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芪芍安胃胶囊 / 黄柴安胃胶囊治疗消化性溃疡伴 HP 感染的疗效及对胃蛋白酶原、胃泌素 -17 的影响 *

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摘要 目的:探讨芪芍安胃胶囊 / 黄柴安胃胶囊用于治疗消化性溃疡伴幽门螺杆菌(HP)感染患者的疗效,分析其对血清胃蛋白酶原(PG)和胃泌素-17(G-17)的影响。方法:选取我院于2017年10月到2019年1月收治的消化性溃疡伴HP感染患者114例,分成观察组(n=57)和对照组(n=57)。给予对照组三联疗法,观察组在对照组的基础上予以芪芍安胃胶囊或黄柴安胃胶囊,疗程均为35d。于治疗前后检测两组血清PG I、PG II、PG I / PG II比值(PGR)和G-17水平。治疗后,两组行疗效评价,比较两组HP转阴率和1年内复发率,记录不良反应。结果:观察组总有效率94.74%,高于对照组总有效率82.46%(P<0.05)。观察组HP转阴率89.47%,高于对照组HP转阴率73.68%(P<0.05)。观察组1年内复发率11.11%,低于对照组1年内复发率27.66%(P<0.05)。观察组不良反应发生率低于对照组(P<0.05)。治疗后,两组血清PG I、PG II、G-17水平均低于治疗前,PGR高于治疗前,且观察组血清PG I、PG II、G-17水平均低于对照组,PGR高于对照组(P<0.05)。结论:芪芍安胃胶囊 / 黄柴安胃胶囊治疗消化性溃疡伴HP感染患者具有良好的临床疗效,能够提高HP转阴率,降低1年内复发率和不良反应,并改善血清PG I、PG II、PGR和G-17水平。

关键词:消化性溃疡;幽门螺杆菌;芪芍安胃胶囊;黄柴安胃胶囊;疗效;胃蛋白酶原;胃泌素-17

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The Curative Effect of Qishao Anwei Capsule / Huangchai Anwei Capsule Treat the Peptic Ulcer with HP Infection and its Influence on Pepsinogen and Gastrin-17*

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ABSTRACT Objective: To investigate the curative effect of Qishao Anwei capsule / Huangchai Anwei capsule treat the patients with peptic ulcer and *Helicobacter pylori* (HP) infection, and to analyze its influence on serum pepsinogen (PG) and gastrin-17 (G-17).

Methods: 114 cases patients with peptic ulcer and HP infection who were admitted to our hospital from October 2017 to January 2019 were selected, they were randomly divided into observation group (n=57) and control group (n=57). The control group was given triple therapy, the observation group was given Qishao Anwei capsule or Huangchai Anwei capsule on the basis of the control group, the courses of treatment were all 35 d. The serum PG I, PG II, PG I / PG II ratio (PGR) and G-17 levels in the two groups were detected before and after treatment. After treatment, the curative effect of the two groups was evaluated, the HP negative conversion rate and recurrence rate within 1 year were compared between the two groups, the adverse reactions were recorded. **Results:** The total effective rate of observation group was 94.74%, which was higher than 82.46% of control group (P<0.05). The negative conversion rate of HP in the observation group was 89.47%, which was higher than 73.68% of the control group (P<0.05). The recurrence rate within 1 year in the observation group was 11.11%, which was lower than 27.66% in the control group (P<0.05). The incidence of adverse reactions in the observation group was lower than control group (P<0.05). After treatment, the serum PG I, PG II and G-17 levels in two groups were lower than those of before treatment, the PGR level was higher than that of before treatment, and the serum levels of PG I, PG II, G-17 of observation group were lower than the control group, the PGR level was higher than that of control group (P<0.05). **Conclusion:** Qishao Anwei

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capsul/Huangchai Anwei capsule treat the patients with peptic ulcer and HP have good clinical curative effect, can increase the negative conversion rate of HP, reduce the recurrence rate within 1 year and adverse reactions, and improve the serum levels of PG I, PG II, PGR and G-17.

Key words: Peptic ulcer; *Helicobacter pylori*; Qishao Anwei capsule; Huangchai Anwei capsule; Curative effect; Pepsinogen; Gas-trin-17

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前言

消化性溃疡是一种常见疾病,近年来伴随物质生活水平提高和饮食习惯改变,其发病率不断上升,发病趋势逐渐年轻化^[1]。消化性溃疡临床常表现为腹痛、烧心、嗳气、反胃等症状,若溃疡出现恶化,可能发展为癌变^[2-4]。幽门螺杆菌(*helicobacter pylori*, HP)可定植于胃肠道黏膜,人群感染率极高,能够破坏胃黏膜组织,因此在治疗消化道溃疡的过程中,根除HP也是治疗重点^[5]。胃蛋白酶原(pepsinogen, PG)和胃泌素均是反映胃黏膜形态和功能的血清学指标,其中PG有PG I和PG II两个亚群,被激活后成为胃蛋白酶,能够分解蛋白质^[6];胃泌素-17(gastrin-17, G-17)是胃肠激素,能够促进胃酸、胃液的分泌^[7]。临床对消化性溃疡的治疗较为成熟,质子泵抑制剂联合两种抗生素的三联疗法是治疗伴有HP感染的消化道溃疡的标准方案之一,但是抗生素的耐药性问题日益严重,三联方案的治疗效果逐年降低^[8]。在消化道疾病方面,中医历来具有疗效突出、副反应轻的优势。芪芍安胃胶囊由白芍、黄芪、白术、党参、枳壳、茯苓等中药构成,可发挥调和脾胃、益气补中、缓急止痛之功效^[9];黄柴安胃胶囊由黄连、黄芩、香附、柴胡等多种中药组成,具有破血逐瘀,通经活络之功效^[10];本研究分别采用三联疗法和三联疗法联合芪芍安胃胶囊/黄柴安胃胶囊治疗,对比两者用于治疗消化性溃疡伴HP感染患者的疗效,并探讨其对血清PG和G-17水平的影响。

1 资料与方法

1.1 一般资料

选择我院于2017年10月到2019年1月收治的消化性溃疡伴HP感染患者114例,西医诊疗标准:参考《消化性溃疡病诊断与治疗规范》^[11];胃镜检查可见消化性溃疡病灶;HP感染阳性。中医诊疗标准:符合《消化性溃疡中医诊疗专家共识意见(2017)》^[12]。纳入标准:患者年龄≥18岁、病程≥3个月,患者及家属知情且签写同意书。排除标准:相关药物禁忌证;妊娠或哺乳期妇女;近3个月内参加过其他药物试验;近2周内使用过抗生素、铋剂、H2受体阻滞剂或质子泵抑制剂;合并血液系统、免疫系统等疾病;合并心、肝、肾等严重器质功能不全。剔除及脱落标准:出现严重不良事件应停止治疗者;受试者依从性差;受试者要求退出本研究。其中男性69例,女性45例,年龄18~75岁,平均年龄(48.26±15.70)岁。患者按照信封抽签法随机分为观察组(n=57)和对照组(n=57)。观察组男性34例,女性23例,平均年龄(47.95±13.86)岁,病程1~4年,平均病程(2.13±0.92)年;溃疡类型:胃溃疡19例,十二指肠溃疡38例。对照组男性36例,女性21例,平均年龄(48.67±15.19)岁,病

程1~4年,平均病程(2.25±0.87)年;溃疡类型:胃溃疡22例,十二指肠溃疡35例。两组一般资料比较无统计学差异(P>0.05),具有可比性。本研究经我院医学伦理委员会批准。

1.2 治疗方法

对照组:予以三联疗法治疗:克拉霉素0.5 g/次、阿莫西林1.0 g/次,3次/d,均餐后口服,连续服用7d;泮托拉唑40 mg/次,2次/d,餐前口服,连续服用35d。治疗期间,无剔除及脱落病例,疗程为35d。观察组:在对照组的基础上,根据脾虚、湿热侧重的不同辩证予以芪芍安胃胶囊/黄柴安胃胶囊治疗:芪芍安胃胶囊或黄柴安胃胶囊,均4粒/次,3次/d,餐前服用,连续服用35d。对于芪芍安胃胶囊或黄柴安胃胶囊的选择依据具体如下:症状有胃脘隐痛、舌淡体胖有齿痕、大便稀溏、喜温喜按、四肢不温、脉沉细者、苔白者则使用芪芍安胃胶囊,其余则使用黄柴安胃胶囊。

1.3 观察指标

(1)治疗前后,两组均行¹³C呼气试验,检查HP感染。治疗后复查随访1年,痊愈、显效和有效患者若胃镜检查出现溃疡或溃疡加重,视为复发,观察两组复发情况。记录两组治疗时不良反应,包括便秘、干呕、腹部胀气、水样便、皮肤过敏、头昏等。(2)治疗前后采集患者空腹静脉血3~5 mL,离心取上清液,以酶联免疫吸附法检测血清PG I、PG II指标,计算PG I/PG II比值(PGR),试剂盒均购于上海江莱生物科技有限公司;采用放射免疫法检测血清G-17水平,试剂盒购于武汉华美生物工程有限公司。

1.4 疗效判定标准

治疗后,两组均行胃镜检查,根据《消化性溃疡中医诊疗专家共识意见(2017)》^[12]行疗效评价,总有效率=(痊愈+显效+有效)例数/总例数×100%。疗效等级分为痊愈、显效、有效和无效。痊愈:疼痛、烧心、嗳气等临床症状消失,溃疡分期为S1或S2,HP转阴;显效:疼痛、烧心等主要临床症状消失,偶有反胃、嗳气,胃镜检查溃疡分期为H2,HP转阴;有效:疼痛、烧心等临床症状有所减轻,胃镜检查溃疡分期为H1,HP感染由(++)转为(+);无效:临床病症、HP感染和胃镜状况没有改善。

1.5 统计学方法

利用SPSS24.0软件进行数据处理,计量资料采用(±s)表示,行t检验。计数资料采用率表示,行²检验。P<0.05为差异具有统计学意义。

2 结果

2.1 疗效比较

观察组治疗后总有效率较对照组高(P<0.05)。见表1。

表 1 治疗后两组临床疗效比较 [例(%)]

Table 1 Comparison of clinical efficacy between the two groups after treatment [n(%)]

Groups	n	Cure	Remarkable effect	Effective	Invalid	Total effective rate
Control group	57	19	15	13	10	47(82.46%)
Observation group	57	23	20	11	3	54(94.74%)
χ^2						4.254
P						0.039

2.2 治疗后两组 HP 转阴率和 1 年内复发情况比较

治疗后, 观察组 HP 转阴率 89.47%, 高于对照组 HP 转阴

率 73.68%; 观察组 1 年内复发率 11.11%, 低于对照组的 27.66% ($P < 0.05$)。见表 2。

表 2 治疗后两组 HP 转阴情况和 1 年内复发情况比较

Table 2 Comparison of HP negative conversion and recurrence in one year between the two groups after treatment

Groups	HP negative conversion		Recurrence within 1 year	
	n	Negative conversion rate	n	Recurrence rate
Control group	57	42(73.68%)	47	13(27.66%)
Observation group	57	51(89.47%)	54	6(11.11%)
χ^2		4.728		4.506
P		0.030		0.034

2.3 治疗前后两组血清学指标比较

两组治疗前 PG I 、PG II 、PGR、G-17 比较无差异 ($P > 0.05$)。两组治疗后 PG I 、PG II 、G-17 较治疗前低, PGR 较治疗前高, 观察组 PG I 、PG II 、G-17 比对照组低, PGR 高于对照组 ($P < 0.05$)。见表 3。表 3 治疗前后两组血清学指标比较($\bar{x} \pm s$)Table 3 Comparison of serological indexes between the two groups before and after treatment ($\bar{x} \pm s$)

Groups	Time	PG I (ng/mL)	PG II (ng/mL)	PGR	G-17(pmoL/L)
Control group(n=57)	Before treatment	256.35± 80.63	48.09± 16.55	5.33± 2.32	31.47± 10.13
	After treatment	208.48± 53.51*	23.62± 8.41*	8.83± 3.59*	20.89± 7.15*
Observation group (n=57)	Before treatment	255.29± 82.08	47.85± 15.96	5.23± 2.28	32.50± 11.16
	After treatment	185.87± 59.64**	17.24± 7.71**	10.78± 4.17**	16.24± 7.26**

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

2.4 两组不良反应情况

观察组治疗时不良反应发生率低于对照组 ($P < 0.05$)。见

表 4 治疗期间两组不良反应情况比较 例(%)

Table 4 Comparison of adverse reactions between the two groups during treatment n(%)

Groups	Dizziness and headache	Gastrointestinal reactions	Rash	Other	Total incidence rate
Control group(n=57)	3	4	1	2	10(17.54%)
Observation group(n=57)	1	1	0	1	3(5.26%)
χ^2					4.254
P					0.039

3 讨论

当胃黏膜组织在胃酸、胃蛋白酶等因素作用下发生炎症反

应, 可出现局部糜烂、破溃等坏死性病变, 最终发展为消化性溃疡, 发病多具有周期性和长期性等特点^[13-15]。消化道溃疡病因多样, 患者群体之间具有异质性, 其中, HP 感染是主要危险因素

之一^[16-18]。HP 感染是一个世界性问题，我国感染率高达 40%~60%，且随着年龄增加而升高^[19]。在消化性溃疡的发病机制中，HP 通过减弱胃黏膜保护作用、刺激胃酸分泌致病，此外，HP 还是胃癌的独立风险因素，因此在治疗消化性溃疡的同时根除 HP 不容忽视^[20-22]。

三联方案是治疗消化性溃疡的传统方法，本研究采用泮托拉唑抑制胃酸分泌，克拉霉素和阿莫西林抗菌，联合应用于对照组，总有效率为 82.46%。而在三联方案的基础上，观察组同时服用芪芍安胃胶囊 / 黄柴安胃胶囊，总有效率高达 94.74%，显著高于对照组。中医讲究辨证施治，消化道溃疡病性属虚实夹杂，脾虚为本，郁热血瘀、气滞湿浊为标，本研究纳入患者皆为脾胃湿热证，其病位在胃，脾胃之气升降失和，久则气血瘀阻，复加外邪伤脾，湿热内生，损伤胃络，最终发为溃疡^[23]。本研究按照脾虚、湿热侧重，对观察组辨证施以芪芍安胃胶囊或黄柴安胃胶囊。芪芍安胃胶囊中有黄芪益气养胃，白芍养血止痛，白术健脾燥湿，茯苓渗湿，甘松悦脾，枳壳理气，甘草和胃；黄柴安胃胶囊则有黄连清热燥湿，柴胡解表和里，黄芩凉血解毒，党参补中养气，香附理气，玄胡活血，陈皮健脾，是以多药配伍，共奏健脾益气、温中和胃、解热祛湿之功^[9]。关于 HP 感染，中医理论认为其与人体正气不足，阴阳失和有关，芪芍安胃胶囊 / 黄柴安胃胶囊中多种药物扶正祛邪，调和阴阳^[24]。而从现代药理学来看^[25,26]，两种中药的主要成分黄芪、黄连等均有抗菌抗病毒作用，因此本研究中观察组 HP 转阴率高于对照组。消化性溃疡病因复杂，饮食习惯、气候变化以及情绪波动均与其密切相关，应时刻警惕复发，本研究中观察组 1 年内复发率低于对照组，此外观察组的不良反应发生率也低于对照组，表明中药的加入有助于降低西药刺激性，保护胃黏膜组织。

消化性溃疡常伴有分泌 PG 的主细胞增殖，PG I、PG II 大量分泌，同时胃黏膜通透性改变，进一步影响 PG 入血^[27,28]。G-17 的主要作用是促进胃酸分泌、促进 PG 分泌，当水平超过正常值，应警惕胃黏膜炎症^[29,30]。本研究检测发现，治疗后，两组血清 PG I、PG II、G-17 水平均低于本组治疗前，PGR 高于本组治疗前，表明两组的治疗均有助于减少胃酸分泌，改善胃黏膜症状。而治疗后观察组血清 PG I、PG II、G-17 水平均低于对照组，PGR 高于对照组，表明在三联方案的基础上同时服用芪芍安胃胶囊 / 黄柴安胃胶囊，对恢复胃黏膜形态和功能的疗效更加明显，安胃胶囊所用吴茱萸、甘松、桂枝、甘草、陈皮等药物均有抑制胃酸分泌、保护胃黏膜的药理作用。

综上所述，芪芍安胃胶囊 / 黄柴安胃胶囊治疗消化性溃疡伴 HP 感染患者，具有良好的临床疗效，能够提高 HP 转阴率，降低 1 年内复发率，减少不良反应发生，并且改善血清 PG 和 G-17 水平，促进胃黏膜形态和功能恢复。芪芍安胃胶囊 / 黄柴安胃胶囊为纯中药制剂，毒副作用小，价格较为低廉，减少患者经济负担，值得临床推广。

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