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自拟狼疮方联合甲基泼尼松龙对系统性红斑狼疮患者 Th1/Th2 细胞因子水平和免疫功能的影响

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[摘要] 目的: 探讨从中西医结合角度自拟狼疮方联合甲基泼尼松龙治疗系统性红斑狼疮(systemic lupus erythematosus, SLE)临床效果, 观察对SLE患者Th1/Th2平衡和免疫功能的影响。方法: 将廊坊市人民医院风湿免疫科2015年3月至2019年6月期间收治的78例SLE患者随机分为对照组和观察组, 两组各39例。对照组给予甲基泼尼松龙治疗, 观察组在对照组基础上自拟狼疮方治疗, 比较两组治疗前后SLE疾病活动度(SLE disease activity index, SLEDAI)评分、中医证候积分、Th1/Th2相关细胞因子和免疫指标, 并评估两组临床疗效。结果: 两组治疗后SLEDAI评分、中医证候积分均显著下降($P<0.05$), 观察组治疗后上述指标显著低于对照组, 差异有统计学意义($P<0.05$); 两组治疗后血清IL-2水平明显升高, IL-4, IL-10水平显著下降($P<0.05$), 观察组治疗后血清IL-2水平高于对照组, IL-4, IL-10水平低于对照组, 差异有统计学意义($P<0.05$); 两组治疗后血清IgG, IgA, IgM均明显降低, 补体C3和C4水平显著提高($P<0.05$), 观察组治疗后血清IgG, IgA, IgM, C3, C4水平均优于对照组($P<0.05$); 观察组临床总有效率92.31%明显高于对照组74.36%, 差异有统计学意义($P<0.05$)。结论: 自拟狼疮方联合甲基泼尼松龙能有效稳定SLE患者病情, 调节Th1/Th2平衡和改善免疫功能, 起到增益临床疗效的作用。

[关键词] 系统性红斑狼疮; 自拟狼疮方; 甲基泼尼松龙; Th1/Th2平衡; 免疫功能

Effect of self-made lupus formula combined with methylprednisolone on Th1/Th2 cytokines and immune function in patients with systemic lupus erythematosus

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Abstract Objective: To investigate the clinical effect of lupus formula combined with methylprednisolone in the

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treatment of systemic lupus erythematosus (SLE) from the perspective of integration of traditional Chinese and Western medicine, and to observe the effect on Th1/Th2 balance and immune function of SLE patients. **Methods:** Seventy-eight SLE patients in our hospital from March 2015 to June 2019 were randomly divided into control group and observation group, 39 cases in each group. The control group was treated with methylprednisolone, and the observation group was treated with lupus formula on the basis of the control group. The SLE disease activity index (SLEDAI) score, TCM syndrome score, Th1/Th2 related cytokines and immune indexes before and after treatment were compared between the two groups, and the clinical efficacy of the two groups was evaluated. **Results:** After treatment, the scores of SLEDAI and TCM syndromes in the two groups decreased significantly ($P<0.05$), and the above indexes in the observation group were significantly lower than those in the control group ($P<0.05$); the levels of IL-2 and IL-10 in the observation group were higher than those in the control group, and the levels of IL-4 and IL-10 were lower than those in the control group ($P<0.05$); after treatment, serum IgG, IgA and IgM in the two groups were significantly reduced, and the levels of C3 and C4 in the complement were significantly increased ($P<0.05$). The levels of IgG, IgA, IgM, C3 and C4 in the observation group were better than those in the control group ($P<0.05$); the total clinical effective rate of the observation group was 92.31%, which was significantly higher than that of the control group 74.36% ($P<0.05$). **Conclusion:** the self-made lupus formula combined with methylprednisolone can effectively stabilize the condition of SLE patients, regulate the balance of Th1/Th2 and improve the immune function, and play a role in enhancing the clinical efficacy.

Keywords systemic lupus erythematosus; self-made lupus formula; methylprednisolone; Th1/Th2 balance; immune function

系统性红斑狼疮(systemic lupus erythematosus, SLE)是一种全身性免疫系统疾病,临床表现复杂多样,且多数患者起病隐匿,早期症状缺乏特异性,随病情进展,逐渐出现累及肾、心、肺部和血液系统等多器官损伤症状,治疗相对棘手,给患者带来沉重身心痛苦和经济负担。目前SLE具体发病机制尚未完全明确,临床缺乏有效根治疗法,SLE相关指南仅推荐采用激素或免疫抑制剂药物治疗,但临床疗效欠佳。Th细胞也称为辅助性T细胞,能分泌多种细胞因子,根据Th细胞分泌细胞不同分为Th1细胞与Th2细胞,二者维持平衡对人体免疫系统发挥正常功能尤为重要。近些年陆续有研究^[1-2]表明:Th1和Th2间细胞因子失衡与SLE患者B淋巴细胞异常活化、增殖及分化紧密相关,Th1/Th2失衡积极参与SLE发生进展全过程。廊坊市人民医院(以下简称本院)风湿免疫科自2009年建科以来不断发展壮大,积极发挥中西医结合治疗特色和中医药优势,为临床SLE治疗积攒宝贵经验。本研究运用中西医结合疗法,探讨自拟狼疮方联合甲基泼尼松龙治疗SLE的临床效果,并观察对患者Th1/Th2失衡和免疫功能的影响。

1 对象与方法

1.1 对象

纳入廊坊市人民医院风湿免疫科收治的78例SLE患者,纳入标准:1)西医诊断参考1997年美国风湿病学会修订的SLE诊断标准,中医诊断参考《中医内科常见病诊疗指南》^[3],符合“阴阳毒”“红蝴蝶疮”的诊断标准;2)年龄18~65岁,具备基本的沟通交流能力,对本研究知情同意。排除标准:1)哺乳妊娠期妇女;2)合并严重心脑血管疾病、严重肝肾功能不全、全身感染、精神神经性疾病、其他类型风湿病或对本研究药物过敏禁忌者;3)近3个月内使用过激素或免疫抑制药物者。采用计算机随机分组法将78例SLE患者分为对照组($n=39$)和观察组($n=39$)。对照组男4例,女35例;年龄18~63(29.78 ± 6.53)岁;病程3~29(14.30 ± 3.58)个月;SLE疾病活动度(SLE disease activity index, SLEDAI)评分评估病情程度,中度34例,重度5例。观察组男5例,女34例;年龄18~62(29.80 ± 6.18)岁;病程3~30(14.32 ± 3.60)个月;病情中度33例,重度6例。两组SLE患者上述基线资料比较差异均无统计学意义($P>0.05$),提示分组均衡,可比性较好。本研究

获得廊坊市人民医院医学伦理委员会批准。

1.2 方法

对照组给予甲基泼尼松龙(浙江仙琚制药股份有限公司)口服治疗, 初始剂量为10~20 mg/d, 持续服用8周后酌情增加剂量, 维持4~8 mg/d治疗。观察组在对照组基础上自拟狼疮方治疗, 组方: 熟地黄20 g、女贞子20 g、山茱萸20 g、墨旱莲15 g、青蒿15 g、太子参15 g、牡丹皮15 g、鸡血藤15 g、白花蛇舌草15 g、当归15 g。1剂/d, 煎制成400 mL药液, 早晚2次口服。两组均持续治疗6个月, 相关对症支持治疗均相同。

1.3 研究指标

参考《中医病症诊断疗效标准》SLE积分评价标准和国际通用SLEDAI评分标准, 记录两组治疗前后中医证候积分和SLEDAI评分; 检测两组治疗前后白介素-2(interleukin-2, IL-2)、IL-4、IL-10和血清免疫球蛋白IgG, IgA, IgM及C3, C4含量, 其中IL-2, IL-4, IL-10采用酶联免疫吸附法检测, 血清IgG, IgA, IgM, C3, C4水平采用间接免疫荧光法检测, 严格按照说明书操作。参考《中医病症诊断疗效标准》SLE描述拟定疗效标准, 显效: 中医主要症状和体征显著改善或基本消失, 实验室指标基本恢复正常, 证候积分减少 $\geq 70\%$; 有效: 主要症状体征有明显减轻, 实验室指标有一定改善或部分改善, 证候积分减少 $\geq 30\%$; 无效: 主要症状体征和实验室指标均无明显改善或继续恶化, 证候积分减少 $< 30\%$ 或增加, 比较两组临床总有效率。

1.4 统计学处理

采用SPSS 20.0统计软件分析相关数据, 计数资料以例(%)表示, 组间行 χ^2 检验; 计量资料经

Levene法和Kolmogorov-Smirnov(K-S)法检验满足正态分布和方差齐性后用均数 \pm 标准差($\bar{x}\pm s$)表示, 组间比较行LSD-*t*检验, 对不满足正态分布的计量资料行非参数检验Mann-Whitney检验。以 $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 两组 SLEDAI 评分和中医证候积分比较

两组治疗前SLEDAI评分、中医证候积分比较差异均无统计学意义($P > 0.05$), 治疗后均有明显下降($P < 0.05$), 观察组治疗后上述指标均低于对照组, 差异有统计学意义($P < 0.05$, 表1)。

2.2 两组 Th1/Th2 相关细胞因子水平比较

两组治疗前血清IL-2, IL-4, IL-10水平比较差异无统计学意义($P > 0.05$), 治疗后IL-2水平明显升高, IL-4, IL-10水平显著下降, 差异有统计学意义($P < 0.05$); 观察组治疗后血清IL-2水平高于对照组, IL-4, IL-10水平低于对照组, 差异有统计学意义($P < 0.05$, 表2)。

2.3 两组免疫功能指标比较

两组治疗前血清IgG, IgA, IgM和补体C3, C4水平比较均无显著差异($P > 0.05$), 治疗后血清IgG, IgA, IgM均明显降低, 补体C3, C4水平显著提高, 差异有统计学意义($P < 0.05$), 观察组治疗后血清IgG, IgA, IgM, C3, C4水平均优于对照组, 差异有统计学意义($P < 0.05$, 表3)。

2.4 两组疗效评估结果比较

观察组总有效率92.31%高于对照组74.36%, 差异有统计学意义($P < 0.05$, 表4)。

表1 两组治疗前后SLEDAI评分和中医证候积分比较($n=39, \bar{x}\pm s$)

Table 1 Comparison of SLEDAI score and TCM syndrome score before and after treatment between the two groups ($n=39, \bar{x}\pm s$)

| 组别 | SLEDAI评分 | | 中医证候积分 | |
|----------|------------------|------------------|------------------|------------------|
| | 治疗前 | 治疗后 | 治疗前 | 治疗后 |
| 对照组 | 12.35 \pm 2.27 | 5.57 \pm 1.04* | 11.51 \pm 2.97 | 8.62 \pm 2.06* |
| 观察组 | 12.32 \pm 2.30 | 4.39 \pm 0.83* | 11.49 \pm 3.02 | 5.48 \pm 1.37* |
| <i>t</i> | 0.058 | 5.538 | 0.029 | 7.926 |
| <i>P</i> | 0.954 | <0.001 | 0.977 | <0.001 |

与本组治疗前比较, * $P < 0.05$ 。

Compared with the group before the treatment, * $P < 0.05$.

表2 两组治疗前后血清IL-2, IL-4, IL-10水平比较($n=39, \bar{x} \pm s$)Table 2 Comparison of serum levels of IL-2, IL-4 and IL-10 between the two groups before and after the treatment ($n=39, \bar{x} \pm s$)

| 组别 | IL-2/(ng·mL ⁻¹) | | IL-4/(ng·mL ⁻¹) | | IL-10/(ng·mL ⁻¹) | |
|----------|-----------------------------|--------------------------|-----------------------------|--------------------------|------------------------------|---------------------------|
| | 治疗前 | 治疗后 | 治疗前 | 治疗后 | 治疗前 | 治疗后 |
| 对照组 | 2.92 ± 0.76 | 3.58 ± 0.92 [#] | 11.85 ± 2.08 | 9.39 ± 1.76 [#] | 51.20 ± 8.27 | 40.16 ± 6.58 [#] |
| 观察组 | 2.94 ± 0.81 | 4.06 ± 0.75 [#] | 11.90 ± 2.12 | 7.23 ± 1.42 [#] | 49.75 ± 8.51 | 32.07 ± 4.75 [#] |
| <i>t</i> | 0.112 | 2.525 | 0.105 | 5.965 | 0.763 | 6.225 |
| <i>P</i> | 0.911 | 0.014 | 0.917 | <0.001 | 0.448 | <0.001 |

与本组治疗前比较, * $P<0.05$ 。

Compared with the group before the treatment, * $P<0.05$.

表3 两组治疗前血清IgG, IgA, IgM, C3, C4水平比较($n=39, \bar{x} \pm s$)Table 3 Comparison of serum IgG, IgA, IgM, C3 and C4 levels between the two groups before the treatment ($n=39, \bar{x} \pm s$)

| 组别 | 时点 | IgG/(g·L ⁻¹) | IgA/(g·L ⁻¹) | IgM/(g·L ⁻¹) | C3/(mg·L ⁻¹) | C4/(mg·L ⁻¹) |
|-----|-----|----------------------------|---------------------------|---------------------------|---------------------------|--------------------------|
| 对照组 | 治疗前 | 20.58 ± 3.47 | 3.51 ± 0.56 | 2.56 ± 0.39 | 0.40 ± 0.06 | 0.09 ± 0.02 |
| | 治疗后 | 16.20 ± 2.73 [#] | 2.97 ± 0.40 [#] | 2.08 ± 0.31 [#] | 0.67 ± 0.15 [#] | 0.21 ± 0.05 [#] |
| 观察组 | 治疗前 | 20.70 ± 3.52 | 3.49 ± 0.53 | 2.57 ± 0.40 | 0.39 ± 0.08 | 0.10 ± 0.03 |
| | 治疗后 | 13.27 ± 2.57 ^{#*} | 2.36 ± 0.32 ^{#*} | 1.67 ± 0.25 ^{#*} | 0.83 ± 0.17 ^{#*} | 0.36 ± 0.06 |

与本组治疗前比较, * $P<0.05$; 与对照组治疗后比较, * $P<0.05$ 。

Comparison with this group before treatment, * $P<0.05$; Comparison with the control group after the treatment, * $P<0.05$.

表4 两组疗效评估结果比较

Table 4 Comparison of efficacy evaluation results between the two groups

| 组别 | 显效/[例(%)] | 有效/[例(%)] | 无效/[例(%)] | 总有效/[例(%)] |
|-----|------------|------------|------------|-------------|
| 对照组 | 11 (28.21) | 18 (46.15) | 10 (25.64) | 29 (74.36) |
| 观察组 | 20 (51.28) | 16 (41.03) | 3 (7.69) | 36 (92.31)* |

与对照组比较, * $P<0.05$ 。

Compared with the control group, * $P<0.05$.

3 讨论

SLE病因复杂多样, 已有观点认为SLE发生和进展与遗传、内分泌异常和环境因素等有关, 是多因素诱导下出现的特异性自身免疫性疾病。患者B淋巴细胞异常增生, T淋巴细胞降低, 体内出现大量抗体和致病性循环免疫复合物, 激活补体系统, 补体活性上升, 进而引起全身炎症反应和免疫病理损伤, 逐渐出现皮肤、肾、神经和关节等病变症状^[4-5]。Th1主要分泌IL-2, Th2主要分泌IL-4和IL-10, Th1/Th2平衡是维持正常免疫功

能的重要基础。近些年机体免疫调节功能紊乱尤其是Th1/Th2失衡成为临床研究SLE的热点, SLE患者临床表现、受累系统等的差异与Th1/Th2失衡程度有一定关联。临床检查发现SLE患者与健康同龄人比较, Th1细胞明显下降, Th2细胞相对占优势, 原因可能与体内诱导向Th1细胞分化的系列细胞因子及其受体减少有关^[6-7]。有报道^[8]发现: SLE患者全身炎症反应易导致血管内皮功能障碍, 且Th1/Th2失衡参与SLE所致内皮功能障碍的发生。

甲基泼尼松龙是临床治疗SLE的常用糖皮质

激素类药物,作用与泼尼松相似,能有效缓解SLE患者炎症反应和抑制免疫应答,缓解临床症状体征和降低SLEDAI评分,但整体疗效欠佳,且长时间大剂量服用易诱发系列不良反应,服药依从性和生活质量明显下降^[9],停药后易复发亦是困扰临床治疗的难点。中医根据描述将SLE归于“阴阳毒”“日晒疮”和“红蝴蝶疮”等范畴,中医证型以阴虚内热型多见^[10-11],肾阴不足,肾阴亏虚,阴虚内热,毒瘀内蕴是SLE病机的关键,因此可采用滋阴补肾、清热活血法施治^[12-13]。本研究在使用甲基泼尼松龙同时自拟狼疮方治疗,熟地黄是一味常用补肾补虚中药,可滋补肾阴,养血补虚;女贞子可滋补肝肾,清虚热;山茱萸可补益肝肾,收敛固涩;墨旱莲可补肾益阴,止血凉血;青蒿可清透虚热,凉血止血,非常适合温邪伤阴、阴虚热者;太子参与人参功效相似,可益气健脾,补气同时亦有补阴功效;牡丹皮清热凉血,适合温毒发斑、血热阴虚者;鸡血藤活血祛瘀;白花蛇舌草清热解毒;当归补血活血。诸药配伍共奏滋补肾阴、清热解毒等功效,且药性平和,长期服用的安全性较好。

本研究从中西医结合角度治疗SLE取得满意疗效,与对照组单纯西医治疗比较,观察组治疗后中医证候积分和SLEDAI评分明显下降,治疗后血清IL-2水平明显高于对照组,IL-4,IL-10水平显著低于对照组,血清IgG,IgA,IgM,C3,C4水平也均优于对照组,临床总有效率高于对照组,与文献[14-15]报道相吻合,提示自拟狼疮方联合甲基泼尼松龙能增益SLE临床疗效,作用机制可能与调节Th1/Th2平衡,改善免疫功能有关。此外本研究中观察组未出现明显不良反应者,说明二者联合治疗安全性值得肯定。总的来说,本研究印证了中西医结合治疗SLE的显著优势,自拟狼疮方可为缓解SLE患者身心痛苦、减轻经济负担。

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