibitory effects against psoriasis for most of psoriasis patients, implying it had strong non-specific anti-inflammatory activity and did not cause drug tolerance. Relapse of psoriasis could be managed by reuse of this drug. Tests done by many foreign or domestic authoritative institutions showed it did not contain hormones []. Thus, long-term use of this drug did not cause adverse reactions such as vascular abnormality and skin atrophy, etc,

Study indicated cellular immunity played a role in the onset and turnover of psoriasis. Patients with psoriasis had compromised humoral immune functions and defects of T lymphocyte function, etc [7]. Diyin table, a biological preparation, contains a variety of active polypeptides, amino acids and trace elements. It directly takes part in many metabolic and biochemical processes, enhances body immunity, maintains normal protein metabolism and trace element balance in human body and effectively regulates the proliferation and differentiation of epidermal keratinocytes, thereby alleviating symptoms [8]. However, Diyin table has relative slow effects and should be used for a long time. Combined therapy of pyrithione zinc aerosol and Diyin table significantly improve the therapeutic effects against psoriasis vulgaris. Although, some mild adverse reactions including dry mouth, skin dryness, desquamation, itching, skin flushing and slight prickling sensation were found in a few patients, they could be relieved by decreasing dosing frequencies and subsequent treatment was not affected. However, the long-term therapeutic efficacy of this combined therapy needs further investigations.

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Received: 2007-11-27

Revised: 2007-12-24