doi: 10.13241/j.cnki.pmb.2021.01.009

·临床研究·

复方苦参汤联合美沙拉嗪对溃疡性结肠炎治疗效果及炎性因子水平的影响*

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摘要 目的：探讨复方苦参汤联合美沙拉嗪对溃疡性结肠炎治疗效果及炎性因子水平的影响。**方法**：以我院 2017 年 1 月至 2019 年 12 月中西医结合科和消化内科收治的 206 例溃疡性结肠炎患者为研究对象，根据随机抽样法将受试者分为对照组和研究组，每组各 103 例，对照组接受美沙拉嗪治疗，研究组在对照组的基础上口服复方苦参汤治疗，比较两组的治疗总有效率，治疗前后黏膜病变、疾病活动指数与各炎性因子水平变化以及用药安全性。**结果**：研究组治疗总有效率较对照组高（$P<0.05$）；治疗后两组肠镜下黏膜病变与疾病活动指数较治疗前均明显改善，且研究组显著优于对照组（$P<0.05$）；治疗后两组白细胞介素（interleukine，IL）-6、IL-8、肿瘤坏死因子(tumor necrosis factor, TNF)-α、C 反应蛋白(C-reactive protein，CRP)及降钙素原(procallcitonin，PCT)等炎性因子水平较治疗前均显著下降，且研究组低于对照组（$P<0.05$）；两组药物所致不良反应发生率比较无统计学差异（$P>0.05$）。**结论**：复方苦参汤联合美沙拉嗪可有效缓解临床症状，改善肠道黏膜病变，降低肠道炎性反应，控制病情进展，疗效安全显著，对促进溃疡性结肠炎患者病情康复具有积极意义。

关键词：复方苦参汤；美沙拉嗪；溃疡性结肠炎；炎性因子；黏膜病变

中图分类号：R574.62 **文献标识码**：A **文章编号**：1673-6273(2021)01-50-04

Effect of Compound Sophorae Decoction Combined with Mesalazine on the Treatment of Ulcerative Colitis and the Level of Inflammatory Factors*

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ABSTRACT Objective: To investigate the effect of compound sophorae decoction combined with mesalazine on the treatment of ulcerative colitis and the level of inflammatory factors. **Methods:** 206 patients with ulcerative colitis were treated in the department of integrated traditional Chinese and western medicine and the department of gastroenterology in our hospital from January 2017 to December 2019, According to the method of random sampling, the subjects were divided into control group and study group, each with 103 cases, the control group was treated with mesalazine, and the study group was treated with compound sophorae decoction orally on the basis of the control group. The total effective rate of treatment, changes in mucosal lesions, disease activity index and inflammatory factors before and after treatment, as well as drug safety were compared between the two groups. **Results:** The total effective rate of the study group was higher than that of the control group ($P<0.05$). After treatment, mucosal lesions and disease activity index under colonoscopy were significantly improved in the two groups compared with before treatment, and the study group was significantly better than the control group ($P<0.05$). After treatment, the levels of IL-6, IL-8, TNF-α, CRP, PCT and other inflammatory factors in the two groups decreased significantly compared with those before treatment, and the levels in the study group were lower than those in the control group ($P<0.05$). There was no significant difference in the incidence of adverse drug reactions between the two groups ($P>0.05$). **Conclusion:** Compound sophorae decoction combined with mesalazine can effectively relieve clinical symptoms, improve intestinal mucosal lesions, reduce intestinal inflammatory reaction, control the progress of the disease, the curative effect is safe and significant, and has positive significance for promoting the rehabilitation of patients with ulcerative colitis.

Key words: Compound sophorae decoction; Mesalazine; Ulcerative colitis; Inflammatory factors; Mucosal lesions

Chinese Library Classification(CLC): R574.62 Document code: A

Article ID: 1673-6273(2021)01-50-04

* 基金项目：国家自然科学基金项目(81774093)

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（收稿日期：2020-03-30 接受日期：2020-04-24）

前言

溃疡性结肠炎是因大肠黏膜及黏膜下层发生慢性、非特异性炎症性病变所致的一种肠道疾病，以长期腹泻、腹痛、里急后重、黏液脓血便为主要临床表现，目前病因尚不明确，但大多学者认为，其病因与病毒及细菌等病原菌感染、遗传、机体免疫、精神等多种因素有关[1,2]。还有研究表明，溃疡性结肠炎的发生发展及病情严重程度与细胞炎性因子水平有关。目前临床上常采用免疫抑制剂、糖皮质激素、氨基水杨酸等药物来缓解患者的临床症状及体征，促进病情康复，尽管具有一定效果，但治疗周期长、不良反应多，且停药后易复发，具有一定局限性[3,4]。中医药在溃疡性结肠炎的治疗中具有独特优势，复方苦参汤作为本科室治疗溃疡性结肠炎的特色自制药，临床效果显著，已有研究证实，复方苦参汤可有效改善溃疡性结肠炎小鼠的结肠粘膜形态学及病理组织学，缓解结肠炎性损伤[5]。为此本研究以我院 2017 年 1 月至 2019 年 12 月中西医结合科和消化内科收治的 206 例溃疡性结肠炎患者，探讨复方苦参汤联合美沙拉嗪对溃疡性结肠炎治疗效果及炎性因子水平的影响，现进行如下报道。

1 资料与方法

1.1 研究对象

以我院中西医结合科和消化内科收治的 206 例溃疡性结肠炎患者为研究对象，根据随机抽样法将受试者分为对照组和研究组，每组各 103 例，研究组中男 56 例，女 47 例；年龄 24-70 岁，平均（45.67±3.42）岁；病程 6 个月 -7 年，平均（3.68±0.72）年；病情分级：轻度 50 例，中度 43 例，重度 10 例；对照组中男 54 例，女 49 例；年龄 25-71 岁，平均（45.34±3.37）岁；病程 8 个月 -6 年，平均（3.54±0.56）年；病情分级：轻度 49 例，中度 42 例，重度 12 例。两组在一般资料无差异（P>0.05）。

1.2 纳入及排除标准

（1）纳入标准：均经结肠镜、病理组织学及实验室相关检查均符合《Ulcerative Colitis》中溃疡性结肠炎相关的诊断标准[6]，知晓本次研究目的及意义后自愿在《知情同意书》上签字。（2）排除标准：活动性胃及十二指肠溃疡、相关药物过敏史、严重的器官功能障碍、其他结肠疾病、恶性肿瘤、近 2 周内应用抗血小板与免疫抑制剂等药物、妊娠及哺乳期妇女、治疗禁忌症及中途退出者。

1.3 方法

所有患者入院后均给予维持水电解质平衡、纠正酸碱紊乱、营养支持、饮食指导等支持治疗，对照组在此基础上口服美沙拉秦缓释颗粒剂（爱的发制药公司，国药准字 H20100063，规格：500 mg/ 袋），每次 500 mg，每日 3 次，连续治疗 8 w。研究组在对照组的基础上口服复方苦参汤治疗，组方：苦参 15 g，地榆炭 15 g，青黛 3 g，三七 3 g，白及 10 g，甘草 10 g。腹痛明显者加延胡索 20 g；便脓血者加牡丹皮、败酱草各 15 g。将诸药水煎至 300 mL 左右于早晚进行分服，每日一剂，连续治疗 8 w。

1.4 观察指标

两组的治疗总有效率，治疗前后采用结肠镜观察黏膜病变情况、疾病活动指数（disease activity index，DAI）与 IL-6、IL-8、TNF-α、CRP 及 PCT 等炎性因子水平变化以及用药安全性。

1.5 评价标准

（1）疗效评价：根据《中医外科病症诊断疗效标准》[7]，显效：目标症状完全消失，结肠镜检查结果显示肠黏膜恢复正常，粪便检查呈阴性，大便次数每日在 2 次以内；有效：目标症状显著缓解，结肠镜检查结果显示肠黏膜明显改善，粪便检查呈阴性，大便次数每日在 2-4 次；无效：目标症状、结肠镜检查结果、及每日大便次数均无明显改善，粪便检查呈阳性；总有效率为显效率与有效率之和。（2）DAI：根据 Sutherland 疾病活动指数表从黏膜表现、腹泻、便血、病情评估 4 个方面进行评价，每项 0-3 分，满分 12 分，分值越低表示病情控制越好[8]。（3）炎性因子：患者持续空腹 8 h 以上于晨起空腹条件下抽取外周静脉血 5 mL，以 3500 r/min 转速离心 10 min 后分离出血清，选择日立 7171 全自动生化分析仪，利用酶联免疫吸附法检测 IL-6、IL-8 及 TNF-α 水平，采用罗氏 E170 电化学发光法检测 PCT 水平；采用特定蛋白分析仪（购自贝克曼公司）利用速率散射比浊法检测 CRP 水平[9,10]。

1.6 统计学方法

采用 SPSS 19.0，以（$\bar{x}\pm s$）描述计量资料，以（%）描述计数资料，比较行 t 检验及 χ^2 检验，P<0.05 有统计学差异。

2 结 果

2.1 疗效对比

研究组治疗总有效率为 94.17 %，显著高于对照组 77.88 %（P＜0.05），见表 1。

表 1 治疗总有效率（例，%）

Table 1 Total therapeutic response rate (n, %)

Groups	n	Excellent	Effective	Invalid	Total effective rate
The study group	103	62（60.19）	35（33.98）	6（5.83）	97（94.17）*
The control group	103	56（54.37）	25（24.27）	22（21.36）	81（77.88）

Note: Compared with the control group, *P<0.05.

2.2 黏膜病变与疾病活动指数

治疗后两组肠镜下黏膜病变与疾病活动指数较治疗前均明显改善，且研究组显著优于对照组（P<0.05），见表 2。

2.3 炎性因子水平变化

治疗后两组 IL-6、IL-8、TNF-α、CRP 及 PCT 等炎性因子水平较治疗前均显著下降，且研究组低于对照组（P＜0.05），见表 3。

表 2 治疗前后黏膜病变与疾病活动指数(例,%)

Table 2 Index of mucosal lesions and disease activity before and after treatment (n, %)

Groups	Time	Mucosal lesions under colonoscopyn(%)				DAI(score)
		Hyperemia edema	Ulcer	Erosion	Granular change	
The study group (n=103)	Pretherapy	103(100.00)	24(23.30)	91(88.35)	53(51.46)	6.69±1.20
	Post-treatment	21(20.39)*#	2(1.94)*#	13(12.62)*#	9(8.74)*#	2.90±0.78*#
The control group (n=103)	Pretherapy	103(100.00)	25(24.27)	90(87.38)	55(53.40)	6.67±1.26
	Post-treatment	45(43.69)*	7(6.80)*	37(35.92)*	27(26.21)*	3.88±0.58*

Note: Compared with the same group before treatment, *P<0.05; compared with the control group after treatment, #P<0.05.

表 3 治疗前后各炎性因子水平变化($\bar{x}\pm s$)

Table 3 Changes of inflammatory factors before and after treatment ($\bar{x}\pm s$)

Group	Time	IL-6(pg/L)	IL-8(pg/L)	TNF-α(mg/L)	CRP(mg/L)	PCT (ng/mL)
The study group (n=103)	Pretherapy	36.76±5.43	352.67±32.43	280.53±31.47	28.24±5.25	1.40±0.27
	Post-treatment	15.33±2.28*#	119.65±16.87*#	123.46±16.89*#	12.45±5.33*#	0.38±0.12*#
The control group (n=103)	Pretherapy	37.53±5.21	350.54±31.76	278.98±33.52	28.38±4.77	1.38±0.31
	Post-treatment	22.69±3.63*	162.58±17.18*	190.31±18.68*	20.14±5.62*	0.82±0.29*

2.4 用药安全性

两组不良反应发生率比较无差异(P>0.05),见表 4。

表 4 用药安全性(例,%)

Table 4 Drug safety (n, %)

Group	n	Rash	Gastrointestinal reaction	Slight headache	The total incidence
The study group	103	1(0.97)	1(0.97)	3(2.91)	5(4.85)
The control group	103	1(0.97)	2(1.94)	4(3.88)	7(6.80)

3 讨论

溃疡性结肠炎是发生于结肠或直肠部位的一种慢性非特异性炎症性肠病,其发病机制可能与肠道粘膜组织免疫功能下降、细菌或病毒等病原体感染肠道、炎性介质增多有关,目前临床尚无特效疗法,只尽可能缓解临床症状、提高生活质量为基本治则[11-15]。美沙拉嗪是一种 5- 氨基水杨酸制剂,可有效改善结肠黏膜病变,抑制炎性介质的合成及释放,进而抑制炎性反应的发生,缓解溃疡性结肠炎症状,促进病情康复[16,17]。

祖国医学认为,溃疡性结肠炎属中医"泄泻"、"肠风"、"便血"范畴,多因脾气不足、寒温失宜、气血失调、湿热蕴结肠道使腑气失调所致,因此应以扶正祛邪、清热解毒、生肌敛疮、行气止痛为主治[18]。复方苦参汤方中苦参清热燥湿,抗炎杀菌作用显著。白及消肿生肌、止血敛疮,其鞣质成分可有效保护创面,抑制病菌滋生,促进溃疡愈合,止血作用显著[19-22]。地榆炭解毒凉血、止血敛疮,药理学研究表明,其有效成分三萜皂苷、鞣质可减少创面渗出,缩短凝血时间,抗菌、收敛作用显著[23-25]。青黛清热凉血解毒,清胃肠之邪热,可降低毛细血管通透性,清除氧自由基,稳定细胞膜通透性,镇痛作用显著[26]。三七化瘀止血、消肿定痛,其有效成分三七皂苷可以抑制内皮细胞炎症因子的分泌及黏附分子表达,有一定的抗炎作用。诸药联用共奏清热解毒、敛疮生肌、止血凉血之功效。现代药理研究表明,复方苦参汤可有效降低促炎因子及氧化介质的表达,抑制肠道炎症反应,减轻结肠组织学损伤程度,修复病变的结肠黏膜,促进病情康复[27-29]。

本研究结果表明,研究组治疗总有效率较对照组更高,与学者邓喜惠[30]的研究类似,该学者采用自拟复方苦参汤治疗溃疡性结肠炎,治疗效果显著高于单纯的西药治疗组,说明复方苦参汤能够显著的增加疗效,但是与本研究的治疗方法有一定的不同,本研究主要是口服,邓喜惠的研究方法主要是保留灌肠治疗,在后续的试验中,可以尝试比较不同的给药方法对疗效的影响。治疗后两组肠镜下黏膜病变与疾病活动指数较治疗前均明显改善,且研究组显著优于对照组,与本课题组杨佳[31]等人的动物实验研究类似,他们采用复方苦参汤联合美沙拉嗪治疗溃疡性结肠炎大鼠,大鼠肠粘膜损伤情况和疾病活动指数明显改善,提示复方苦参汤联合美沙拉嗪可有效促进结肠黏膜修复,控制病情进展。有研究表明,IL-6、IL-8、TNF-α、CRP 及 PCT 等炎性因子可直接破坏肠黏膜稳态,在疾病的发生、发展中具有促进作用[32]。本研究结果显示,治疗后两组患者 IL-6、IL-8、TNF-α、CRP 及 PCT 等炎性因子水平较治疗前均显著下降,且研究组低于对照组;提示复方苦参汤联合美沙拉嗪可有效抑制结肠黏膜炎性反应,促进病情好转。这与徐萌[33]等人的前期研究类似,溃疡性结肠炎小鼠模型结肠组织中 IL-1β 和 TNF-α 的表达均升高,给予复方苦参汤联合美沙拉嗪治疗后,可以起到显著的增效作用,且 IL-1β 和 TNF-α 的表达均降低,说明复方苦参汤联合美沙拉嗪能够降低肠道炎症反应。其原因

主要是因为复方苦参汤能够干预相关的信号通路,促进肠内 T 细胞凋亡,从而减轻肠道炎症反应,缓解了肠粘膜的损害,使得肠粘膜局部免疫功能功能得到改善,达到治疗的目的,这可能是复方苦参汤治疗溃疡性结肠炎的机制之一。目前国外对于复方苦参汤治疗溃疡性结肠炎还没有应用。两组药物所致不良反应发生率比较无统计学差异。提示复方苦参汤联合美沙拉嗪不增加药物不良反应,安全性较高。

综上所述,复方苦参汤联合美沙拉嗪可有效缓解临床症状,改善肠道黏膜病变,降低肠道炎性反应,控制病情进展,疗效安全显著,对促进溃疡性结肠炎患者病情康复具有积极意义。本研究也有一定的不足,病例资料少,来源单一,也没有进行机制的探究,后期需要探究复方苦参汤联合美沙拉嗪治疗溃疡性结肠炎患者的作用机制和信号通路,为治疗提供靶点。

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