

注射用益气复脉(冻干)联合沙库巴曲缬沙坦治疗慢性心力衰竭疗效及对患者hs-cTnT、NT-proBNP及左心室功能的影响

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摘要: **目的** 探讨注射用益气复脉(冻干)联合沙库巴曲缬沙坦治疗慢性心力衰竭的疗效及对患者高灵敏度肌钙蛋白(hs-cTnT)、氨基端前心钠肽(NT-proBNP)及左心室功能的影响。**方法** 选取2020年1月—2022年12月东营市第五人民医院收治的慢性心力衰竭患者200例为研究对象,根据患者治疗方案不同分为对照组和试验组,每组各100例。对照组在常规治疗基础上采用沙库巴曲缬沙坦钠片治疗,每天2次,初始剂量每次50 mg,后根据患者病情调整剂量,每天最多不超过200 mg。试验组在对照组治疗基础上,联用注射用益气复脉(冻干),5.2 g加入葡萄糖注射液250 mL中,静脉滴注,每天1次。两组均接受持续2周的治疗。统计并比较两组的治疗效果,分别于治疗前后测定血清hs-cTnT、NT-proBNP和转化生长因子 $\beta 1$ (TGF- $\beta 1$)水平,分别于治疗前后行超声心动图检查,检测患者的左室收缩末期内径(LVESD)、左室舒张末期内径(LVEDD)、左室射血分数(LVEF)、左室短轴缩短率(FS)。观察治疗期间两组患者低血压、皮疹、高血钾症、血管性水肿等不良反应的发生情况。**结果** 试验组治疗总有效率为98.00%,显著高于对照组的88.00% ($P < 0.05$)。治疗前,两组患者血清hs-cTnT、NT-proBNP、TGF- $\beta 1$ 水平比较,差异无统计学意义 ($P > 0.05$);治疗后,两组患者血清hs-cTnT、NT-proBNP、TGF- $\beta 1$ 水平均较同组治疗前显著降低,且试验组各指标水平均显著低于对照组 ($P < 0.05$)。治疗前,两组患者左心室功能指标LVESD、LVEDD、LVEF、FS比较,差异均无统计学意义 ($P > 0.05$);治疗后,两组患者LVESD、LVEDD均较本组治疗前显著降低 ($P < 0.05$),而LVEF及FS均较本组治疗前显著升高 ($P < 0.05$),且试验组各指标改善程度均优于对照组 ($P < 0.05$)。试验组发生不良反应3例,总发生率为3.00%,显著低于对照组的15.00% ($P < 0.05$)。**结论** 注射用益气复脉(冻干)联合沙库巴曲缬沙坦治疗慢性心力衰竭,可改善患者左心室功能,降低心肌受损;还可降低hs-cTnT、NT-proBNP水平,减少药物不良反应,增强临床疗效。

关键词: 注射用益气复脉(冻干);慢性心力衰竭;沙库巴曲缬沙坦;左心室功能;高灵敏度肌钙蛋白;氨基端前心钠肽;转化生长因子 $\beta 1$

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Effects of Yiqi Fumai Lyophilized Injection combined with sacubitril/valsartan on chronic heart failure and its effect on hs-cTnT, NT-proBNP and left ventricular function of patients

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Abstract: Objective To investigate the efficacy of Yiqi Fumai Lyophilized Injection (YQFM) combined with sacubitril/valsartan in the treatment of chronic heart failure and the effects on high-sensitivity troponin (hs-cTnT), N-terminal pro brain natriuretic peptide (NT-proBNP) and left ventricular function in patients with chronic heart failure. **Methods** A total of 200 patients with chronic heart failure admitted to the Fifth People's Hospital of Dongying City from January 2020 to December 2022 were selected as the research objects. According to the different treatment schemes of patients, they were divided into the control group and the experimental group, with 100 cases in each group. On the basis of routine treatment, patients in the control group were treated with Sacubitril Valsartan Sodium Tablets, which was taken twice a day on an empty stomach or with food, with an initial dose of 50 mg each time.

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After that, the dosage was adjusted according to the patient's condition, with a maximum of 200 mg per day. On the basis of treatment in the control group, patients in the experimental group received a combination of YQFM, and 5.2 g of YQFM was added to 250 mL of Glucose Injection, intravenous drip once a day. Both groups received treatment lasting for two weeks. The therapeutic effects of the two groups were counted and compared. Serum hs-cTnT, NT-proBNP and transforming growth factor $\beta 1$ (TGF- $\beta 1$) were measured before and after treatment. Horizontal echocardiography was performed before and after treatment to measure the left ventricular end systolic diameter (LVESD), left ventricular end diastolic diameter (LVEDD), LVEF, and left ventricular short axis shortening rate (FS) of the patients. The incidence of adverse reactions such as hypotension, rash, hyperkalemia and angioedema in the two groups were observed during the treatment. **Results** The total effective rate of the experimental group was 98.00%, significantly higher than the 88.00% of the control group ($P < 0.05$). Before treatment, the serum hs-cTnT, NT-proBNP, and TGF- $\beta 1$ levels of patients in both groups were measured and there were no statistically significant difference in level comparison between two groups ($P > 0.05$). After treatment, the serum levels of hs-cTnT, NT-proBNP, and TGF- $\beta 1$ in both groups of patients were significantly lower than before treatment in the same group, and the levels of all indicators in the experimental group were significantly lower than those in the control group ($P < 0.05$). Before treatment, there was no statistically significant difference in left ventricular function indicators LVESD, LVEDD, LVEF, and FS between the two groups of patients ($P > 0.05$). After treatment, LVESD and LVEDD in both groups of patients were significantly reduced compared to before treatment in the same group ($P < 0.05$), while LVEF and FS were significantly increased compared to before treatment in same group ($P < 0.05$), and the improvement degree of all indicators in the experimental group was better than that in the control group ($P < 0.05$). There were three cases of adverse reactions in the experimental group, with a total incidence rate of 3.00%, significantly lower than the 15.00% in the control group ($P < 0.05$). **Conclusion** YQFM combined with sacubitril valsartan can improve left ventricular function and reduce myocardial damage in patients with chronic heart failure. On the other hand, it can reduce the levels of hs-cTnT and NT-ProBNP, reduce adverse drug reaction, and enhance clinical efficacy.

Key words: Yiqi Fumai Lyophilized Injection; chronic heart failure; sacubitril/valsartan; left ventricular function; high sensitivity troponin; N-terminal brain natriuretic peptide precursor; transforming growth factor $\beta 1$

在临床上,慢性心力衰竭是一种常见心血管疾病,也是心脏疾病的终末期,主要症状为呼吸困难、下肢水肿等,易造成恶性心律失常、心源性猝死,严重威胁患者的生命安全。对于慢性心力衰竭患者的治疗,既要在短期内缓解症状,又要延缓心肌重构,避免疾病恶化^[1]。沙库巴曲缬沙坦是目前治疗此类疾病的常用药,具有利尿、扩张血管、降血压等作用,但部分患者治疗后仍未达到理想效果,而且停药后易复发,整体疗效不佳。注射用益气复脉(冻干)是一种新型药,具有生津养阴、益气复脉、增加心肌代谢的作用,多用于慢性心力衰竭合并冠心病的治疗中^[2-3]。本研究选取200例慢性心力衰竭患者为研究对象,探讨注射用益气复脉(冻干)联合沙库巴曲缬沙坦的治疗效果,为临床更高效合理用药提供参考。

1 资料与方法

1.1 一般资料

选取2020年1月—2022年12月东营市第五人民医院收治的慢性心力衰竭患者200例为研究对象,其中,女性83例,男性117例;年龄37~70岁,平均年龄(56.59±6.37)岁;病程1~11年,平均病程(6.52±0.53)年;NYHA心功能分级:II级96例、

III级69例、IV级35例。

1.2 纳入标准和排除标准

1.2.1 纳入标准 (1)符合《中国心力衰竭诊断和治疗指南2014》^[4]中关于慢性心力衰竭的诊断标准,伴有水肿、呼吸困难等症状;(2)左室射血分数(LVEF)≤40%;(3)患者资料齐全;(4)意识清楚,自愿参与调查。

1.2.2 排除标准 (1)严重感染患者;(2)对本研究所用药物过敏者;(3)恶性肿瘤患者;(4)急性心力衰竭患者;(5)高钾血症患者。

1.3 治疗方法

两组患者入院后,均接受血糖、血压控制,调节水电解质紊乱等对症治疗,并指导其低脂、低盐饮食和运动,戒烟酒。对照组接受沙库巴曲缬沙坦钠片(Novartis Pharma Schweiz AG,批准文号HJ20170362,批号SFA68)治疗,空腹或和食物同服,每天2次,初始剂量每次50 mg,后根据患者病情调整剂量,每天最多不超过200 mg。试验组在对照组治疗基础上,联用注射用益气复脉(冻干)(天士力之骄药业有限公司生产,国药准字Z20060463,批号20191125、20200210、20210434、20220104、20220531),将注射用益气复脉(冻干)5.2 g加入葡

葡萄糖注射液 250 mL 中,静脉滴注,每天1次。两组均接受持续2周的治疗。

1.4 观察指标

1.4.1 疗效判定 参照《中药新药临床研究指导原则》^[5]制定,症状、体征缓解,心功能分级提高2级及以上,为显效;症状、体征改善,心功能分级提高1级及以上,为好转;症状、体征未发生变化,或病情加重,为无效。

总有效率=(显效+好转)例数/总例数

1.4.2 血清指标检测 分别于治疗前后采集两组患者空腹静脉血 3 mL,离心处理(3 000 r·min⁻¹离心 15 min)取血清,应用罗氏 E170 全自动电化学发光分析仪检测高灵敏度肌钙蛋白(hs-cTnT)水平,应用 Elecsys 2010 全自动荧光免疫分析仪检测氨基端前心钠肽(NT-proBNP)水平,应用 ELISA 试剂盒(上海信裕生物科技有限公司,型号 XY-9001E)检测转化生长因子β1(TGF-β1)水平。

1.4.3 左心室功能指标检测 分别于治疗前后用 LOGIQ7-PRO 型彩色多普勒超声仪行超声心动图检查,检测患者的左室收缩末期内径(LVESD)、左室舒张末期内径(LVEDD)、LVEF、左室短轴缩短率(FS)。

1.4.4 不良反应情况观察 观察治疗期间两组患者低血压、皮疹、高血钾症、血管性水肿等不良反应的发生情况。

1.5 统计学处理

采用 SPSS 27.0 软件处理数据,计数资料用例数或百分比表示,组间比较采用χ²检验;符合正态分布的计量资料用 $\bar{x} \pm s$ 表示,组间比较采用t检验。 $P < 0.05$ 为差异具有统计学意义。

2 结果

2.1 两组患者基线资料比较

根据治疗方案不同,200例患者分为对照组和试验组,每组各100例。对照组女41例,男59例;年龄最小者38岁,最大者70岁,平均年龄(52.65±

5.46)岁;病程最短1年,最长11年,平均病程(6.02±0.49)年;心功能分级:II级49例、III级34例、IV级17例。试验组女42例,男58例;年龄最小者37岁,最大者69岁,平均年龄(52.63±5.41)岁;病程最短1年,最长10年,平均病程(5.99±0.51)年;心功能分级:II级47例、III级35例、IV级18例。两组上述基线资料比较,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2周后,试验组治疗显效、好转共98例,总有效率为98.00%,显著高于对照组的88.00%($P < 0.05$)。见表1。

表1 两组临床疗效比较

Table 1 Comparison of clinical efficacy between two groups

组别	n/例	显效/例	好转/例	无效/例	总有效率/%
对照	100	43	45	12	88.00
试验	100	50	48	2	98.00*

与对照组比较: * $P < 0.05$

* $P < 0.05$ vs control group

2.3 两组血清 hs-cTnT、NT-proBNP 和 TGF-β1 水平比较

治疗前,两组患者血清 hs-cTnT、NT-proBNP、TGF-β1 水平比较,差异无统计学意义($P > 0.05$);治疗后,两组患者血清 hs-cTnT、NT-proBNP、TGF-β1 水平均较同组治疗前显著降低,且试验组各指标水平均显著低于对照组($P < 0.05$)。见表2。

2.4 两组患者左心室功能指标比较

治疗前,两组患者左心室功能指标 LVESD、LVEDD、LVEF、FS 比较,差异均无统计学意义($P > 0.05$);治疗后,两组患者 LVESD、LVEDD 均较本组治疗前显著降低($P < 0.05$),而 LVEF 及 FS 均较本组治疗前显著升高($P < 0.05$),且试验组各指标改善程度均优于对照组($P < 0.05$)。见表3。

表2 两组血清 hs-cTnT、NT-proBNP 和 TGF-β1 水平比较 ($\bar{x} \pm s$)

Table 2 Comparison of serum hs-cTnT, NT-proBNP, and TGF-β1 levels between two groups ($\bar{x} \pm s$)

组别	n/例	时间	hs-cTnT/(μg·L ⁻¹)	NT-proBNP/(pg·mL ⁻¹)	TGF-β1/(ng·L ⁻¹)
对照	100	治疗前	1.92±0.43	536.30±94.56	335.60±72.45
		治疗后	1.30±0.31*	468.35±52.01*	287.41±35.22*
试验	100	治疗前	1.90±0.41	536.25±94.52	335.58±72.41
		治疗后	0.79±0.22**	320.63±30.11**	154.22±33.66**

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 两组患者左心室功能指标比较 ($\bar{x} \pm s$)Table 3 Comparison of left ventricular function index between two groups ($\bar{x} \pm s$)

组别	n/例	时间	LVESD/mm	LVEDD/mm	LVEF/%	FS/%
对照	100	治疗前	54.42±6.03	61.98±7.36	36.82±3.71	35.82±4.16
		治疗后	48.51±5.21 [*]	56.91±4.13 [*]	49.60±5.22 [*]	46.80±5.60 [*]
试验	100	治疗前	54.40±6.01	61.95±7.32	36.80±3.65	35.80±4.12
		治疗后	44.22±5.01 ^{*#}	50.21±4.25 ^{*#}	56.80±5.41 ^{*#}	54.23±5.70 ^{*#}

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

2.5 两组不良反应情况比较

统计显示,试验组发生不良反应3例,总发生率为3.00%,显著低于对照组的15.00% ($P < 0.05$)。见表4。

表4 两组不良反应发生情况比较

Table 4 Comparison of Adverse Reactions between two groups

组别	n/例	皮疹/例	血管性水肿/例	低血压/例	高钾血症/例	总发生率/%
对照	100	7	2	3	3	15.00
试验	100	2	1	0	0	3.00 [*]

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

3 讨论

慢性心力衰竭是中老年人常见病,病情迁延不愈,需要长时间住院治疗,对患者生活质量、生命安全的影响极大。研究表明^[6-7],心功能不全和多个系统激活关系紧密,如肾素-血管紧张素-交感神经系统等,通过对这些系统的激活,使患者心功能发生变化,从而加重心肌功能受损,加速心功能恶化。另外,随着左心室的充盈扩大,逆向传至肺静脉,导致肺静脉回流异常、肺小动脉收缩,继而影响患者的心肺功能^[8-9]。目前,临床多采用 β 受体阻滞剂、血管扩张剂等药物治疗慢性心力衰竭,常见如沙库巴曲缬沙坦,其是沙库巴曲和缬沙坦的复合制剂,前者为脑啡肽酶抑制剂,可升高脑钠肽水平,对抗交感神经激活产生的副作用,用药后可快速达到峰值,具有药物见效快、生物利用率高的特点;后者是降压药,可阻断血管紧张素II受体,降低血压水平,同时还能逆转高血压引发的左心室肥厚,改善患者的远期预后^[10-11]。有报告显示,虽然此类药物效果显著,但单独使用易引发低血压、血管性水肿等不良反应,影响治疗效果^[12]。

在中医领域,慢性心力衰竭属于“心悸”范畴,

由过度疲劳、外邪入侵等导致心脏受损,故以温阳通肺、活血益气作为治疗原则。注射用益气复脉(冻干)是一种中药制剂,由五味子、红参、麦冬组成^[13],其中红参可滋补元气,麦冬可生津养阴、止渴,五味子可收敛心气,诸药联用共奏益气、生津之功效。现代药理研究表明,红参可增强心肌收缩力,强化机体耐缺氧能力,从而促进心肌细胞RNA、DNA合成;麦冬可修复受损心肌细胞,改善心功能^[14]。注射用益气复脉(冻干)和沙库巴曲缬沙坦联合使用可获得理想的治疗效果。

本研究以200例慢性心力衰竭患者为对象,结果表明试验组治疗总有效率高于对照组,且不良反应发生率低于对照组 ($P < 0.05$)。在血清指标水平、左心室功能指标方面,试验组的改善作用同样优于对照组 ($P < 0.05$),提示注射用益气复脉(冻干)联合沙库巴曲缬沙坦治疗可有效改善慢性心力衰竭患者症状、血清指标与心功能指标,且能够减少药物不良反应的发生,从而提高治疗效果,促进患者早日康复^[15]。现代药理研究表明,注射用益气复脉(冻干)可抑制交感神经,降低血液中的hs-cTnT、NT-proBNP浓度,同时提高患者心脏顺应性,增强心脏泵功能,从而增加左心室舒张末期面积,改善患者心功能,和沙库巴曲缬沙坦联用可发挥药物协同作用,实现标本兼治的目的^[16-17]。此外,沙库巴曲缬沙坦长期使用会引发高钾血症、低血压等不良反应,而注射用益气复脉(冻干)不良反应少,少数可出现轻微发热、皮疹等。研究^[18]表明,注射用益气复脉(冻干)治疗慢性心力衰竭伴低血压效果理想,患者血压水平升高,心功能改善。方剂中五味子和红参中含有皂苷,能够对钙离子通道起到拮抗作用,并具有抵抗自由基的作用,促进患者血流改变,促使冠脉血管扩张,利于减少外周阻力,增加血流量,对血压进行有效调节,且不会增加心率^[19]。

本研究结果表明,对慢性心力衰竭患者进行注射用益气复脉(冻干)和沙库巴曲缬沙坦联合治疗,

一方面可改善患者左心室功能,降低心肌受损;另一方面可降低hs-cTnT、NT-ProBNP水平,减少药物不良反应,增强临床疗效,值得推广。

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