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宣肺平喘方治疗小儿哮喘的疗效观察 及其对呼出气一氧化氮的影响

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[摘要] 目的: 评价宣肺平喘方治疗小儿哮喘的临床疗效及其对呼出气一氧化氮(FeNO)的影响。方法: 将80例支气管哮喘患儿按随机数字表法分为对照组与研究组, 每组各40例。对照组予西医规范治疗, 研究组在西医规范治疗的基础上, 加予口服宣肺平喘方, 连续治疗2周后, 比较患者在临床疗效、中医症候积分、炎症指标[白细胞计数(white blood cell count, WBC)、高敏C反应蛋白(high-sensitivity C-reactive protein, hs-CRP)、白介素-6(IL-6)]、肺功能[1秒用力呼气容积(FEV₁)、1秒用力呼气容积与用力肺活量的比值(FEV₁/FVC)]及FeNO的差异。结果: 经治疗, 对照组总有效率82.5%, 研究组为92.5%, 研究组临床疗效优于对照组, 差异有统计学意义($P<0.05$)。治疗前, 两组在气喘、胸闷、咳嗽、咳痰等症状上, 差异无统计学意义($P>0.05$); 治疗后, 研究组在症状改善上优于对照组, 差异有统计学意义($P<0.05$)。与治疗前相比, 对照组治疗后除胸闷症状外, 其余症状均显著改善, 差异有统计学意义($P<0.05$); 研究组在各症状均显著改善, 差异有统计学意义($P<0.05$)。治疗前, 两组在WBC, hs-CRP, IL-6, FEV₁, FEV₁/FVC及FeNO等指标上, 差异无统计学意义($P>0.05$); 治疗后, 2组各指标相比, 差异有统计学意义($P<0.05$ 或 $P<0.01$)。两组经治疗, 各项指标均显著改善, 差异有统计学意义($P<0.05$ 或 $P<0.01$)。结论: 宣肺平喘方治疗小儿哮喘疗效确切, 能显著改善患儿症状, 降低炎症指标, 改善肺功能, 且无明显不良反应, 联合西药治疗效果更佳。

[关键词] 宣肺平喘方; 小儿哮喘; 临床疗效; 呼出气一氧化氮

Therapeutic effect of Xuanfei Pingchuan Recipe on children with asthma and its effect on FeNO

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Abstract **Objective:** To evaluate the clinical efficacy of Xuanfei Pingchuan Recipe in treating children with asthma and

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its effect on exhaled nitric oxide (FeNO). **Methods:** Eighty children with bronchial asthma were divided into a control group and a study group according to the random number table method, 40 cases in each group. The control group was treated with Western medicine. The research group was treated with oral Xuanfei Pingchuan Recipe on the basis of Western medicine standard treatment. After 2 weeks of continuous treatment, the patients were compared in clinical efficacy, TCM symptom scores, inflammation index (WBC, hs-CRP, IL-6), lung function (FEV₁, FEV₁/FVC) and FeNO. **Results:** After the treatment, the total effective rate of the control group was 82.5%, and that of the study group was 92.5%. The clinical effect of the study group was better than that of the control group, and the difference was statistically significant ($P<0.05$). Before the treatment, the differences between the two groups in asthma, chest tightness, cough, cough and other symptoms were not statistically significant ($P>0.05$). After the treatment, the study group was better than the control group in terms of symptom improvement. The difference was statistically significant ($P<0.05$). After the treatment, the control groups were significantly improved except for the symptoms of chest tightness, and the difference was statistically significant ($P<0.05$). The study group showed significant improvement in each symptom, and the difference was statistically significant ($P<0.05$, $P<0.01$). Before the treatment, there were no significant differences in WBC, hs-CRP and IL-6 between the two groups ($P>0.05$). After the treatment, the inflammatory indexes of the study group were significantly lower than the control group, and the difference was statistically significant ($P<0.05$). After the treatment, the inflammatory indexes of the two groups were significantly decreased, and the difference was statistically significant ($P<0.05$, $P<0.01$). Before the treatment, there was no significant difference in the indexes of FEV₁, FEV₁/FVC and FeNO between the two groups ($P>0.05$). After the treatment, the indexes of the study group were significantly better than the control group, and the difference was statistically significant ($P<0.01$). After the treatment, the indexes of the two groups were significantly improved, and the difference was statistically significant ($P<0.01$). **Conclusion:** Xuanfei Pingchuan Recipe is effective in the treatment of children with asthma, can significantly improve the symptoms of children, reduce inflammation indicators, improve lung function, and have no obvious adverse reactions. The clinical efficacy is better when combined with western medicine treatment.

Keywords Xuanfei Pingchuan Recipe; pediatric asthma; clinical efficacy; FeNO

支气管哮喘是以气道慢性炎症和气道高反应为特征的异质性疾病^[1]，由于其发病率逐年升高而整体控制水平不佳，给患儿的身心健康带来严重的影响^[2]。现代医学主要通过糖皮质激素来有效治疗和控制哮喘的发作，但仍有部分患儿疗效不佳。同时，由于长期的激素吸入可能出现较为严重的不良反应，使得患儿治疗的依从性不高^[3]。中医药治疗哮喘历史悠久，积累了丰富的宝贵经验。研究表明：中医药在小儿哮喘中起到抗炎解痉、减少气道高反应等作用，但只重视“治因”而忽略了“治气”，不能快速止喘。前期研究^[6-7]亦发现宣肺平喘方能够降低血清中炎症因子，改善临床症状等。同时在“治气与治因相结合”的指导思想^[8]下，本研究将宣肺平喘方应用于小儿哮喘，已取得理想效果。

1 对象与方法

1.1 对象

选取2017年1月至2018年10月于溧阳中医医院儿科就诊的患儿80例，按随机数字表法分为对照组与研究组，每组各40例。其中对照组男24例，女16例；年龄2~11(6.43 ± 0.57)岁；病程0.5~5.0(2.71 ± 0.87)年；研究组男22例，女18例；年龄3~12(6.37 ± 0.61)岁；病程0.4~5.0年(2.68 ± 0.73)。经统计学分析，两组患者一般基线资料差异无统计学意义($P>0.05$)，具有可比性。本研究经溧阳市中医医院医学伦理委员会批准，患者均签署知情同意书。

1.2 诊断标准

西医疾病诊断依据2016年《儿童支气管哮喘

诊断与防治指南》诊断标准^[1]: 1)反复喘息、咳嗽、气促、胸闷, 多与刺激、运动、呼吸道感染及过度通气等有关, 常在夜间和/或凌晨发作或加剧; 2)发作时两肺可闻及散在或弥漫性的哮鸣音, 以呼气相为主, 呼气相延长; 3)上述症状和体征经抗哮喘治疗有效, 或自行缓解; 4)排除其他疾病引起的喘息、咳嗽、气促、胸闷; 5)临床表现不典型者, 应至少具备以下1项: ①证实存在可逆性气流受限: 支气管舒张试验阳性、抗炎治疗后肺通气功能改善; ②支气管激发试验阳性; ③最大呼气峰流量(peak expiratory flow, PEF)日间变异率≥13%。符合第1~4条或第4~5条者, 可诊断为哮喘。

中医证型诊断参考《中医儿科学》哮喘病关于痰热阻肺证的诊断^[2]: 主症为咳嗽喘息, 声高息涌, 咳痰稠黄, 身热咽红; 次症为面赤, 口干, 尿黄, 便秘; 舌脉纹为舌质红, 苔黄, 脉滑数, 指纹紫。

纳入标准: 1)符合哮喘的西医诊断标准和中医证型诊断; 2)哮喘急性发作; 3)治疗前未行其他中药治疗; 4)对本研究使用药物不过敏; 5)签署知情同意书。排除标准: 1)危及生命的危重症患者; 2)合并有其他重大疾病, 如先心病等; 3)合并严重肺部感染患者; 4)不能配合治疗; 5)其他需终止研究者。

1.3 治疗方法

两组患者均予吸氧、平喘、抗感染等西医基础治疗。对照组加予孟鲁司特钠[默沙东(中国)有限公司, 国药准字J20120072, 10 mg/片], 2~5岁, 1次/d, 4 mg/次; 6~12岁, 1次/d, 5 mg/次。研究组在对照组基础上加用宣肺平喘方(溧阳市中医院药剂科提供), 组方如下: (蜜制)麻黄6 g, (苦)杏仁6 g, 石韦30 g, (生)甘草6 g, (浙)贝母10 g, 平地木20 g, 荆芥穗10 g, 蝉蜕6 g, 钩藤3 g(后下), 乌梅6 g。煎药机浓煎(100 mL/袋), 2~5岁, 50 mL/次, 早晚分服; 6~12岁, 100 mL/次, 早晚分服。均连续治疗2周。

1.4 观察指标

1.4.1 临床疗效判定

采用唐晓燕等^[10]的判定标准。显效: 患儿喘息等临床症状均基本消失, 哮鸣音体征消失, 且1秒用力呼气容积(FEV₁)≥正常预计值的80%; 有效: 患儿临床症状部分消失, 体征基本消失, 且FEV₁<正常预计值的80%; 无效: 患儿临床症状、

体征及FEV₁均未得到改善, 甚至加重。总有效率=(显效+有效)/总数×100%。

1.4.2 中医症候积分

参照《支气管哮喘中医证候诊断标准》^[11], 对患儿的气喘、胸闷、咳嗽及咳痰打分, 按照无、轻度、中度、重度分别记0, 1, 2, 3分。

1.4.3 肺功能

肺功能指标包括FEV₁、1秒用力呼气容积与用力肺活量的比值(FEV₁/FVC)等。

1.4.4 呼出气一氧化氮

采用Aerocrine AB公司检测仪, 检测患儿的呼出气一氧化氮(FeNO)水平。

1.4.5 炎症指标

取患儿静脉血4 mL, 以3 000 r/min离心10 min得到血清, 分2份, 1份采用免疫比浊法测定白细胞计数(white blood cell count, WBC)、高敏C反应蛋白(high-sensitivity C-reactive protein, hs-CRP), 1份采用ELISA法检测白介素-6(IL-6)。

1.4.6 不良反应

主要监测患儿的肝肾功能及是否过敏。

1.5 统计学处理

采用SPSS 20.0统计软件进行数据分析, 等级资料予秩和检验; 计数数据以予 χ^2 检验; 计量资料以均数±标准差($\bar{x}\pm s$)表示, 组内比较予配对样本t检验, 组间比较予独立样本t检验。 $P<0.05$ 为差异有统计学意义。

2 结果

2.1 临床疗效

对照组总有效率82.5%, 研究组为92.5%, 研究组临床疗效优于对照组, 差异有统计学意义($P<0.05$, 表1)。

2.2 中医症候积分

治疗前, 两组在气喘、胸闷、咳嗽、咳痰等症状上, 差异无统计学意义($P>0.05$)。治疗后, 研究组在症状改善上优于对照组, 差异有统计学意义($P<0.05$)。对照组除胸闷症状外, 其余症状均显著改善, 差异有统计学意义($P<0.05$); 研究组在气喘、胸闷、咳嗽、咳痰等症状均显著改善, 差异有统计学意义($P<0.05$, 表2)。

2.3 肺功能及 FeNO

治疗前, 两组在FEV₁、FEV₁/FVC及FeNO等

指标上, 差异无统计学意义($P>0.05$); 治疗后, 两组各项指标均显著改善, 差异有统计学意义, 但研究组的各项指标明显优于对照组, 差异有统计学意义($P<0.01$, 表3)。两组患儿肺功能及FeNO情况详见图1。

2.4 炎症指标

治疗前, 两组在WBC, hs-CRP, IL-6等指标上, 差异无统计学意义($P>0.05$); 治疗后, 两

组经治疗后, WBC, hs-CRP, IL-6等炎症指标均显著下降, 差异有统计学意义, 但研究组的各炎症指标明显低于对照组, 差异有统计学意义($P<0.05$, 表4)。两组患儿炎症指标情况详见图2。

2.5 不良反应

治疗过程中, 两组患者均未出现肝肾功能异常及过敏, 差异无统计学意义($P>0.05$)。

表1 两组临床疗效比较(n=40)

Table 1 Comparison of clinical effects between the 2 groups (n=40)

组别	显效/[例(%)]	有效/[例(%)]	无效/[例(%)]	总有效率/%
对照组	15(37.5)	18(45.0)	7(17.5)	82.5
研究组	25(62.5)	12(30.0)	3(7.5)	92.5
U/ χ^2		2.284		4.414*
P		0.022		0.036

* χ^2 检验。

* χ^2 test.

表2 两组中医症候积分比较(n=40)

Table 2 Comparison of TCM symptom scores between the 2 groups (n=40)

组别	气喘/分		胸闷/分		咳嗽/分		咳痰/分	
	治疗前	治疗后	治疗前	治疗后	治疗前	治疗后	治疗前	治疗后
对照组	1.88 ± 0.99	1.43 ± 0.93*	1.40 ± 0.87	1.03 ± 0.92	1.85 ± 0.98	1.30 ± 1.11*	1.73 ± 0.85	1.30 ± 0.99*
研究组	1.75 ± 0.93	0.98 ± 0.89*	1.58 ± 0.93	0.60 ± 0.67 ^Δ	1.80 ± 0.91	0.80 ± 0.79*	1.78 ± 0.92	0.80 ± 0.82 ^Δ
t	0.582	2.209	0.882	2.360	0.237	2.315	0.253	2.453
P	0.562	0.030	0.380	0.021	0.813	0.024	0.801	0.016

与治疗前相比, * $P<0.05$, ^Δ $P<0.01$ 。

Compared with before treatment, * $P<0.05$, ^Δ $P<0.01$.

表3 两组肺功能及FeNO比较(n=40)

Table 3 Comparison of lung function and exhaled nitric oxide between the 2 groups (n=40)

组别	FEV ₁ /L		FEV ₁ /FVC/%		FeNO/parts per billion	
	治疗前	治疗后	治疗前	治疗后	治疗前	治疗后
对照组	1.62 ± 0.21	2.18 ± 0.36 ^Δ	66.15 ± 7.19	70.80 ± 6.14 ^Δ	42.30 ± 12.50	25.90 ± 8.16 ^Δ
研究组	1.56 ± 0.25	2.54 ± 0.31 ^Δ	67.40 ± 6.90	80.83 ± 6.10 ^Δ	44.85 ± 10.76	21.10 ± 7.92
t	1.146	4.828	0.793	7.327	0.978	2.670
P	0.255	<0.001	0.430	<0.001	0.331	0.009

与治疗前相比, ^Δ $P<0.01$ 。

Compared with before treatment, ^Δ $P<0.01$.

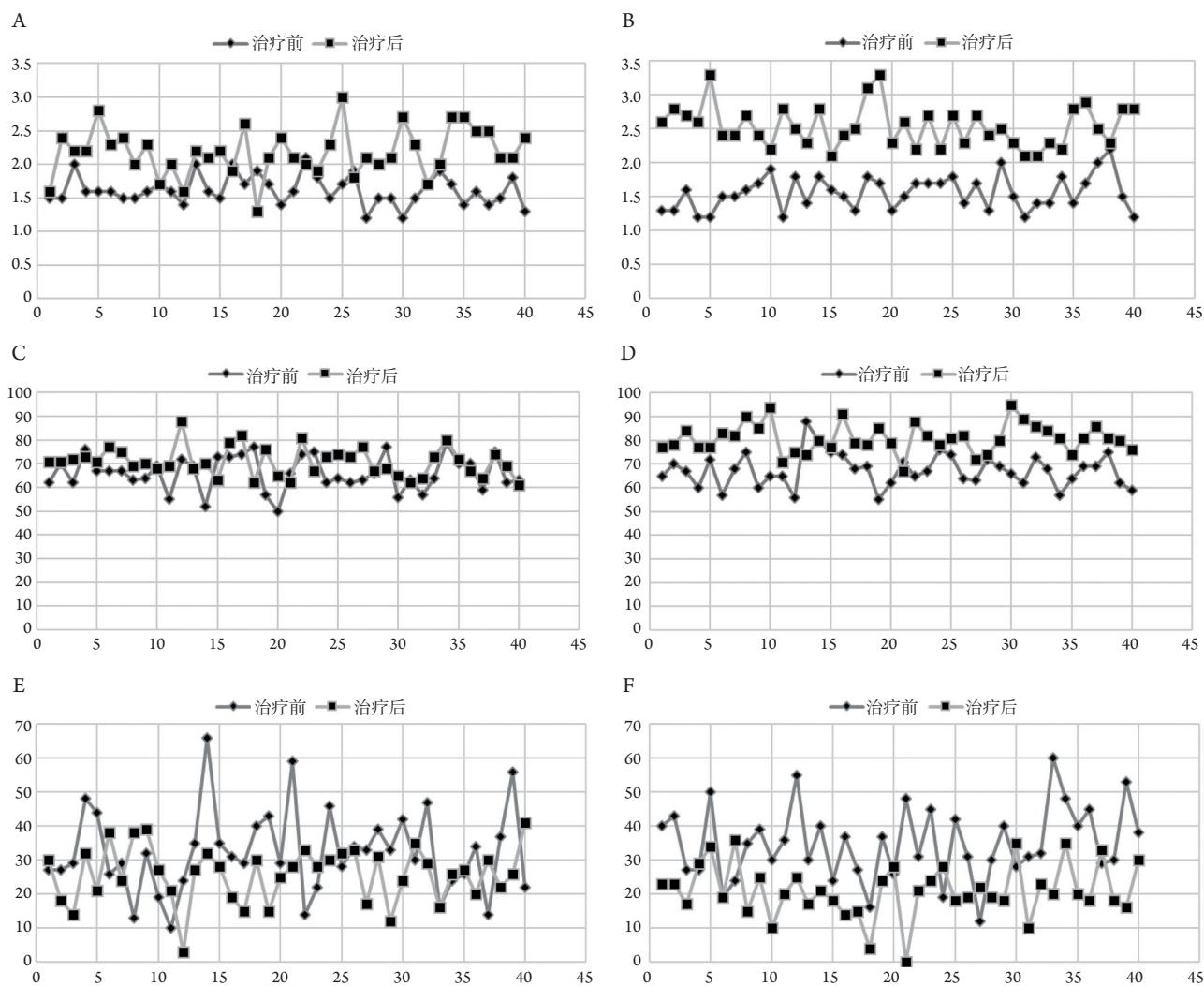


图1 两组患儿肺功能及FeNO情况

Figure 1 Pulmonary function and FeNO status between the 2 groups

(A)对照组治疗前后FEV₁; (B)研究组治疗前后FEV₁; (C)对照组治疗前后FEV₁/FVC; (D)研究组治疗前后FEV₁/FVC; (E)对照组治疗前后FeNO; (F)研究组治疗前后FeNO。

(A) FEV₁ before and after treatment in the control group; (B) FEV₁ before and after treatment in the study group; (C) FEV₁/FVC before and after treatment in the control group; (D) FEV₁/FVC before and after treatment in the study group; (E) FeNO before and after treatment in the control group; (F) FeNO before and after treatment in the study group.

表4 两组炎症指标比较(n=40)

Table 4 Comparison of inflammation indicators between the 2 groups (n=40)

组别	WBC/(10 ⁹ ·L ⁻¹)		hs-CRP/(mg·L ⁻¹)		IL-6/(pg·mL ⁻¹)	
	治疗前	治疗后	治疗前	治疗后	治疗前	治疗后
对照组	12.16 ± 3.71	9.76 ± 3.29*	38.24 ± 13.71	8.61 ± 3.18 [△]	13.27 ± 2.09	7.20 ± 2.85*
研究组	11.95 ± 3.78	8.05 ± 2.53*	40.52 ± 15.13	6.62 ± 2.88 [△]	13.39 ± 2.23	5.42 ± 1.96*
t	0.103	2.638	0.352	2.717	0.036	3.023
P	0.875	0.026	0.745	0.011	0.944	0.001

与治疗前相比, *P<0.05, [△]P<0.01。

Compared with before treatment, *P<0.05, [△]P<0.01.

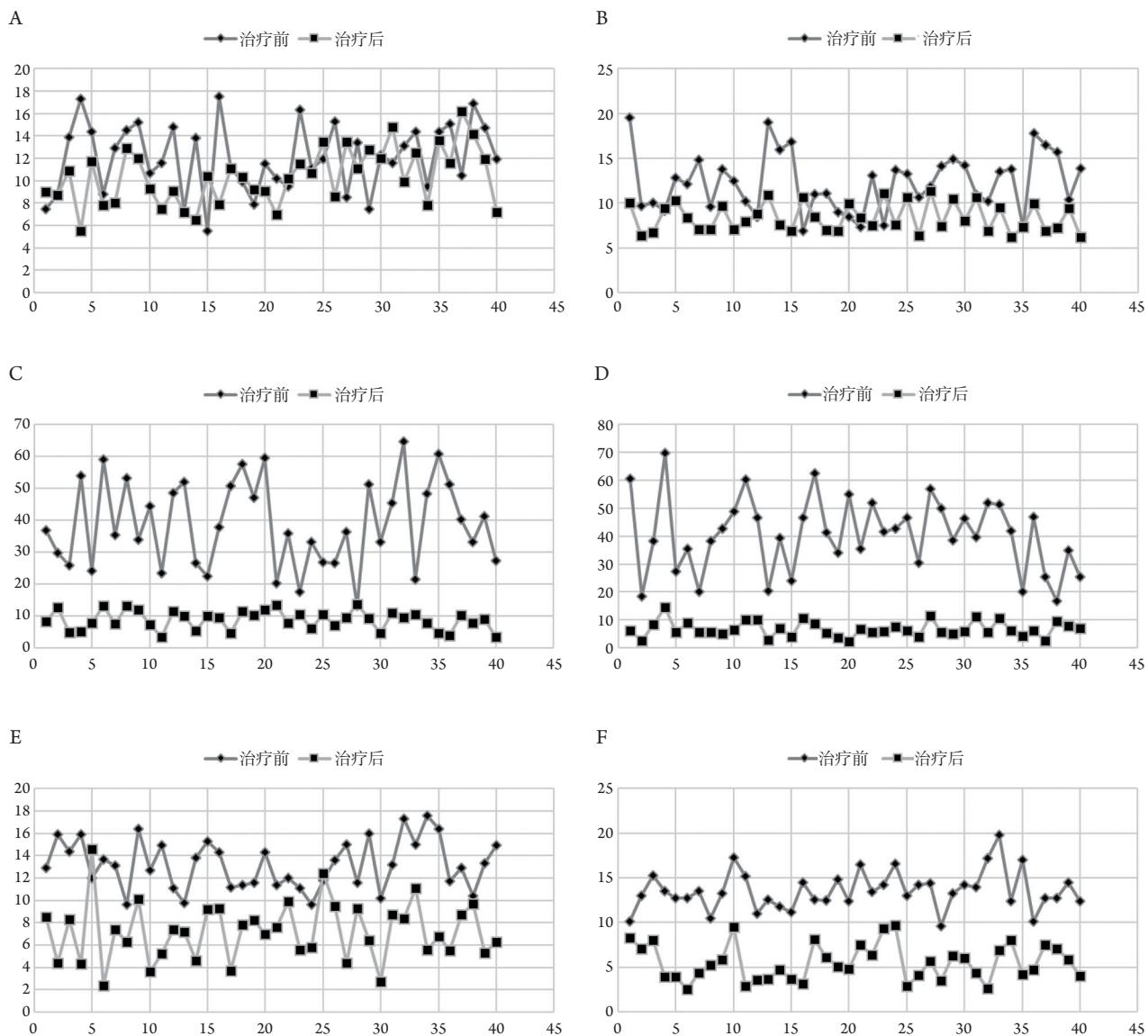


图2 两组患儿炎症指标情况

Figure 2 Inflammation indicators between the 2 groups

(A)对照组治疗前后WBC; (B)研究组治疗前后WBC; (C)对照组治疗前后hs-CRP; (D)研究组治疗前后hs-CRP; (E)对照组治疗前后IL-6; (F)研究组治疗前后IL-6。

(A) WBC before and after treatment in the control group; (B) WBC before and after treatment in the study group; (C) hs-CRP before and after treatment in the control group; (D) hs-CRP before and after treatment in the study group; (E) IL-6 before and after treatment in the control group; (F) IL-6 before and after treatment in the study group.

3 讨论

支气管哮喘以反复发作的喘息、气促、胸闷、咳嗽为主要临床表现，常在夜间和/或凌晨发作或加剧，是儿童时期的常见慢性疾病^[12]。其治疗药物包括糖皮质激素、白三烯调节剂、长效β₂受体激动剂等抗炎的控制药物和速效吸入β₂受体激动剂、短效口服β₂受体激动剂、吸入抗胆碱能药物等

快速解除支气管痉挛的缓解药物。2016年发布的《儿童支气管哮喘诊断与防治指南》提倡分级联合用药，但仍有许多患儿疗效欠佳。

支气管哮喘属于传统医学“哮病”“喘病”等范畴，认为其乃是肺脾肾虚弱，痰饮伏肺而为夙根，每感邪而发。《丹溪心法》首次命名“哮喘”，提出“已发攻邪，未发扶正”的论述。再结合小儿发病时常伴有“肝常有余”的症状，宣肺平

喘方亦可谓专攻小儿哮喘。宣肺平喘方由麻黄、杏仁、石韦、甘草、浙贝、平地木、葶苈子、蝉蜕、钩藤和乌梅等组成。方中蜜麻黄宣畅肺气，苦杏仁肃降肺气，二者一升一降，平喘止咳以治肺气，共为君药；同时，肺与大肠相表里，杏仁兼能润肠通便，通肠腑以泻肺热。石韦，《长沙药解》谓之“清金泻热”，其能清金热、治痰火；浙贝母擅长清热化痰；生甘草气平以清肺热；平地木既能化痰，又能平喘；此四者清化痰热以治病因，共为臣药；兼顾到小儿“脾常不足”的特点，故选轻清之浙贝母而不败胃，味甘之甘草以养脾气，既防伤脾胃，又不致补太过。小儿“肝常有余”，故予钩藤配蝉衣祛风止痉，以防变证；葶苈子泻肺平喘；乌梅敛肺止咳；四者共为佐助药。又以甘草调和诸药。诸药同用，共奏清肺化痰、平喘止咳之效。

“治气”旨在快速止喘，“治因”在于求本，有利于加快患儿症状的改善。现代药理研究亦证实，麻黄、杏仁可抑制表皮生长因子生成，从而起到缓解支气管平滑肌痉挛的作用^[13]，石韦通过抗炎等缩短哮喘的病程^[14]，甘草、浙贝、乌梅等均有具有化痰抗炎等作用^[15]。

FeNO是反映气道炎症的敏感非特异性指标，但对于明确的哮喘患者而言，FeNO则是早期诊断指标。由于其检验快捷、安全、简单，尤其适用于儿童哮喘的检测诊断。本次研究发现：宣肺平喘方联合西药基础治疗后，研究组在临床疗效、症状改善、炎症指标(WBC, hs-CRP, IL-6)、肺功能(FEV₁, FEV₁/FVC)及FeNO等方面上，均优于对照组($P<0.05$)。提示本方可能具有抗炎、降低气道高反应、缓解气道痉挛等作用。

综上，宣肺平喘方治疗小儿哮喘疗效确切，可能通过抗炎、降低气道高反应、缓解气道痉挛等作用改善患儿症状，降低炎症指标，改善肺功能，同时无明显不良反应，疗效显著。

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