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补肺活血胶囊联合喘可治注射液对慢性阻塞性肺疾病稳定期患者肺功能、 血气指标以及血液流变学的影响*

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摘要 目的:探讨补肺活血胶囊联合喘可治注射液对慢性阻塞性肺疾病(COPD)稳定期患者肺功能、血气指标以及血液流变学的影响。方法:选取我院于2017年8月到2019年12月期间接收的126例COPD稳定期患者,按照随机数字表法将患者分为对照组(n=63)和研究组(n=63),对照组给予静注喘可治注射液,研究组在对照组的基础上联合补肺活血胶囊治疗,均治疗12周。比较两组患者疗效、肺功能、血气指标以及血液流变学,记录两组治疗期间不良反应情况。结果:治疗12周后,研究组的临床总有效率84.13%(53/63)高于对照组66.67%(42/63)(P<0.05)。两组第1秒用力呼气容积(FEV₁)、用力肺活量(FVC)、FEV₁/FVC均较治疗前升高,且研究组高于对照组(P<0.05)。两组治疗12周后动脉氧分压(PaO₂)较治疗前升高,且研究组高于对照组(P<0.05);两组治疗12周后动脉二氧化碳分压(PaCO₂)较治疗前降低,且研究组低于对照组(P<0.05)。两组血浆黏度、纤维蛋白原、全血黏度水平均下降,研究组较对照组低(P<0.05)。两组不良反应发生率比较无差异(P>0.05)。结论:COPD稳定期患者在喘可治注射液的基础上联合补肺活血胶囊治疗,血气指标、肺功能以及血液流变学可得到显著改善,且用药安全性好,疗效较好。

关键词:补肺活血胶囊;喘可治注射液;慢性阻塞性肺疾病;稳定期;肺功能;血气指标;血液流变学

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The Effect of Bufeihuoxue Capsule Combined with Chuankezhi Injection on Pulmonary Function, Blood Gas Index and Hemorheology in Patients with Stable Chronic Obstructive Pulmonary Disease*

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ABSTRACT Objective: To explore the effect of bufeihuoxue capsule combined with Chuankezhi Injection on pulmonary function, blood gas index and hemorheology in patients with stable chronic obstructive pulmonary disease (COPD). **Methods:** 126 patients with stable COPD received by our hospital from August 2017 to December 2019 were selected, the patients were divided into control group (n=63) and study group (n=63) according to the random number table method. The control group was given Chuankezhi injection, the study group was treated with bufeihuoxue Capsule on the basis of the control group, all patients were treated for 12 weeks. The therapeutic effect, pulmonary function, blood gas index and hemorheology of the two groups were compared, and the adverse reactions during the treatment were recorded. **Results:** 12 weeks after treatment, the total clinical effective rate of the study group was 84.13% (53/63) higher than 66.67% (42/63) of the control group (P<0.05). The forced expiratory volume in the first second (FEV₁), forced vital capacity (FVC) and FEV₁/FVC in the two groups were higher than those before treatment, and the study group were higher than those of the control group (P<0.05). The partial pressure of oxygen (PaO₂) of the two groups increased at 12 weeks after treatment, and the study group was higher than that of the control group (P<0.05). The arterial partial pressure of carbon dioxide (PaCO₂) of the two groups decreased after 12 weeks treatment, and the study group was lower than that of the control group (P<0.05). The levels of whole blood viscosity, plasma viscosity and fibrinogen in the two groups decreased, and the study group were lower than those of control group (P<0.05). There was no significant difference in the incidence of adverse reactions between the two groups (P>0.05). **Conclusion:** Bufeihuoxue capsule combined with Chuankezhi injection can improve the blood gas, pulmonary function, index and hemorheology in the patients with stable COPD, its curative effect is better, and it's in good drug safety.

Key words: Bufeihuoxue capsule; Chuankezhi injection; Chronic obstructive pulmonary disease; Stable period; Pulmonary function; Blood gas index; Hemorheology

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前言

慢性阻塞性肺疾病(COPD)属呼吸科的常见疾病,临床常伴气促、咳嗽、咯痰等症状^[1]。该病具有较高的致残率及病死率,根据既往资料统计^[2],我国40岁以上的人群中,COPD的患病率高达13.7%,已成为我国较为严重的公共卫生问题。临床根据COPD的病情严重程度,分为急性加重期和稳定期,处于COPD稳定期的患者各项症状较为轻微,但仍存在不完全可逆的气流受限现象,需尽快给予有效治疗^[3,4]。喘可治注射液为中药制剂,当前已广泛应用于哮喘、COPD、慢性支气管炎等疾病的临床治疗中,且可获得一定的疗效^[5]。补肺活血胶囊亦属中成药,有益气活血、补肺固肾之功效,既往常用于肺心病属气虚血瘀证^[6]。本研究我院采用补肺活血胶囊联合喘可治注射液治疗COPD稳定期患者,疗效较好,报道如下。

1 资料与方法

1.1 临床资料

选取我院于2017年8月到2019年12月期间接收的126例COPD稳定期患者,纳入标准:(1)患者均知情且签署同意书;(2)西医诊断标准参考《慢性阻塞性肺疾病诊治指南(2013年修订版)》^[7],处于稳定期;中医诊断标准符合《慢性阻塞性肺疾病中医证候诊断标准(2011版)》^[8]中的主证:咳吐不利、腰膝酸软、呼吸短浅,次证:舌苔白润、舌象暗紫、声低气怯。(3)经胸部X线检查确诊,第1秒用力呼气容积占用力肺活量之比(FEV_1/FVC)<70%。排除标准:(1)合并支气管哮喘、肺结核、支气管扩张等肺疾者;(2)对本次研究用药存在禁忌者;(3)合并精神疾患,无法配合本次研究者;(4)合并恶性肿瘤者;(5)半年内接受过糖皮质激素类药物治疗者;(6)造血系统严重原发性疾病者;(7)妊娠期或哺乳期妇女。依随机数字表法分为研究组(n=63)和对照组(n=63),研究组男35例,女28例,年龄39~72岁,平均(53.14±4.62)岁;病程2~11年,平均(5.31±1.17)年;慢性阻塞性肺病全球倡议(GOLD)分级^[9]:I级20例,II级26例,III级17例;体质量指数21~26 kg/m²,平均(23.81±0.87)kg/m²。对照组男34例,女29例,年龄41~73岁,平均(53.78±4.39)岁;病程1~10年,平均(5.17±1.18)年;GOLD分

级:I级21例,II级28例,III级14例;体质量指数20~27 kg/m²,平均(23.94±0.93)kg/m²。两组临床资料无差异($P>0.05$),具有可比性。本次研究经医院伦理学委员会批准进行。

1.2 方法

患者入院后均给予止咳、化痰、吸氧、抗感染、营养支持、维持水电解质平衡等。在此基础上,对照组给予喘可治注射液(广州万正药业有限公司,规格:每支装2 mL,国药准字Z20010172)治疗,静脉注射,4 mL/次,2次/d。研究组在对照组的基础上联合补肺活血胶囊(广东雷允上药业有限公司,规格:每粒装0.35 g,国药准字Z20030063)治疗,口服,4粒/次,3次/d。两组均连续治疗12周。

1.3 指标评价

(1)记录两组临床疗效。总有效率=治愈率+好转率。参照标准^[10]:治愈:肺功能检查显示 $FEV_1/FVC\geq 70\%$,咳嗽、咳痰等临床症状消失,痰涂片检查及血清炎性因子均提示正常。好转:肺功能检查显示 FEV_1/FVC 较之前有所改善,上述临床症状基本消失,痰涂片检查及血清炎性因子趋于正常值。无效:症状未改善或者恶化。(2)记录两组不良反应。(3)于治疗前、治疗12周后抽取患者清晨空腹静脉血4 mL,分为2管,其中一管应用ABL80血气分析仪(丹麦雷度公司生产)检测血气指标:动脉氧分压(PaO_2)、动脉二氧化碳分压($PaCO_2$)。另一管采用BV-100血液流变仪(北京泰诺德公司生产)检测血液流变学指标:全血黏度、血浆黏度、纤维蛋白原。(4)采用日本杰斯特公司生产的便携式肺功能仪检测所有患者治疗前后的第1秒用力呼气容积(FEV_1)、用力肺活量(FVC),计算 FEV_1/FVC ,均连测3次,取平均值。

1.4 统计学方法

数据分析采用SPSS25.0软件。计数资料以[n(%)]表示,行卡方检验。计量资料以($\bar{x}\pm s$)表示,行t检验。 $P<0.05$ 为差异有统计学意义。

2 结果

2.1 两组疗效比较

治疗12周后,研究组的临床总有效率84.13%(53/63)高于对照组的66.67%(42/63)($P<0.05$);具体见表1。

表1 两组疗效比较例(%)

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

Groups	Cure	Getting better	Invalid	Total efficiency
Control group (n = 63)	16(25.40)	26(41.27)	21(33.33)	42(66.67)
Study group (n = 63)	20(31.75)	33(52.38)	10(15.87)	53(84.13)
χ^2				5.177
P				0.023

2.2 两组肺功能比较

两组治疗前 FEV_1/FVC 、 FEV_1 、FVC比较无差异($P>0.05$);两组治疗12周后 FEV_1 、 FEV_1/FVC 、FVC均较治疗前升高,研究组较对照组高($P<0.05$);具体见表2。

2.3 两组血气分析指标比较

两组治疗前 $PaCO_2$ 、 PaO_2 比较无差异($P>0.05$);两组治疗12周后 PaO_2 较治疗前升高,研究组较对照组高($P<0.05$);两组治疗12周后 $PaCO_2$ 较治疗前降低,研究组较对照组低($P<0.05$);具体见表3。

表 2 两组肺功能指标比较($\bar{x} \pm s$)
Table 2 Comparison of pulmonary function indexes between the two groups($\bar{x} \pm s$)

Groups	FEV ₁ (L)		FVC(L)		FEV ₁ /FVC	
	Before treatment	12 weeks after treatment	Before treatment	12 weeks after treatment	Before treatment	12 weeks after treatment
Control group (n=63)	1.36± 0.34	1.77± 0.31*	2.38± 0.41	2.60± 0.42*	0.57± 0.03	0.68± 0.04*
Study group (n=63)	1.34± 0.29	1.97± 0.30*	2.33± 0.39	2.74± 0.32*	0.58± 0.05	0.72± 0.07*
t	0.355	3.312	0.701	2.105	1.361	3.938
P	0.723	0.001	0.484	0.037	0.176	0.000

Note: compared with before treatment, *P<0.05.

表 3 两组血气分析指标比较($\bar{x} \pm s$, mmHg)
Table 3 Comparison of blood gas analysis indexes between the two groups($\bar{x} \pm s$, mmHg)

Groups	PaCO ₂		PaO ₂	
	Before treatment	12 weeks after treatment	Before treatment	12 weeks after treatment
Control group (n=63)	59.85± 6.56	53.37± 5.67*	63.04± 5.36	67.35± 6.38*
Study group (n=63)	59.49± 5.62	48.05± 6.51*	62.92± 6.43	71.48± 5.32*
t	0.331	4.891	0.114	3.946
P	0.741	0.000	0.910	0.000

Note: compared with before treatment, *P<0.05.

2.4 两组血液流变学指标比较

两组治疗前血浆黏度、全血黏度、纤维蛋白原比较无差异

(P>0.05);两组治疗 12 周后血浆黏度、全血黏度、纤维蛋白原均下降,研究组较对照组低(P<0.05);具体见表 4。

表 4 两组血液流变学指标比较($\bar{x} \pm s$)
Table 4 Comparison of hemorheology indexes between the two groups($\bar{x} \pm s$)

Groups	Whole blood viscosity(mPa·s)		Plasma viscosity(mPa·s)		Fibrinogen(g/L)	
	Before treatment	12 weeks after treatment	Before treatment	12 weeks after treatment	Before treatment	12 weeks after treatment
Control group (n=63)	8.54± 1.21	6.09± 1.25*	6.29± 0.59	4.04± 0.48*	5.38± 0.26	4.12± 0.27*
Study group (n=63)	8.49± 1.03	4.25± 1.27*	6.24± 0.43	2.66± 0.32*	5.32± 0.34	2.75± 0.23*
t	0.250	8.068	0.544	18.987	1.113	30.658
P	0.803	0.000	0.588	0.000	0.268	0.000

Note: compared with before treatment, *P<0.05.

2.5 两组不良反应发生率比较

治疗期间,对照组出现 2 例恶心呕吐、3 例胃肠道不适,不良反应发生率为 7.94%(5/63);研究组出现 5 例胃肠道不适、2 例恶心呕吐,不良反应发生率为 11.11%(7/63);两组不良反应发生率比较无明显差异($\chi^2=0.368$, P=0.544)。

3 讨论

近年来,随着人们生活环境的逐渐恶化,人口老龄化的加剧,COPD 的发病率呈逐年递增趋势^[1]。COPD 的主要病理特征在于肺功能呈持续性的下降状态,伴随着病情进展,还可继发慢性肺源性心脏病等并发症,威胁患者生命健康^[12,13]。现临床有关 COPD 稳定期的具体发病机制尚不十分明确,大多数研究认为 COPD 的发生与肺泡巨噬细胞、中性粒细胞等炎症细胞的激活密切相关,炎症细胞激活后可释放多种炎症因子,导致气道

壁损伤和修复过程反复发生,最终引发气道狭窄^[14-16]。而 COPD 长期的低氧血症状态,可导致患者肺泡通气功能受损,引起动静脉分流和弥散功能障碍,通气 / 血流比例失衡,最终引起肾脏的肾小球旁器释放红血球生长素,使得红细胞压积随之升高,血浆黏度、全血黏度、纤维蛋白原水平升高,引起机体血液流变学异常^[17,18]。因此,通过改善患者血气指标、症状与体征、血液流变学、肺功能等均有利于改善患者临床治疗效果。

传统的西医治疗肺部疾病存在药物不良反应较大等缺陷,而祖国医学中认为 COPD 可归属于 "喘症" "肺胀" 以及 "痰饮" 等范畴,主要病机为肺肾两虚,且痰异常。肺为起之主,肾为根本,肺肾虚弱,正气不复,气虚累及脾胃,加之血行受阻,血脉不通^[19]。因此,对于 COPD 稳定期治疗应以 "补" 和 "化" 为主。喘可治注射液的主要成分为淫羊藿、巴戟天,有止咳平喘、温肾助阳之功效,具有抗过敏、增强细胞免疫及体液免疫功能、

抗应激、舒张气道平滑肌、抗炎、祛痰、抗菌、止咳等作用^[20]。补肺活血胶囊的主要成分为赤芍、黄芪、补骨脂等,其中黄芪性味甘、微温,有益肺健脾、补脾肺肾之功,为补气要药;赤芍性微寒,味苦,有散瘀止痛、消热凉血之效;补骨脂药性苦、辛、温,有补脾健胃、补肾壮阳之效,上述诸药联用,共奏补肺益肾、益气活血之功效^[21]。鉴于 COPD 稳定期的发病机制较为复杂,单一的药物治疗一直未能达到理想的预期效果,本研究通过联合补肺活血胶囊、喘可治注射液治疗,以期获得更好的临床效果。

本次研究结果显示,补肺活血胶囊联合喘可治注射液治疗可进一步提高治疗效果。肺功能检查是诊断 COPD 的金标准,可有效评估患者预后^[22]。随着 COPD 疾病进展,患者会出现肺血管异常、肺实质破坏等病理改变,使得肺气体交换能力减弱,继而可引起低氧血症或高碳酸血症,导致 PaO₂ 降低或 PaCO₂ 升高^[23,24]。而血液的高凝状态也是 COPD 病情进展的主要原因之一,表现为血浆黏度、全血黏度、纤维蛋白原等血液流变学指标的异常升高^[25,26]。本研究中补肺活血胶囊联合喘可治注射液治疗还可有效改善机体肺功能、血气指标及血液流变学指标。可能是因为补肺活血胶囊具有补肺固肾功效,可调节机体血气,增强机体免疫力,有利于促进肺功能恢复^[27,28]。药理研究表明补肺活血胶囊中黄芪的有效成分多糖、黄酮类似物以及黄芪皂甙等,可以有效改善心肌功能,增强免疫力和抗氧化作用;补骨脂的有效成分补骨脂素可松弛,增加冠状动脉血流量,利于机体肺功能及血液流变学的改善;赤芍中所含的有效成分赤芍总苷可有效改善毛细血管微循环,促进血液流通,同时还具有抗炎、抗菌以及抗氧化等功效^[29,30]。此外,本研究还观察了两组用药安全性,结果显示两组不良反应发生率未见显著差异,可见本研究中的联合治疗方案安全可靠,可能是因为两种药物均为中成药,符合中医药一贯的低毒、低副作用特征。

综上所述,补肺活血胶囊联合喘可治注射液治疗 COPD 稳定期患者的疗效较好,可有效改善患者肺功能、血气指标以及血液流变学,且不增加不良反应发生率,安全可靠。

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