



针刺蝶腭神经节治疗变应性鼻炎的临床随机对照试验*

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【摘要】目的 评价针刺蝶腭神经节(sphenopalatine ganglion, SPG)治疗变应性鼻炎(allergic rhinitis, AR)的临床疗效及安全性。**方法** 采用随机对照试验设计,将120例AR患者按1:1比例分为试验组(针刺SPG,每周2次,疗程2周)和对照组(口服富马酸卢帕他定片,每日10 mg,疗程2周)。主要结局指标为治疗后1周及2周的鼻炎症状与体征积分;次要结局指标为鼻炎伴随症状评分(total non-nasal symptom score, TNNSS)及鼻结膜炎生活质量问卷(rhinoconjunctivitis quality of life questionnaire, RQLQ)评分。**结果** 试验组和对照组各排除4例,最终每组各56例完成研究。治疗2周后,试验组与对照组总有效率分别为82.1%与87.5%,差异无统计学意义。两组治疗后各时点症状、体征积分、TNNSS及RQLQ评分均较治疗前下降,差异有统计学意义($P < 0.001$)。广义估计方程(GEE)分析显示,两组在多数指标上改善趋势一致,但存在“组别×时间”交互作用,提示试验组在治疗第1周对鼻塞症状的改善优于对照组[试验组:2.0(1.0, 2.0) vs. 对照组:2.0(1.0, 2.0),交互项 $P=0.023$]。森林图分析进一步表明,治疗1周时鼻塞症状的标准化均数差(SMD)为-0.420(95%置信区间:-0.795, -0.046),至第2周时所有指标SMD的95%置信区间均跨越0点。安全性方面,试验组不良事件发生率与对照组比较差异无统计学意义。**结论** 针刺SPG与口服富马酸卢帕他定均可有效改善AR患者的症状与生活质量,短期总体疗效相当。但针刺SPG在缓解鼻塞症状方面起效更快,且安全性良好。

【关键词】 针刺 蝶腭神经节 变应性鼻炎 随机对照试验

A Randomized Controlled Clinical Trial of Acupuncture at the Sphenopalatine Ganglion for the Treatment of Allergic Rhinitis

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【Abstract】Objective To evaluate the clinical efficacy and safety of acupuncture at the sphenopalatine ganglion (SPG) for the treatment of allergic rhinitis (AR). **Methods** A randomized controlled trial design was used. A total of 120 patients with AR were randomly assigned in a 1:1 ratio to either the experimental group (acupuncture on the SPG, twice a week for 2 weeks) or the control group (oral loperamide fumarate tablets, 10 mg daily for 2 weeks). The primary outcome measures were nasal symptom and sign scores at 1 and 2 weeks after treatment. Secondary outcome measures included the total non-nasal symptom score (TNNSS) and the rhinoconjunctivitis quality of life questionnaire (RQLQ) score. **Results** Four cases were excluded from both the experimental group and the control group. Ultimately, 56 cases in each group completed the study. After two weeks of treatment, the total effective rates were 82.1% for the experimental group and 87.5% for the control group, with no statistically significant difference. At each time point after treatment, the symptom scores, sign scores, TNNSS, and RQLQ scores in both groups decreased compared to baseline, and these differences were statistically significant ($P < 0.001$). Generalized estimating equation (GEE) analysis showed that the improvement trends for most indicators were consistent between the two groups, but there was a "group × time" interaction, indicating that improvement in nasal congestion symptoms in the experimental group was greater than in the control group during the first week of treatment (experimental group: 2.0 [1.0, 2.0] vs. control group: 2.0 [1.0, 2.0]).

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interaction $P = 0.023$). Forest plot analysis further showed that the standardized mean difference (SMD) for nasal congestion symptoms at one week of treatment was -0.420 (95% confidence interval: $-0.795, -0.046$), and the 95% confidence intervals for all indicators' SMD at two weeks crossed zero. Regarding safety, there was no statistically significant difference in the incidence of adverse events between the experimental and control groups. **Conclusion** Acupuncture on the SPG and oral administration of lupidine fumarate can both effectively alleviate symptoms and improve the quality of life for patients with AR. The overall short-term efficacy is comparable. However, acupuncture on the SPG is more effective in relieving nasal congestion and has a good safety profile.

[Key words] Acupuncture Sphenopalatine ganglion Allergic rhinitis Randomized controlled trial

变应性鼻炎(allergic rhinitis, AR)是一种临床常见的慢性鼻炎,主要表现为鼻痒、喷嚏、鼻塞和流涕等症状。AR是一种高度普遍且全球发病率不断上升的过敏性疾病^[1-2],给社会医疗资源带来沉重负担^[3]。国内邓晓园等^[4]发现我国未成年人AR平均患病率在17%左右。AR分类:根据对患者生活质量影响的严重程度分为轻度AR和中重度AR,根据AR症状持续时间分为间歇性AR与持续性AR,根据发病机制分为免疫球蛋白E(immunoglobulin E, IgE)介导的AR和非IgE介导的AR。目前西医治疗主要包括药物和免疫治疗,但药物存在副作用和依赖性,免疫治疗周期长、费用高。针刺疗法作为替代选择,因副作用小、成本低,已被纳入美国耳鼻咽喉头颈外科学会《变应性鼻炎临床实践指南》中的可选方案之一^[5]。

鼻腔针灸在减轻鼻腔症状严重度和改善AR生活质量方面似乎优于鼻外针和西医,且无明显不良事件报告^[6]。蝶腭神经节(sphenopalatine ganglion, SPG)是鼻腔副交感神经的重要调控中枢,针刺SPG可通过调节自主神经功能缓解鼻部症状,被认为是将传统针刺与现代解剖相结合的创新疗法。既往研究提示该疗法可改善AR症状、提高生活质量,并具有一定优势^[7],但现有研究多为小样本单中心试验,且缺乏高质量的随机对照试验证据。

鉴于此,本研究以指南推荐的一线治疗药物——富马酸卢帕他定作为对照,比较针刺SPG与药物治疗在症状改善、生活质量及安全性方面的短期疗效,为针刺SPG的临床应用提供更客观的数据支持。

1 资料与方法

1.1 研究对象

本研究为前瞻性研究。经成都中医药大学附属医院医学伦理委员会审查批准(伦理审查号:2023KL-066-01),并在中国临床试验注册中心完成注册(中国临床试验注册中心编号:ChiCTR2300075891),受试者已签署知情同意书。

纳入标准:(1)2023年10月-2025年2月到成都中医药大学附属医院耳鼻喉科门诊就诊且确诊为AR的患者。

AR西医诊断标准:参照中国变应性鼻炎诊断和治疗指南(2022年,修订版)^[8]中制定的AR诊断标准:①既往有个人过敏史或家族史;②阵发性喷嚏、清水样涕、鼻痒和鼻塞等症状出现2个或以上,每天症状持续或累计在1 h以上,可伴有流泪、眼痒和眼红等眼部症状;③前鼻镜或鼻内镜下常见鼻黏膜苍白、水肿,鼻腔水样分泌物;④实验室检查:鼻黏膜激发试验、变应原皮肤试验、血清或鼻分泌物IgE等检查有助于明确诊断。患者需满足典型的鼻部症状及相应体征,以保障研究群体的同质性与结论的可靠性。AR中医诊断标准:参照《中医耳鼻咽喉科学》^[9]中的“鼻鼽”诊断标准,发作时以鼻痒、打喷嚏、流清涕为主要症状,常伴有鼻塞,部分患者伴有嗅觉减退、耳痒、眼痒、咽痒、哮喘等症状,并结合中医辨证分型(如肺气虚寒、脾气虚弱、肾阳不足、肺经伏热等)。(2)年龄18~65岁,性别不限。(3)既往体健,未进行AR相关治疗或已经停止治疗2周以上。(4)受试者签署知情同意书。

排除标准:(1)孕妇及哺乳期妇女;(2)合并其他疾病如哮喘、心血管、认知功能障碍、重度鼻息肉、艾滋病等严重疾病者;(3)不能耐受针刺治疗的患者;(4)既往对富马酸卢帕他定片药物过敏的患者。剔除与脱落标准:(1)不符合标准或违规:误纳入的受试者及违反试验原则的情况;(2)不依从方案:擅自服药、未配合治疗、未完成疗程、未定期复诊或失联;(3)健康问题:出现严重不良事件、临床试验前未查出的全身性疾病;(4)其他:AR加重需其他治疗,或研究者判断不适合继续试验。终止标准:(1)出现不可接受的高比例严重不良事件,经数据与安全监查委员会评估后建议终止;(2)实验干预措施不良事件概率过高。

1.2 样本量估算

本研究遵循临床试验随机、对照原则,依据患者就诊时间顺序编号,按计算机生成的随机数字表,以1:1比例随机分配至试验组和对照组。本研究比较针刺SPG与口服药物治疗的有效率差异,采用两独立样本率差异比较的样本量估算公式(Z近似),设试验组有效率0.80^[10]、对照组有效率0.96^[11],采用单侧检验 $\alpha = 0.05$ 。代入公式

$$n = \frac{(Z_{1-\alpha} + Z_{1-\beta})^2 \cdot [p_1(1-p_1) + p_2(1-p_2)]}{(p_1 - p_2)^2}, \text{ 式中 } p_1 = 0.80,$$

$p_2 = 0.96$, 得出 $n \approx 47.9$ 。考虑约20%脱落率, 计划总入组120例。每组60例。

1.3 治疗方案

试验组: 针具使用一次性塑柄针灸针, 规格0.35 mm×55 mm。操作方法如下: 首先以碘伏消毒针刺区域, 定位颧颞结节下方穿刺点, 选取55 mm针具进行针刺。施术者坐位于患侧耳后约30°, 用左手扶持患者头部稍向对侧倾斜, 调整至SPG、进针点、施术者眼睛三点位于同一直线。随后, 右手持针向前缓慢平行进针。当针尖抵达目标位置时, 患者多出现向鼻部或口唇放射的触电感或麻木感, 行针刺刺激2~3下后立即出针, 不予留针。取针后以无菌棉签压迫针刺点5 min。针刺后嘱患者24 h内避免咀嚼坚硬食物及大幅度张口动作。疗程安排: 每周治疗2次, 每次间隔3~4 d, 一共治疗2周, 共4次。每次仅针刺单侧穴位, 左右交替进行。具体顺序如下: ①若一侧症状较为明显, 则优先针刺症状较重一侧; ②若双侧症状无明显差异, 则先针刺左侧; ③治疗期间须停用与本病相关的药物及其他疗法。不良事件处理: 若出现局部血肿, 24 h内予冷敷处理, 24 h后改为热敷。若发生晕针、滞针、弯针、断针等情况, 按照标准应急预案进行处理, 并详细记录事件经过。

对照组: 予以口服富马酸卢帕他定片, 每日1次, 每次10 mg。疗程共计14 d, 共累计服用14次。治疗期间禁止使用其他与此病治疗有相关的药物及其他治疗方法。若出现轻度不良反应, 如嗜睡、疲劳等, 可不予停药, 但需密切观察症状变化。若出现严重药物不良反应, 如过敏反应等, 应立即停药, 并进行对症治疗, 同时密切监测患者生命体征, 做好详细记录。

1.4 观察指标

1.4.1 主要观察指标

治疗前以及治疗后1周和2周的症状积分^[8]: 包括鼻塞、喷嚏、流涕、鼻痒4个症状指标, 各自分为0~3分; 体征积分: 依据鼻腔检查结果, 观察鼻甲肿胀程度等, 0~3分。得分越高说明鼻炎症状越重。

1.4.2 次要观察指标

治疗前以及治疗后1周和2周的鼻炎伴随症状评分表(Total Non-Nasal Symptom Score, TNNSS)^[12]: 评估鼻炎相关伴随症状严重程度, 包含5个项目, 每个症状存在记1分, 不存在记0分, 总分0~5分, 分数越高, 说明鼻炎伴随症状越严重; 鼻结膜炎生活质量问卷^[13](Rhinoconjunctivitis Quality of Life Questionnaire, RQLQ): 包含7个核心维度, 采用Likert 7级评分法, 0分代表无症状困扰, 6分表示极度

困扰, 分数越高, 表明鼻结膜炎对患者生活质量的影响越严重。

1.4.3 其他指标

主要观察患者针刺SPG和口服卢帕他定治疗过程中的一些不良反应等安全性情况。

1.5 临床疗效与安全性评定标准

参照《变应性鼻炎的诊治原则和推荐方案》及《中国变应性鼻炎诊断和治疗指南(2022年, 修订版)》^[8], 根据(治疗前总分-治疗后总分)÷治疗前总分×100%计算结果评定AR的疗效(治疗总分=症状积分+体征积分): ①显效: ≥66%; ②有效: 26%~65%; ③无效: ≤25%。总有效=显效+有效。安全性评价标准^[14]: 1级, 安全, 无任何不良反应; 2级, 比较安全; 3级, 有安全性问题, 有中等程度的不良反应, 做处理后可继续给药及针刺治疗; 4级, 因不良反应中止试验。

1.6 统计学方法

采用Python statsmodels库进行数据分析。计量资料经Shapiro-Wilk检验显示呈非正态分布, 以中位数(P_{25} , P_{75})表示; 计数资料以频数和百分比表示。基线资料的组间比较分别采用Mann-Whitney U检验或卡方检验。

针对症状积分、体征积分、TNNSS、RQLQ积分及各项症状评分等纵向重复测量数据, 采用广义估计方程(GEE)进行分析。模型设定因变量服从高斯分布, 采用恒等链接函数, 作业相关矩阵设为可交换结构。鉴于数据非正态分布特性, 采用稳健标准误进行参数估计。模型纳入组别、时间及“组别×时间”交互项, 以评价治疗效果随时间的动态变化及组间差异趋势。 $P < 0.05$ 为差异有统计学意义。

为直观比较两组治疗后各时点的疗效差异绘制森林图。图中呈现的效应量为标准化均数差(standardized mean difference, SMD), 即Hedges's g值, 并计算其95%置信区间(confidence interval, CI)。SMD的计算基于治疗后两组各指标得分的均值、标准差及样本量。所有计算及图形绘制均使用Python的statsmodels及metafor包完成。森林图中, 若SMD点估计值及其95%CI水平线段完全位于垂直的无效线(0点)左侧, 则表明试验组疗效优于对照组; 若跨越无效线, 则提示组间差异无统计学意义。

2 结果

试验组和对照组各脱落4例, 最终共有112例患者的完整数据并纳入分析, 每组各56例。

2.1 两组患者基线资料比较

结果见表1。两组患者在年龄、性别、病程、过敏

表 1 两组患者基线资料比较

Table 1 Comparison of baseline characteristics between groups

Indicator	Experimental group (n = 56)	Control group (n = 56)	Statistic	P
Age/yr.*	34.5 (27.0, 45.2)	39.0 (28.8, 46.0)	U = 1 362.5	0.233
Disease course/year*	2.5 (1.0, 5.2)	3.0 (2.0, 10.0)	U = 1 289.5	0.103
Female/case (%)	38 (67.9)	30 (53.6)	$\chi^2 = 1.83$	0.176
Smoking history/case (%)	5 (8.9)	5 (8.9)	—	1.000
Drinking history/case (%)	8 (14.3)	13 (23.2)	$\chi^2 = 0.94$	0.333
Family allergy history/case (%)	21 (37.5)	18 (32.1)	$\chi^2 = 0.16$	0.692
Total symptom score*	6.0 (4.8, 7.0)	6.0 (5.0, 8.0)	U = 1 476.5	0.593
Sign score*	2.0 (1.0, 2.0)	2.0 (1.0, 2.0)	U = 1 658.0	0.581
TNNSS score*	2.0 (2.0, 3.2)	3.0 (2.0, 4.0)	U = 1 319.5	0.137
RQLQ score*	57.0 (43.8, 89.0)	66.0 (45.0, 82.0)	U = 1 509.5	0.736

TNNSS: Total Non-Nasal Symptom Score; RQLQ: Rhinoconjunctivitis Quality of Life Questionnaire. * Data are presented as median (P₂₅, P₇₅).

史、吸烟饮酒史及入组前症状体征积分、TNNSS及 RQLQ评分等方面差异无统计学意义。

2.2 两组患者主要结局指标和次要结局指标比较

结果见表2。GEE分析结果显示,两组患者在接受治疗后,各项临床症状均得到改善。无论试验组还是对照

组,随着治疗时间的推移,症状积分、各单项症状[喷嚏、流涕、鼻塞(除第1周外)、鼻痒]、体征积分、TNNSS及 RQLQ积分均较基线呈下降趋势,时间效应差异有统计学意义(P<0.001)。

尽管第1周两组鼻塞症状与基线相比均未显示显著

表 2 两组患者所有疗效指标的比较

Table 2 Comparison of all efficacy indicators between groups

Variable	Experimental group (n = 56)	Control group (n = 56)	Interaction P	Time effect P	Group effect P
Sneeze					0.118
Baseline	1.0 (0.0, 1.0)	1.0 (0.0, 2.0)	—	—	
1 week	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	0.627	< 0.001	
2 weeks	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	0.295	< 0.001	
Rhinorrhea					0.926
Baseline	3.0 (1.0, 3.0)	3.0 (1.0, 3.0)	—	—	
1 week	1.5 (1.0, 2.0)	1.0 (1.0, 2.0)	0.838	< 0.001	
2 weeks	1.0 (1.0, 2.0)	1.0 (0.8, 2.0)	0.308	< 0.001	
Nasal obstruction					0.378
Baseline	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	—	—	
1 week	2.0 (1.0, 2.0)	2.0 (1.0, 2.0)	0.023	0.396	
2 weeks	1.0 (1.0, 2.0)	1.5 (1.0, 2.0)	0.187	< 0.001	
Nasal itching					0.612
Baseline	1.0 (0.0, 2.0)	1.0 (1.0, 2.0)	—	—	
1 week	1.0 (0.0, 1.0)	1.0 (0.0, 1.0)	0.162	< 0.001	
2 weeks	1.0 (0.0, 1.0)	0.0 (0.0, 1.0)	0.205	< 0.001	
Total symptom score					0.546
Baseline	6.0 (4.8, 7.0)	6.0 (5.0, 8.0)	—	—	
1 week	4.0 (3.0, 6.0)	4.0 (3.0, 5.0)	0.627	< 0.001	
2 weeks	3.0 (2.8, 5.0)	3.0 (2.0, 4.0)	0.295	< 0.001	
Sign score					0.680
Baseline	2.0 (1.0, 2.0)	2.0 (1.0, 2.0)	—	—	
1 week	1.0 (0.8, 1.2)	1.0 (0.0, 2.0)	0.833	< 0.001	
2 weeks	1.0 (0.0, 1.0)	1.0 (0.0, 1.0)	0.397	< 0.001	
TNNSS score					0.159
Baseline	2.0 (2.0, 3.2)	3.0 (2.0, 4.0)	—	—	
1 week	2.0 (1.0, 2.0)	1.0 (1.0, 3.0)	0.374	< 0.001	
2 weeks	2.0 (1.0, 2.0)	1.0 (1.0, 2.0)	0.129	< 0.001	
RQLQ score					0.687
Baseline	57.0 (43.8, 89.0)	66.0 (45.0, 82.0)	—	—	
1 week	42.0 (32.0, 54.5)	37.0 (28.0, 52.5)	0.634	< 0.001	
2 weeks	30.0 (23.5, 45.0)	30.0 (21.0, 43.0)	0.428	< 0.001	

TNNSS: Total Non-Nasal Symptom Score; RQLQ: Rhinoconjunctivitis Quality of Life Questionnaire. Data are presented as median (P₂₅, P₇₅). P-values were derived from the generalized estimating equations (GEE) model. The group effect P represents the overall difference between the two groups; the time effect P represents the overall trend of change over time; the interaction P represents the Group × Time interaction, indicating whether the magnitude of change from baseline to the follow-up time points differs significantly between the two groups (i.e., whether the time trends differ between groups).

改善(时间效应 $P=0.396$),但在组间疗效比较方面,大多数指标的改善趋势在两组间保持一致,并未表现出明显的组间差异或总体交互作用,提示两种治疗方案在总体疗效上相当。值得注意的是,针对“鼻塞”症状,分析发现存在“组别×时间”交互作用($\chi^2=5.15, P=0.023$)。GEE交互作用分析显示在治疗第1周时,试验组鼻塞症状的改善幅度优于对照组(交互项系数 $\beta=-0.482$)。表明试验组在治疗1周时缓解鼻塞症状具有起效更快的特点。而在治疗第2周时,两组的改善程度趋于一致($P>0.05$)。

2.3 森林图分析

为更直观地展示针刺SPG与口服富马酸卢帕他定在短期疗效上的差异程度,本研究绘制了治疗后1周及2周主要疗效指标的森林图(图1)。该图呈现了各项指标的SMD,即Hedges'g值及其95%CI。

森林图分析显示,在治疗第1周,除鼻塞外,其余各项指标(症状积分、TNNSS、RQLQ积分、体征积分、喷嚏、

流涕、鼻痒)的SMD值95%CI均跨越0点,表明这些指标在两组间的差异无统计学意义。值得注意的是,治疗1周时鼻塞症状的SMD为 -0.420 (95%CI: $-0.795, -0.046, P=0.027$),其置信区间完全位于0点左侧,提示试验组在改善鼻塞症状方面,于治疗早期(1周)优于对照组。

至治疗第2周,所有疗效指标的SMD值95%CI均跨越0点,包括鼻塞症状的SMD也变为 -0.175 (95%CI: $-0.546, 0.196, P=0.353$),差异不再有统计学意义。这表明两种疗法在2周治疗结束时,总体疗效相当。

2.4 两组患者疗效比较

如表3所示,治疗1周后,试验组与对照组的总有效率均为58.9%,差异无统计学意义。治疗2周后,对照组总有效率为87.5%,试验组为82.1%,差异仍无统计学意义。结果表明,在为期2周的治疗过程中,针刺SPG与口服富马酸卢帕他定均能取得较高的临床有效率,且两种疗法的总体疗效相当。

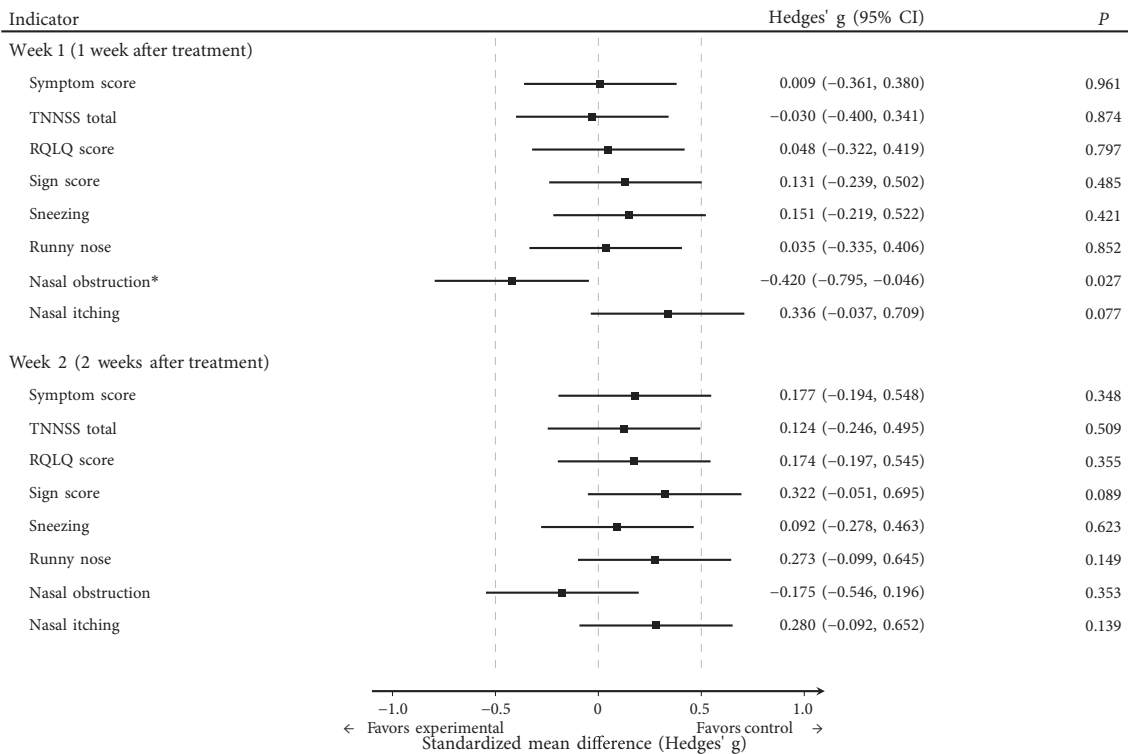


图 1 治疗后1周及2周主要疗效指标的森林图

Fig 1 Forest plot of the main efficacy indicators at 1 week and 2 weeks after treatment

Data are presented as standardized mean difference (SMD) and 95% confidence intervals. *SMD < 0 favors the experimental group.

表 3 治疗后1周及2周两组疗效评价

Table 3 Efficacy evaluation of both groups at 1 week and 2 weeks after treatment

Time point	Effective/case (%)		Markedly effective/case (%)		Total effective/case (%)		P
	Control group	Experimental group	Control group	Experimental group	Control group	Experimental group	
1 week of treatment	29 (51.8)	28 (50.0)	4 (7.1)	5 (8.9)	33 (58.9)	33 (58.9)	1.000
2 weeks of treatment	37 (66.1)	35 (62.5)	12 (52.5)	11 (47.8)	49 (87.5)	46 (82.1)	0.599

2.5 两组患者安全性指标比较

试验组有2例出现针刺后颞颌关节疼痛,经热敷后缓解,均未导致脱落。对照组有5例出现服药后嗜睡,其中1例因嗜睡伴头昏退出研究(该例包含在对照组前述的4例脱落病例中)。其余研究对象均无不良事件发生。不良事件发生率组间比较差异无统计学意义。

3 讨论

AR作为一种常见的慢性炎症性疾病,其症状持续性与反复性严重影响患者的生活质量及工作效率。AR与特应性皮炎、哮喘有相关性^[15-16]。AR的潜在病理机制目前认为是由IgE介导的I型超敏反应^[17],Notch同源物2(Notch2)影响适应性调节性T细胞(aTreg)动态并减轻AR^[18]。鼻腔微生物群在AR的起始和进展中起着关键作用^[19]。目前西医治疗有药物治疗和过敏原特异性免疫疗法(AIT)^[20],药物治疗有糖皮质激素、抗组胺药物、白三烯受体拮抗剂、肥大细胞稳定剂、盐水冲洗等,其中以抗组胺药物为主,但长期使用可能存在嗜睡、依赖性等副作用,其他还有手术治疗、鼻光疗法(RPT)等^[21-22]。

研究表明物理治疗过敏性鼻炎,包括光疗和脉冲磁场,伴随着AR主要症状强度降低、生活质量提升以及鼻呼吸客观特征的改善^[23]。针刺疗法作为非药物干预手段,已被多个国际指南纳入AR的辅助治疗方案。针刺SPG治疗AR安全有效,SPG作为调节鼻腔自主神经功能的关键节点,针刺SPG被认为是一种结合传统中医理论与现代神经解剖学的创新疗法,可应用到AR的临床治疗^[24]。针刺SPG可恢复机体“阴阳平衡”状态^[25-26],该疗法比常规针灸的短期效果更为明显^[27]。改良的针刺SPG可有效改善AR患者的症状和生活质量,复发率较低^[28]。富马酸卢帕他定片属于第二代口服抗组胺药物,对鼻塞症状的改善效果更佳,安全性好^[29]。本研究采用富马酸卢帕他定片作为对照组药物,并以14 d的时间作为总疗程,符合AR临床指南推荐用药方案建议,通过随机对照设计,系统评估了针刺SPG治疗AR的短期疗效与安全性。

本研究发现,无论是针刺SPG还是口服富马酸卢帕他定,患者在治疗1周及2周后的鼻部症状积分、体征积分、TNNSS及RQLQ积分均较基线下降,说明两种干预措施均能有效缓解AR症状、改善生活质量。尤其值得注意的是,在鼻塞症状的改善方面,GEE分析显示存在“组别×时间”交互作用,提示针刺SPG在治疗第1周时对鼻塞的缓解速度优于富马酸卢帕他定。这一结果可能与针刺SPG直接调节鼻腔副交感神经张力、改善局部血流与黏膜水肿有关,体现了针灸“通利鼻窍、行气活血”的中医理

论特色^[6,30]。从中医理论角度分析,鼻塞多因“肺气不利、窍道壅滞”,SPG位于颞颥之下,深处经络交汇之处,针刺该处可激发经气,疏通阳明经气,从而迅速缓解鼻塞^[31-32]。SPG具有清热疏风,通利官窍的作用。本研究结果提示,针刺SPG在改善AR患者鼻塞症状方面具有起效快、针对性强的优势,这为临床中针对以鼻塞为主诉的AR患者提供了优选方案。

此外,两组在喷嚏、流涕、鼻痒等其余症状的改善上趋势一致,说明针刺与药物在整体症状控制方面疗效相当。在安全性方面,试验组仅2例出现轻度颞颌关节不适,经热敷后缓解;而对照组有5例出现嗜睡,1例因头晕退出研究。尽管组间不良事件发生率无明显差异,但试验组表现出更好的耐受性与更低的中枢抑制作用,符合针灸“治外治内、调和气血”的整体调节理念。

森林图结果进一步支持了上述发现,并为疗效的时程差异提供了直观证据。森林图显示,在治疗第1周,鼻塞症状的SMD(-0.420)置信区间完全位于0点左侧,表明试验组在改善鼻塞方面的早期疗效优于对照组。这一结果与GEE分析中“组别×时间”交互作用一致,提示针刺可能通过快速调节SPG功能、减轻鼻腔黏膜水肿与血管扩张,从而在短期内更有效地缓解鼻塞。至治疗第2周,所有指标包括鼻塞的SMD置信区间均跨越0点,说明两种疗法在疗程结束时总体疗效趋于一致。森林图不仅印证了针刺在特定症状上的早期优势,也直观反映了两组在多数症状和生活质量指标上无明显差异的整体趋势,增强了结果的可视化与解释力。

本研究仍存在一定局限性:首先,为单中心、小样本研究,随访时间较短(仅2周),未能评估中长期疗效;其次,缺乏安慰针或假针刺对照,可能影响结果的特异性解释;此外,未对患者进行中医证型分层分析,未来可进一步探讨不同证型对针刺响应的差异。

综上所述,针刺SPG与口服富马酸卢帕他定均可有效改善AR患者的临床症状与生活质量,二者总体疗效相当。然而,针刺在缓解鼻塞症状方面显示出更快的起效速度,且安全性良好,体现了针灸干预的独特优势。未来应开展多中心、大样本、长随访的研究,并纳入神经电生理或影像学指标,进一步揭示针刺SPG治疗AR的作用机制,为其临床推广应用提供更高级别的证据支持。

* * *

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利益冲突 所有作者均声明不存在利益冲突

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