

肠安胶囊治疗溃疡性结肠炎 32 例临床研究

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摘要 目的:探讨肠安胶囊对溃疡性结肠炎的治疗作用及机理。方法:将 62 例溃疡性结肠炎患者随机分为两组,分别给予肠安胶囊、补脾益肠丸口服,疗程均为 3 个月。观察临床、病理疗效,治疗前后肠镜征象、血清免疫球蛋白、补体 C₃、血清超氧化物歧化酶(SOD)、过氧化脂质(LPO)的变化。结果:治疗组临床总有效率为 93.80%,肠镜、病理疗效分别为 81.30%、84.40%,对血清免疫球蛋白、补体 C₃、SOD、LPO 也有明显的改善和抑制作用,与对照组比较有显著性差异($P<0.05$ 或 $P<0.01$)。结论:说明肠安胶囊对溃疡性结肠炎有显著的治疗作用,其机理可能与抑制结肠粘膜损伤,促进溃疡修复,增强机体清除自由基和抗氧化能力,调节免疫机能有关。

主题词 结肠炎,溃疡性/中医药疗法 @ 肠安胶囊

为了进一步摸索溃疡性结肠炎(UC)的治疗规律,提高中医中药疗效,我们根据中医传统理论,结合 UC 的证治规律,提出了从脾肺论治 UC 的新思路、新方法。并将据此拟定的方药应用于临床,取得了较好的临床疗效。近年来,我们将验方改制成肠安胶囊,为证实其疗效,我们开展了以下临床研究。

1 临床资料

诊断标准参照 1993 年太原全国慢性非感染肠道疾病学术研讨会制定的《慢性非特异性溃疡性结肠炎诊断标准》^[1]制定。纳入病例标准及排除病例标准均参照《中药新药临床研究指导原则》^[2]制定。

本组病例均来源于 1995 年 3 月~1998 年 3 月江苏省中医院消化科门诊及病房住院的患者,肠镜以治疗前及停止治疗后半个月以内的检查为准,治疗后肠镜复查进行活检时尽可能在原病变部位钳取,肠镜及病理检查均由专人负责。62 例患者中,门诊患者 38 例,住院患者 24 例,随机分为治疗组 32 例,对照组 30 例。治疗组男 19 例,女 13 例;年龄 19~64 岁,平均 41.65 ± 10.2 岁;病程 2 个月~35 年;病情属轻度者 10 例,中度 20 例,重度 2 例。对照组男 18 例,女 12 例;年龄 21~65 岁,平均 40.20 ± 11.5 岁;病程 1 个月~29 年;病情属轻度者 9 例,中度 19 例,重度 2 例。两

组患者在性别、年龄、职业、病程、病情等方面均无明显差异,具有可比性($P>0.05$)。

2 治疗及观察方法

2.1 治疗方法:治疗组予肠安胶囊(药物组成:黄芪、白术、黄芩、半夏、陈皮、桔梗等,每粒胶囊含生药 0.5g,江苏省中医院制药厂生产)口服,每次 5 粒(2.5g),每日 4 次。对照组予补脾益肠丸(深圳南方制药厂生产)口服,每次 6g,每日 3 次。两组均 3 个月为 1 个疗程,服药 1 个疗程。治疗期间停药一切影响本试验的药物。

2.2 观察内容和方法:临床症状:采用统一的表格于用药前记录患者腹泻、腹痛、脓血便、粘液便、里急后重、纳差、腹胀、乏力、舌质、舌苔、脉象等临床表现,以后间隔 1 周记录 1 次,至疗程结束。

结肠镜检:按 UC 结肠镜下诊断标准制定,主要观察结肠粘膜的充血、水肿、糜烂、溃疡等,按患者病变部位(直肠、乙状结肠、降结肠、横结肠、升结肠)分别记分,其标准为^[3]:结肠粘膜无充血、水肿、糜烂、溃疡记 0 分;轻度充血、水肿,无或轻度糜烂,溃疡无或散在分布、数量 ≤ 3 个,周边轻度红肿记 1 分;中度充血、水肿,中度糜烂或伴出血,溃疡散在分布 > 3 个,周边明显红肿记 2 分;重度充血、水肿,重度糜烂,触之有明显出血,溃疡分布多,表面布满脓苔,周边显著红肿记 3 分。

粘膜活检:按 UC 粘膜活体组织病理诊断标准,在用药前后,对结肠粘膜的炎细胞浸润、糜烂、溃疡、隐窝脓肿、腺体排列异常、杯状细胞减少等指标记录。

血清免疫球蛋白 IgA、IgG、IgM、补体 C₃ 含量测定:采用琼脂单向扩散法测定,扩散板购自上海上生生物制品经营部。

血清过氧化脂质(LPO)、超氧化物歧化酶(SOD)含量测定:LPO 采用 TBA 比色法,SOD 采用 NBT 法,试剂盒均购自南京建成生物化工研究所。

数据分析及统计处理:资料采用 t 检验,方差分析的 F 检验和 q 检验, χ^2 检验进行统计学处理。

3 结果

疗效标准:参考卫生部《中药新药治疗慢性非特异性溃疡性结肠炎的临床研究指导原则》,及 1978 年、1987 年两次全国性学术会议的疗效评定标准制定如

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下标准:临床痊愈:临床症状消失,结肠镜等检查粘膜恢复正常,停药后观察6个月无复发。显效:临床症状基本消失,结肠镜等检查粘膜轻度炎症反应及部分假息肉形成或粘膜充血水肿、糜烂、溃疡减轻2度以上。有效:临床症状好转或结肠镜等检查粘膜病变有所好转,充血水肿、糜烂、溃疡减轻1度以上。无效:临床症状和结肠镜等检查无改善。

结果:治疗组32例,临床痊愈8例,显效12例,有效10例,无效2例,总有效率为93.8%。对照组30例,临床痊愈2例,显效7例,有效13例,无效8例,总有效率73.3%。治疗组明显优于对照组($P<0.05$)。

病理疗效:用药前后结肠粘膜活体组织病理检查示,治疗组32例,治愈8例,显效12例,有效7例,无效5例,总有效率84.4%。对照组30例,治愈2例,显效7例,有效10例,无效9例,总有效率63.3%。治疗组明显优于对照组($P<0.05$)。

治疗前后肠镜征象改善情况:表1示,两组治疗后肠镜征象均有改善,治疗组充血、水肿、糜烂、溃疡的积分均有显著降低(P 均 <0.01)。对照组充血、水肿积分有显著降低(P 均 <0.05)。两组治疗后比较,治疗组充血、水肿积分明显低于对照组(P 均 <0.01)。

两组患者治疗前后血清免疫球蛋白及补体 C_3 含量变化:表2示,治疗组治疗后免疫指标IgG、IgM、 C_3 均显著降低(P 均 <0.01),对照组仅IgG显著降低($P<0.01$)。

两组患者治疗前后血清SOD、LPO的含量比较:表3示,治疗后治疗组血清SOD显著上升($P<0.01$)、LPO显著下降($P<0.01$),对照组血清SOD、LPO治疗前后差异无显著性(P 均 >0.05)。

4 讨论

UC一般以腹痛、腹泻、里急后重、血性粘液便为主要表现,多归属于中医“泄泻”、“痢疾”、“滞下”等病范畴。传统中医理论认为,泄泻与脾虚湿盛关系最为密切,而对于肺气失调、痰流大肠的致病机制则常被医家忽视。肠安胶囊的组方,不但重视脾运不健、痰湿留滞,在UC发病机制中的决定性作用,也注意肺气不调、大肠失约对本病发生的影响,兼顾肺与大肠的关系。故用药以益气健脾补肺的黄芪为主药,配合白术运脾和中,桔梗开宣肺气;佐以二陈化痰除湿,黄芩清热排脓。方中黄芪、白术、二陈同用,健脾运、祛痰湿、杜起病之源;黄芪、黄芩、桔梗配合,补肺虚、清肺热、宣肺气,复肺宣肃之能,助大肠传导之机。黄芩、桔梗亦能清热排脓、收敛生肌,有修复粘膜溃疡并具有止痛作用,因而取得良好的疗效。

表1 两组治疗前后肠镜积分情况比较($\bar{x}\pm s$)

组别	例数	充血	水肿	糜烂	溃疡
治疗组	疗前	32 2.63±0.49	2.28±0.46	1.81±0.64	1.53±0.56
	疗后	32 1.13±0.34 Δ^*	0.81±0.54 Δ^*	0.47±0.57 **	0.38±0.55 **
对照组	疗前	30 2.50±0.51	2.20±0.41	1.90±0.71	1.50±0.57
	疗后	30 2.13±0.57 *	1.90±0.61 *	1.70±0.70	1.40±0.86

与本组疗前比较, $^*P<0.05$, $^{**}P<0.01$; 与对照组疗后比较, $\Delta P<0.01$ 。下同

表2 两组治疗前后血清免疫球蛋白及补体 C_3

含量比较(g/L, $\bar{x}\pm s$)

组别	例数	IgG	IgM	IgA	C_3
治疗组	疗前	32 15.04±1.36	1.86±0.33	2.42±0.30	1.69±0.29
	疗后	32 12.79±1.47 **	1.12±0.34 **	2.39±0.18	1.45±0.27 **
对照组	疗前	30 14.89±0.66	1.78±0.31	2.37±1.31	1.65±0.24
	疗后	30 12.81±0.72 **	1.72±0.30	2.41±0.21	1.59±0.22

表3 两组治疗前后血清SOD、LPO含量比较($\bar{x}\pm s$)

组别	例数	SOD(nU/ml)	а	LPO(mol/L)
治疗组	疗前	32 57.82±4.92		8.51±0.69
	疗后	32 69.64±4.15 **		6.79±0.36 **
对照组	疗前	30 57.41±3.97		8.57±0.52
	疗后	30 58.43±4.37		8.51±0.27

研究表明,患者胃肠道黄嘌呤氧化酶的含量远远高于其它组织,氧自由基的代谢失衡在胃肠粘膜损伤中起着重要作用^[4]。经过肠安胶囊治疗,32例患者血液LPO含量下降,SOD活力升高,推测肠安胶囊具有抑制黄嘌呤氧化酶活性,增强机体抗氧化能力的作用,因而能够抑制病变肠粘膜过度产生氧自由基,达到抵抗自由基损伤、保护肠道粘膜的目的。多数学者认为,UC属于自身免疫性疾病^[5]。异常的免疫反应或正常免疫调节的破坏是UC发病的重要环节^[6],本组62例患者经过3个月的治疗,治疗组患者血清IgG、IgM、 C_3 下降,较治前差异明显($P<0.01$)。

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ABSTRACTS FROM ORIGINAL ARTICLES

Clinical observation on 53 cases of pyloric helicobacterium relative gastritis treated with supplementing Qi, removing heat and activating blood circulation methods

Wang Yue

It is raised that Qi — deficiency of spleen and stomach is pathological basis for this disease and retention of damp—heat in collaterals is a main pathological key, and supplementing Qi and strengthening spleen, removing heat and dampness, and activating blood circulation and dredging collaterals are basic therapeutic principle. Based on this, Qing You Yang Wei Capsule was developed for treatment of this disease. Clinical study indicated that Qing You Yang Wei Capsules had a better therapeutic effect on pyloric helicobacterium relative gastritis . Of the 53 cases in the treatment group, 6 cases were clinically cured, 18 cases were markedly effective, 24 cases were effective and 5 cases were ineffective, the total effective rate being 90. 56%. And of the 50 cases in the control group, 5 were clinically cured, 13 were markedly effective, 20 were effective and 12 were ineffective, with a total effective rate of 76%. The total effective rate in the treatment group was slightly higher than that in the control group. The eradicating rate of the Chinese drug for pyloric helicobacterium was 66. 03%, approaching to that of the control group. The recurrence rate in the treatment group was 13. 33%, significantly lower than 41. 66% in the control group. Qing You Yang Wei Capsules not only directly kills bacteria, but also improves stomach, accumulation in the abdomen, belching, poor appetite, weakness, gastric discomfort with acid regurgitation, and other symptoms, and also improves congestion, edema, inflammatory cell infiltration, gland atrophy, proliferation of gastric mucosa and other pathological state.

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Key words: Gastritis/microbiology infection of helicobacterium/TCM therapy gastritis/TCM therapy

(Original article on page 114)

Study on correlativity of development of illness state with changes of biochemical indexes in the cases of hepatitis B and E with overlapping infections of the liver and gallbladder dampness—heat type

Wang Yuqun, Xing Lianjun, Zhang Wei, et al.

As the patient of hepatitis B and E overlapping infection of liver and gallbladder damp — heat type compared with the patient of simple hepatitis E of liver and gallbladder damp — heat type, attack was very rapid, jaundice exacerbated progressively and hepatic function damaged severely. After

treatment the state of illness restored more slowly and the duration of illness was obviously prolonged. At the same time, it was found that the biochemical indexes (hyaluronic acid, total bile acid) increased significantly at acute stage, and the indexes in the patient of overlapping infection in the time for recovering normality at restoration stage was longer than that in the patient of simple hepatitis E, with a significantly difference between the two groups. It is indicated that lesion of the liver in the patient of overlapping infection of hepatitis B and E was more severe than the simple hepatitis E, with no good prognosis.

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Key words: Hepatitis, type E/diagnosis hepatitis, type B/diagnosis liver and gallbladder dampness and heat/diagnosis

(Original article on page 117)

Clinical study on treatment of 32 cases of ulcerative colitis with Chang An Capsules

Liu Wanli, Shen Hong, Shan Zhaowei, et al.

In order to explore the therapeutic action and mechanisms of Chang An Capsules for treatment of ulcerative colitis, 62 cases were randomly divided into two groups and treated with oral administration of Chang An Capsules and Bu Pi Yi Chang Pill respectively, for 3 therapeutic courses. Clinical observation, pathological therapeutic effects, and changes of enteroscopic sign, serum immunoglobulin, complement C₃, serum superoxide dismutase (SOD) and lipid peroxide (LPO) before and after treatment were observed. Results indicated that in the treatment group, the total effective rate was 93. 80%, the therapeutic effects for enteroscopy and pathology were 81. 30% and 84. 40% respectively, and serum immunoglobulin, complement C₃, serum superoxide dismutase (SOD) activity and lipid peroxide (LPO) were improved or inhibited, with significant difference compared with the control group ($P < 0. 05$ or $P < 0. 01$). It is suggested that Chang An Capsules has an obvious therapeutic action, and its mechanism is possibly related with inhibition of lesion of intestinal mucosa, promotion of ulcerative repair, strengthening of removing free radicals and anti — oxidation ability, and regulation of immunological function.

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Key words: Colitis, ulcerative/TCM therapy @ Chang An Capsules

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