

注射用益气复脉(冻干)治疗老年冠心病合并慢性心力衰竭伴低血压的临床观察

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摘要: **目的** 观察注射用益气复脉(冻干)治疗老年冠心病合并慢性心力衰竭(CHF)伴低血压患者的临床疗效及安全性。**方法** 回顾性收集2018年2月—2022年2月在贵州医科大学附属医院中医科住院的老年冠心病合并CHF伴低血压患者90例为研究对象,根据治疗方案不同分为对照组和试验组,每组各45例。对照组患者仅行抗心衰治疗,试验组在对照组基础上给予注射用益气复脉(冻干)5.2 g用5%葡萄糖注射液或0.9%氯化钠注射液250 mL溶解,静脉滴注,每天1次,连续使用14 d。治疗后观察两组的临床疗效,比较两组患者治疗前后心功能指标[左室射血分数(LVEF)、氨基端前心钠肽(NT-proBNP)、6 min步行试验距离(6MWD)]和血压水平。观察治疗期间两组不良反应发生情况。**结果** 治疗后,试验组总有效率为95.56%,显著高于对照组的84.44% ($P < 0.05$)。治疗前两组患者LVEF、NT-proBNP、6MWD比较,差异无统计学意义 ($P > 0.05$);治疗后两组患者LVEF和6MWD均较本组治疗前显著增加 ($P < 0.05$), NT-proBNP均较本组治疗前显著降低 ($P < 0.05$),且试验组LVEF和6MWD显著高于对照组 ($P < 0.05$), NT-proBNP显著低于对照组 ($P < 0.05$)。治疗前两组患者平均收缩压和舒张压比较,差异均无统计学意义 ($P > 0.05$);治疗后,两组患者平均收缩压和舒张压均较本组治疗前显著升高 ($P < 0.05$),且试验组治疗后平均收缩压和舒张压均显著高于对照组 ($P < 0.05$)。治疗期间对照组不良反应发生率为11.11%,试验组不良反应发生率为6.67%,两组比较,差异有统计学意义 ($P < 0.05$)。**结论** 注射用益气复脉(冻干)治疗老年冠心病合并CHF伴低血压患者临床疗效肯定,改善患者心功能,并升压平稳,具有较高安全性。

关键词: 注射用益气复脉(冻干);慢性心力衰竭;氨基端前心钠肽;左室射血分数;6 min步行试验距离;低血压

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Clinical observation of Yiqi Fumai Lyophilized Injection in treatment of elderly patients with coronary heart disease, chronic heart failure and hypotension

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Abstract: **Objective** To observe the clinical efficacy and safety of Yiqi Fumai Lyophilized Injection in the treatment of coronary heart disease with chronic heart failure (CHF) and hypotension. **Methods** A total of 90 elderly patients with coronary heart disease with chronic heart failure (CHF) and hypotension hospitalized in the Department of Traditional Chinese Medicine of the Affiliated Hospital of Guizhou Medical University from February 2018 to February 2022 were retrospectively collected as the research objects. According to different treatment schemes, they were divided into the control group and the experimental group, with 45 cases in each group. Patients in the control group only received anti heart failure treatment (including sufficient rest, oxygen inhalation, correction of arrhythmia, control of blood pressure, and maintenance of electrolytes, application β -receptor blockers, angiotensin II receptor antagonists, angiotensin converting enzyme inhibitors, etc). On the basis of the control group, the patients in experimental group were given 5.2 g of Yiqi Fumai Lyophilized Injection, dissolved in 250 mL of 5% Glucose Injection or 0.9% Sodium Chloride Injection, intravenous drip once a day, for 14 consecutive days. After 14 days of treatment the clinical efficacy of the two groups was observed, and the heart function indexes [(left ventricular ejection fraction (LVEF), N-terminal fragment of brain natriuretic peptide

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(NT-proBNP), and 6-minute walk test distance (6MWD)] and blood pressure were compared between the two groups before and after treatment. The occurrence of adverse reactions in both groups during the treatment period were observed. **Results** After 14 days of treatment, the total effective rate of the experimental group was 95.56%, significantly higher than 84.44% in the control group ($P < 0.05$). There was no statistically significant difference in LVEF, NT-proBNP, and 6MWD between the two groups of patients before treatment ($P > 0.05$). After treatment, LVEF and 6MWD in both groups of patients significantly increased compared to before treatment in same group ($P < 0.05$), while NT-proBNP significantly decreased compared to before treatment in same group ($P < 0.05$). LVEF and 6MWD in the experimental group were significantly higher than those in the control group ($P < 0.05$), while NT-proBNP was significantly lower than those in the control group ($P < 0.05$). There was no statistically significant difference in average systolic and diastolic blood pressure between the two groups of patients before treatment ($P > 0.05$). After 14 days of treatment, the average systolic and diastolic blood pressure of both groups of patients significantly increased compared to before treatment in same group ($P < 0.05$), and the average systolic and diastolic blood pressure of the experimental group after treatment was significantly higher than that of the control group ($P < 0.05$). During the treatment period, the incidence of adverse reactions in the control group was 11.11%, while the incidence of adverse reactions in the experimental group was 6.67%. The difference between the two groups was statistically significant ($P < 0.05$). **Conclusion** The clinical efficacy of Yiqi Fumai Lyophilized Injection in the treatment of elderly patients with coronary heart disease complicated with CHF and hypotension is positive, and it can improve the patients' cardiac function, stabilize the pressure rise, and has high safety.

Key words: Yiqi Fumai Lyophilized Injection; chronic heart failure; N-terminal pro-brain natural peptide; left ventricular ejection fraction; 6-minute walking test distance; hypotension

随着我国人口老龄化的加剧,冠心病、高血压发病率的增加,慢性心力衰竭(CHF)的发病率逐年上升^[1]。冠心病是我国慢性心力衰竭患者的第二大危险因素^[2];CHF是因心肌收缩力减弱,导致心脏血液不能有效充分泵至全身进行循环,无法满足组织代谢需要的临床综合征^[3-4]。我国CHF住院率占同期心血管疾病的20%,死亡率达到40%,提示CHF预后较差^[5]。血压对老年冠心病合并CHF患者的临床治疗及病情的转归有重要的影响^[6-7]。心力衰竭(心衰)诊疗指南中指出 β -受体阻滞剂、血管紧张素II受体拮抗剂(ARB)、血管紧张素转化酶抑制剂(ACEI)治疗心力衰竭的重要性,对血压偏低的心衰患者,这些药物会加重低血压,成为治疗中的一个难点^[8]。老年冠心病合并CHF伴低血压患者为了纠正低血压,长时间、大剂量使用多巴胺,使其病残率和死亡率均较高^[9],因此需要寻求一种治疗老年冠心病合并CHF伴低血压的安全有效的方法。中医药在心血管疾病诊疗中应用广泛,中医药在稳定病情、改善心功能、提高生存质量等方面具有独特优势。注射用益气复脉(冻干)源于经典古方生脉散,由红参、麦冬和五味子3味中药组成,临床上主要用于治疗冠心病劳累型心绞痛及慢性心功能不全等心血管系统疾病。现代药理研究表明注射用益气复脉(冻干)具有增强心脏收缩功能、延缓心室重构、改善能量代谢、改善微循环障碍以及抗氧化等药理作用^[10]。研究还发现注射用益气复脉(冻干)通过改善心肌缺血、重构心肌细胞外基质、减少

心肌组织损伤、减少炎症因子的释放、抑制肾素-血管紧张素-醛固酮系统(RAAS)激活等作用改善心衰症状,还能预防和纠正低血压的发生^[11-12]。本研究以老年冠心病合并CHF伴低血压患者为观察对象,观察注射用益气复脉(冻干)的治疗效果及安全性,为临床合理用药提供参考。

1 资料与方法

1.1 一般资料

回顾性收集2018年2月—2022年2月在贵州医科大学附属医院中医科住院治疗的老年冠心病合并CHF伴低血压90例患者资料。其中男50例,女40例;年龄61~83岁;平均年龄(70.76±9.62)岁;病程3~21年;平均病程(7.32±6.87)年;NYHA心功能分级:II级11例、III级66例、IV级13例;平均收缩压(86.86±5.94)mmHg(1 mmHg=0.133 kPa),平均舒张压(58.06±7.62)mmHg。

1.2 诊断、纳入及排除标准

1.2.1 诊断标准 冠心病诊断标准参照《冠心病合理用药指南(第2版)》中冠心病诊断标准^[13];CHF诊断标准参照《中国心力衰竭诊断和治疗指南(2018)》中CHF的诊断标准^[14];低血压诊断标准参照《内科学》所制定的低血压诊断标准^[15];低血压一般指收缩压<90 mmHg或舒张压<60 mmHg。

1.2.2 纳入标准 (1)有冠心病史;(2)符合CHF诊断标准,伴有低血压的住院患者;(3)年龄60岁以上;(4)中医辨证属于气阴两虚型;(5)患者资料完整。

1.2.3 排除标准 (1)先天性心脏病、急性期的心肌梗死、严重的心脏瓣膜疾病、心律失常患者;(2)合并多器官衰竭、血液系统疾病、休克、肿瘤或其他严重疾病的患者;(3)对注射用益气复脉(冻干)过敏或拒绝使用该药物的患者。

1.3 治疗方法

入组的患者均行抗心衰治疗(包括充分休息、吸氧、纠正心律失常、控制血压、维持电解质;应用ACEI、ARB、 β 受体阻滞剂等)。对照组仅行抗心衰治疗,试验组在对照组基础上给予注射用益气复脉(冻干)(天津天士力之骄药业有限公司,国药准字Z20060463,规格:每瓶0.65 g,批号:20171202、20180425、20180833、20190526、20191021、20200313、20200819、20210407、20211013)5.2 g,用5%葡萄糖注射液或0.9%氯化钠注射液250 mL溶解,静脉滴注,每天1次,连续使用14 d。

1.4 观察指标

1.4.1 疗效评定标准 参照《中药新药临床研究指导原则》^[6]拟定。显效:临床症状和体征明显改善,心功能较治疗前至少提高2个级别,收缩压 >100 mmHg或舒张压 >70 mmHg。有效:临床症状和体征较治疗前有改善,心功能较治疗前提高1个级别,收缩压 >90 mmHg或舒张压 >60 mmHg。无效:临床症状和体征无改善或加重,心功能未见提高或者下降。

总有效率=(显效+有效)例数/总例数

1.4.2 心功能相关指标检测 分别于治疗前及治疗后采用PHILIPS IE33彩色多普勒超声诊断仪测量患者左室射血分数(LVEF)。分别于治疗前及治疗后采集患者静脉血,采用Biosite快速心衰诊断仪器检测抗凝样本中的氨基端前心钠肽(NT-proBNP)水平,试剂盒由成都爱兴科技有限公司提供。分别于治疗前及治疗后采用6 min步行试验距离(6MWD)^[17],测定患者6 min步行距离。

1.4.3 血压监测 治疗期间监测血压,告知患者若有胸闷、心区不适及时联系医护人员。血压采用YE680B鱼跃电子血压计(江苏鱼跃医疗设备股份有限公司)测定,每天测量2次,分别记录治疗前、后两组患者的舒张压和收缩压。

1.4.4 不良反应情况观察 治疗过程中观察两组患者的不良反应发生情况,包括皮肤潮红、皮疹、口干等情况。

1.5 统计学分析

采用SPSS 25.0统计软件处理数据。计量资料

以 $\bar{x} \pm s$ 表示,组间比较采用 t 检验;计数资料以例或百分率表示,组间比较采用 χ^2 检验。 $P < 0.05$ 表示差异具有统计学意义。

2 结果

2.1 两组患者基线资料比较

根据治理方案不同将患者分为对照组和试验组,每组各45例。对照组男21例,女24例,平均年龄 (71.22 ± 10.39) 岁,平均病程 (7.45 ± 6.75) 年,心功能分级:II级6例、III级34例、IV级5例。试验组男29例,女16例,平均年龄 (70.53 ± 10.32) 岁,平均病程 (7.31 ± 6.79) 年,心功能分级:II级5例、III级32例、IV级8例。两组患者各项基线资料比较,差异无统计学意义($P > 0.05$),具有可比性。

2.2 两组疗效比较

治疗14 d后,对照组总有效率为84.44%,试验组总有效率为95.56%,两组比较,差异有统计学意义($P < 0.05$),见表1。

表1 两组疗效比较

Table 1 Comparison of clinical efficacy between two groups

组别	n/例	显效/例	有效/例	无效/例	总有效率/%
对照	45	17	21	7	84.44
试验	45	20	23	2	95.56*

与对照组比较:* $P < 0.05$

* $P < 0.05$ vs control group

2.3 两组心功能相关指标比较

治疗前两组患者LVEF、NT-proBNP、6MWD比较,差异无统计学意义($P > 0.05$);治疗后两组患者LVEF和6MWD均较本组治疗前显著增加($P < 0.05$),NT-proBNP均较本组治疗前显著降低($P < 0.05$),且试验组LVEF和6MWD显著高于对照组($P < 0.05$),NT-proBNP显著低于对照组($P < 0.05$),见表2。

2.4 两组血压比较

治疗前两组患者平均收缩压和舒张压比较,差异均无统计学意义($P > 0.05$);治疗14 d后,两组患者平均收缩压和舒张压均较本组治疗前显著升高($P < 0.05$),且试验组治疗后平均收缩压和舒张压均显著高于对照组($P < 0.05$),见表3。

2.5 两组不良反应比较

治疗期间对照组共有5例患者发生不良反应,发生率为11.11%,试验组共有3例患者发生不良反应,发生率为6.67%,两组比较,差异有统计学意义($P < 0.05$),见表4。

表2 两组LVEF、NT-proBNP和6MWD水平比较 ($\bar{x} \pm s$)Table 2 Comparison of LVEF, NT-proBNP and 6MWD levels between two groups ($\bar{x} \pm s$)

组别	n/例	时间	LVEF/%	NT-proBNP/(pg·L ⁻¹)	6MWD/m
对照	45	治疗前	38.64±5.82	4 536.42±687.45	183.64±25.82
		治疗后	44.62±5.63 [*]	1 767.46±266.24 [*]	308.56±30.75 [*]
试验	45	治疗前	38.72±6.04	4 624.35±648.26	179.75±26.63
		治疗后	47.32±4.45 ^{*#}	1 586.32±238.41 ^{*#}	338.68±32.67 ^{*#}

与同组治疗前比较: ^{*}P<0.05; 与对照组治疗后比较: [#]P<0.05^{*}P<0.05 vs same group before treatment; [#]P<0.05 vs control group after treatment表3 两组血压比较 ($\bar{x} \pm s$)Table 3 Comparison of blood pressure between two groups ($\bar{x} \pm s$)

组别	n/例	时间	收缩压/mmHg	舒张压/mmHg
对照	45	治疗前	87.13±5.82	58.34±7.45
		治疗后	94.42±5.63 [*]	68.46±3.24 [*]
试验	45	治疗前	86.82±6.04	57.92±8.22
		治疗后	116.02±4.12 ^{*#}	88.32±3.41 ^{*#}

与同组治疗前比较: ^{*}P<0.05; 与对照组治疗后比较: [#]P<0.05; 1 mmHg=0.133 kPa^{*}P<0.05 vs same group before treatment; [#]P<0.05 vs control group after treatment; 1 mmHg=0.133 kPa

表4 两组不良反应比较

Table 4 Comparison of adverse reactions between two groups

组别	n/例	皮肤潮红/例	皮疹/例	口干/例	总发生率/%
对照	45	3	1	1	11.11
试验	45	0	1	2	6.67 [*]

与对照组比较: ^{*}P<0.05^{*}P<0.05 vs control group

3 讨论

CHF是冠心病的终末阶段,因心排血量不足引起组织、器官灌注不足,产生肺或体循环瘀血,常伴随低血压、心律失常等引起的头晕、心慌、胸闷、气促等症^[18-19]。对人体健康危害最严重的心血管病症之一的CHF^[20],其发病机制为心肌损伤使交感神经系统、RAAS及内源性神经内分泌因子的兴奋性增高,促进心肌重塑^[21];加之心力衰竭使神经体液发生改变造成心脏负担加重,导致疾病恶化。阻断心肌重构是治疗心衰的关键^[22]。临床上使用强心剂、利尿剂和血管扩张剂治疗CHF时,联合β-受体阻滞剂、ARB、ACEI等药物,有抑制激活的神经-内分泌系统^[23],改善心肌能量代谢及重建血运^[24]的作用。但这些药物治疗CHF时易引起低血压。而注射用

益气复脉(冻干)对心衰心室重构有抑制作用,还可以有效缓解和改善症状^[25-26],同时能预防和纠正低血压的发生^[11-12]。

CHF属祖国医学“心悸”“胸痹”范畴,以气阴两虚型常见,治以益气养阴、活血化瘀。注射用益气复脉(冻干)源自生脉散,红参能益气滋阴,麦冬养阴生津,益气敛阴生津,三药共奏具有益气复脉、养阴生津之效。可有效缓解气阴两虚型CHF患者头晕、心慌、胸闷、气促等症。药理研究发现,红参不仅能增强心肌收缩力、降低血管阻力、减轻心脏负荷、改善心肌细胞抗缺氧能力、保护心肌细胞的作用^[24],还能有效调节血压,且不会增加心率^[27];麦冬有稳定心肌细胞膜、正性肌力、降低心肌耗氧量、改善心肌供血、减缓心率、抑制心室重构的作用^[28];五味子有增强心肌收缩力、改善心肌缺血、抗氧化^[29-30]、提高心输出量、提升血压的作用^[31]。此外,注射用益气复脉(冻干)能加速儿茶酚胺的分泌,抑制心肌细胞Na⁺, K⁺-ATP酶活性,降低体循环阻力^[32-33];亦能促进垂体-肾上腺素分泌,增强心肌收缩能力,增加心输出量,使血压升高^[34-35];还能抑制RAS系统和炎症因子的过度激活,改善心衰症状和升高血压,从而改善治疗CHF药物的低血压不良反应^[11-12]。

本研究结果表明,注射用益气复脉(冻干)联合ACEI、ARB等药物治疗老年冠心病合并CHF伴低血压患者,不仅能改善患者心衰症状及心功能,还能预防化学药引起的低血压不良反应,具有安全性可靠、疗效确切、升压平稳的作用。

利益冲突 所有作者均声明不存在利益冲突

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