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参松养心胶囊联合胺碘酮对心力衰竭后室性心律失常患者的应用效果 及对心率变异性影响*

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摘要 目的:探讨对心力衰竭后室性心律失常患者应用参松养心胶囊联合胺碘酮进行治疗的效果。**方法:**选择 150 例心力衰竭后室性心律失常,根据随机数字表法,将 150 例患者分为 A 组、B 组、C 组,每组 50 例。所有患者均行常规抗心力衰竭治疗,A 组患者给予参松养心胶囊治疗,B 组患者给予胺碘酮片治疗;C 组给予胺碘酮片联合参松养心胶囊治疗。对比三组的疗效,对比三组治疗前后的心功能指标、24 h 动态心电图指标、心率变异性指数,对比三组治疗过程中的不良反应发生情况。**结果:**C 组治疗有效率明显较 A 组、B 组高($P<0.05$),A 组、B 组间对比无统计学意义($P>0.05$)。与治疗前相比,A、B、C 三组的 LVDs、LVDd 降低,LVEF、CO、SV 明显升高,且 C 组较 A、B 组比较有相同趋势($P<0.05$);A 组与 B 组间对比无统计学意义($P>0.05$)。与治疗前相比,A、B、C 三组的室性心动过速数量、室性早搏数量、QTd 明显降低,QTc 升高,且 C 组较 A、B 组比较有相同趋势($P<0.05$);A 组与 B 组间对比无统计学意义($P>0.05$)。三组不良反应发生率比较无差异($P>0.05$)。**结论:**与单独应用参松养心胶囊、胺碘酮相比,参松养心胶囊联合胺碘酮会提高疗效,且应用安全,可能与其可改善患者的心率变异性有关。

关键词:参松养心胶囊;胺碘酮;心率变异性;心力衰竭后室性心律失常;应用效果

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Effect of Shensong Yangxin Capsule Combined with Amiodarone on Heart Rate Variability in Patients with Ventricular Arrhythmia after Heart Failure*

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ABSTRACT Objective: To explore the effect of Shensong Yangxin capsule combined with amiodarone in patients with ventricular arrhythmia after heart failure. **Methods:** One hundred and fifty ventricular arrhythmias after heart failure were selected, and 150 patients were divided into groups A, B, and C with 50 patients in each group. All patients received routine anti-heart failure treatment, group A patients were given Shensong Yangxin capsule treatment, group B patients were given amiodarone tablet treatment; Group C was treated with amiodarone tablet combined with Shensong Yangxin capsule. The efficacy of the three groups was compared, and the cardiac function index, 24 h dynamic electrocardiogram index and heart rate variability index before and after treatment were compared, and the occurrence of adverse reactions during treatment was compared between the three groups. **Results:** The treatment effective rate of group C was significantly higher than the other groups ($P<0.05$), but there was no statistical significance between group A and group B ($P>0.05$). Moreover, groups A, B, and C had decreased LVDs, increased LVEF, CO, and SV and showed the same trend compared with Group A and B ($P<0.05$); there was no significant comparison between group A and B ($P>0.05$). Compared with before treatment, the number of ventricular tachycardia, QTd, ventricular beats, increased QTc, and the same trend in group A and C compared with group A and B ($P<0.05$); there was no significant comparison between group A and B ($P>0.05$). There was no difference in the incidence of adverse reactions between the three groups ($P>0.05$). **Conclusion:** Compared with Shensong Yangxin capsule and amiodarone alone, Shensong Yangxin capsule combined with amiodarone will improve the efficacy and safe application, which may be related to the improvement of heart rate variability in patients.

Key words: Shensong Yangxin capsule; Amiodarone; Heart rate variability; Ventricular arrhythmia after heart failure; Application effect

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前言

各种心脏疾病的严重阶段为心力衰竭,疾病发病率高,疾病危害性大,引起心力衰竭的主要因素是心肌梗死^[1]。有研究发现^[2],近十年来,我国 ST 段抬高型心肌梗死患者的人数不断增加,使得心肌梗死后心力衰竭的发病率也不断增加,因此心肌梗死后患者心力衰竭的防治、猝死率降低方面有重要意义。心力衰竭患者死亡多是因恶性心律失常、进行性心力衰竭诱发的心源性猝死引起的^[3]。近年来,随着血管紧张素转换酶抑制剂、 β 受体阻滞剂等心脏重塑药的应用,降低了进行性心力衰竭引起的死亡率,使得因恶性心律失常引起的心衰患者死亡占比升高^[4]。有研究发现^[5],与普通人群相比,心力衰竭患者猝死发生率是其 6~9 倍,而其中约有一半以上患者因恶性心律失常诱发的心源性猝死,恶性心律失常患者多表现为心室颤动、室性心动过速等,临床中需给予积极治疗。ACC/AHA 心衰指南认为,尽早应用 β 受体阻滞剂、ACEI 是慢性心力衰竭患者的治疗基石^[6]。而对于心力衰竭合并室性心律失常患者的治疗中, β 受体阻滞剂会明显降低心力衰竭患者心律失常的发生^[7],若心力衰竭患者存在明显的液体潴留情况,需禁用 β 受体阻滞剂,否则会加重患者的心力衰竭症状^[8]。胺碘酮对患者的生存终点是中

性作用,但是仍有可能使得患者甲状腺功能出现异常,并使肺纤维化,所以导致该药物的临床应用有所限制^[9]。当前发现中药可干预心肌细胞离子通道、控制神经内分泌系统过度激活,同时其副作用相对较少,患者可耐受^[10]。参松养心胶囊是目前常用的纯中药制剂,可用于室早、房颤的治疗,同时无负性肌力作用,可用于抗心律失常^[11]。基于此,本研究将参松养心胶囊联合胺碘酮应用于心力衰竭后室性心律失常患者,进行了分析。

1 资料与方法

1.1 病例资料

本研究为前瞻性研究。选择来我院 2022 年 1 月至 2023 年 10 月的心力衰竭后室性心律失常患者 150 例。西医诊断标准:心力衰竭符合诊断标准^[12],同时室性心律失常的诊断标准^[13]。中医诊断标准:气阴两虚型。

纳入标准:接受心力衰竭用药剂量稳定的标准治疗超过 3 个月;知情同意。排除标准:恶性肿瘤者;合并心脏瓣膜病者;难以控制的高血压者;合并心脏瓣膜病者;患者近 3 个月内出现急性冠脉综合征者;自主神经功能障碍者;异位心律者。

根据随机数字表法,将 150 例患者分为 A 组、B 组、C 组。三组基本资料对比无统计学意义($P>0.05$)。

表 1 三组一般资料对比

Table 1 Comparison of the three groups of general data

Groups	n	Male /Female	Age(Year)	Course of disease (Year)	Underlying disease			Cardiac function classification		
					Coronary heart disease	Dilated cardiomy- opathy	Hyperten- sive heart disease	Grade II	Grade III	Grade IV
Group A	50	27/33	66.45±3.52	8.25±1.89	17	15	18	19	24	7
Group B	50	28/22	66.89±3.02	8.14±1.75	18	13	19	21	23	6
Group C	50	31/19	65.34±2.89	8.35±1.94	21	13	16	19	23	8
F/ χ^2		3.608	1.253	1.421		0.924			0.520	
P		0.165	0.351	0.298		0.921			0.972	

1.2 方法

所有患者均行常规抗心力衰竭治疗,包括利尿、强心、心肌营养剂、血管扩张等,A 组患者给予参松养心胶囊治疗,每次 4 粒,每天 3 次;B 组患者给予胺碘酮片治疗,每次 0.2 g,每天 3 次,服用 5~7 d,之后逐渐减少剂量,直至 0.1 g/次,每天 1 次,服药期间,可根据生理指标调整胺碘酮用量,若患者有严重的窦性心动过缓或传导阻滞,或出现其他恶性心律失常,则立即停止用药;C 组给予胺碘酮片联合参松养心胶囊治疗,药物服用方法及注意事项同 A、B 组。

两组患者均连续用药 4 周后对比其应用效果。

1.3 观察指标

1.3.1 对比三组的疗效 治疗后患者室性期前收缩发作次数降低 >90%或完全消失,临床体征、症状消失为显效;治疗后患者的室性心动过速发作次数降低 >50%或室性期前收缩发作次数降低 50%~90%,临床体征、症状改善为有效;治疗后未达到有效标准为无效^[14]。

1.3.2 对比三组治疗前后的心功能指标 左心室射血分数(LVEF)、左心室收缩内径(LVDs)、舒张期内径(LVDd)、心排量(CO)、每搏量(SV),取 3 个心动图周期取均值。

1.3.3 对比三组治疗前后的 24 h 动态心电图指标 包括室性心动过速数量、室性早搏数量、校正 QT 间期(QTc)、QT 间隔离散(QTd)水平。

1.3.4 对比三组治疗前后的心率变异性指数 包括每 5 min N-N 间期平均值标准差(SDANN)、窦性心率 R-R 间期标准差(SDNN)、相邻 N-N 间期差值均方根(RMSSD)值。

1.4 统计学方法

SPSS23.0 软件,计数资料频数表示,卡方检验分析,计量资料 $\bar{x}\pm s$ 表示,单因素方差检验,组间两两对比 SNK 法, $P<0.05$ 为差异有统计学意义。

2 结果

2.1 对比三组的疗效

C组疗效明显较A组、B组高($P<0.05$),A组、B组间对比 无差异($P>0.05$)。

表1 三组的疗效对比(n/%)

Table 1 The efficacy of the three groups was compared(n/%)

Groups	n	Remarkable	Effective	In vain	Effective rate
Group A	50	18	17	15	35(70.00)
Group B	50	20	19	11	39(78.00)
Group C	50	25	23	2	48(96.00) ¹⁾²⁾
χ^2					11.680
P					0.003

Note: Compared with group A, ¹⁾ $P<0.05$; Compared with group B, ²⁾ $P<0.05$.

2.2 对比三组治疗前后的心功能指标

CO、SV 明显升高, 且 C 组较 A、B 组比较有相同趋势($P<0.05$);A 组与 B 组间对比无差异($P>0.05$)。与治疗前相比,A、B、C 三组的 LVDs、LVDd 降低,LVEF、

表2 对比三组治疗前后的心功能指标($\bar{x}\pm s$)

Table 2 The indexes of cardiac function before and after treatment were compared between the three groups($\bar{x}\pm s$)

Groups	Times	LVDs(mm)	LVEF(%)	LVDd(mm)	CO(L/min)	SV(mL)
Group A	Before treatment	36.98±3.56	42.10±3.12	51.12±4.10	4.21±0.99	39.34±3.23
	After treatment	32.15±2.12 ³⁾	46.62±3.89 ³⁾	42.09±3.55 ³⁾	4.89±1.09 ³⁾	42.78±4.12 ³⁾
Group B	Before treatment	37.34±3.89	41.98±3.78	51.90±4.57	4.14±0.88	39.10±2.89
	After treatment	31.89±2.29 ³⁾	47.01±4.10 ³⁾	41.56±3.89 ³⁾	5.12±1.23 ³⁾	44.10±3.89 ³⁾
Group C	Before treatment	37.05±3.12	41.56±3.77	51.66±5.23	4.30±1.19	38.75±4.28
	After treatment	28.78±1.88 ¹⁾²⁾³⁾	51.09±5.12 ¹⁾²⁾³⁾	38.78±4.44 ¹⁾²⁾³⁾	5.67±1.25 ¹⁾²⁾³⁾	55.41±5.22 ¹⁾²⁾³⁾

Note: Compared with before treatment, ³⁾ $P<0.05$.

2.3 对比三组治疗前后的 24 h 动态心电图指标

搏数量、QTd 明显降低,QTc 升高, 且 C 组较 A、B 组比较有相同趋势($P<0.05$);A 组与 B 组间对比无差异($P>0.05$)。与治疗前相比,A、B、C 三组的室性心动过速数量、室性早

表3 对比三组治疗前后的 24 h 动态心电图指标($\bar{x}\pm s$)

Table 3 The 24 h holter electrocardiogram indexes before and after treatment were compared between the three groups($\bar{x}\pm s$)

Groups	Times	Number of ventricular tachycardia (one / 24 h)	Number of premature ventricular beats (one / 24 h)	QTc(ms)	QTd(ms)
Group A	Before treatment	63.75±5.12	481.52±38.52	416.78±32.12	67.41±8.41
	After treatment	48.12±4.85 ³⁾	345.12±30.12 ³⁾	507.41±35.12 ³⁾	60.74±6.42 ³⁾
Group B	Before treatment	64.12±5.78	485.10±39.41	415.10±33.10	67.89±7.45
	After treatment	46.10±5.10 ³⁾	342.40±28.75 ³⁾	506.74±35.41 ³⁾	58.10±5.98 ³⁾
Group C	Before treatment	64.19±6.12	484.10±40.12	417.12±30.45	67.10±7.41
	After treatment	40.10±4.88 ¹⁾²⁾³⁾	300.10±24.15 ¹⁾²⁾³⁾	521.20±36.41 ¹⁾²⁾³⁾	50.40±4.89 ¹⁾²⁾³⁾

2.4 对比三组治疗前后的心率变异性指数

与治疗前相比,A、B、C 三组的 SDANN、SDNN、RMSSD 明显升高,且 C 组以上指标明显较 A、B 组高($P<0.05$);A 组与 B 组间对比无差异($P>0.05$)。

2.5 对比三组治疗过程中不良反应情况

治疗过程中三组不良反应发生率无差异($P>0.05$)。

3 讨论

心力衰竭是一种表现为心脏无法有效地泵血以满足身体

正常代谢需求的临床综合征, 该疾病是一种慢性进展性疾病, 疾病预后较差, 是较多心脏疾病的终末期,5 年生存率较低^[16]。近年来, 随着临床中 ACEI、 β_1 受体阻滞剂、利尿剂的广泛应用,心力衰竭患者的生活质量有了明显改善,但心理衰竭患者的死亡率仍较高,而死亡原因主要是心源性猝死、恶性心律失常,约 50%~75%死亡患者与室性心律失常有关^[17]。心力衰竭患者主要为室性心律失常,其会诱发加重心力衰竭,会使患者产生恶性心律失常,成为心源性猝死的一个主要原因^[18]。因此对于心力衰竭后室性心律失常需给予积极的防治,随着中医药技

表 4 对比三组治疗前后的心率变异性指数($t/ms, \bar{x} \pm s$)Table 4 The heart rate variability index before and after treatment was compared between the three groups($t/ms, \bar{x} \pm s$)

Groups	Times	SDANN	SDNN	RMSSD
Group A	Before treatment	127.41±18.75	108.41±21.10	32.75±3.74
	After treatment	152.41±19.74 ³⁾	175.42±25.15 ³⁾	42.10±4.12 ³⁾
Group B	Before treatment	126.74±17.42	107.88±20.47	33.45±4.12
	After treatment	155.78±20.12 ³⁾	178.42±26.42 ³⁾	43.52±4.85 ³⁾
Group C	Before treatment	128.42±20.41	108.89±22.75	32.99±3.99
	After treatment	189.41±22.45 ¹⁾²⁾³⁾	201.23±19.75 ¹⁾²⁾³⁾	49.75±5.42 ¹⁾²⁾³⁾

表 5 对比三组治疗过程中的不良反应发生情况(n/%)

Table 5 The occurrence of adverse reactions during treatment was compared between the three groups(n/%)

Groups	n	Gastric distension	Hepatic injury	Nausea and vomiting	Incidence rate
Group A	50	1	0	1	2(4.00)
Group B	50	2	1	2	5(10.00)
Group C	50	2	2	2	6(12.00)
χ^2					2.190
P					0.335

术的发展,中西医结合已成为心力衰竭后室性心律失常患者的常用治疗方法^[19]。

中医认为心力衰竭病位在心,属于虚实夹杂、本虚标实之证,发病病因为水停、痰阻、气滞、血瘀,其心气心阳亏虚为本,气滞血瘀、痰饮寒凝为标,心主血脉^[20]。心力衰竭患者发病人群多为 60 岁以上,中医证型为气阴两虚^[21]。当心力衰竭患者的证型是气阴两虚型,则其治疗原则为宁心安神、益气养阴,方用生脉散合炙甘草汤加减。中成药参松养心胶囊是以生脉散为基础,用于气血两虚型心力衰竭伴心悸患者的中药制剂^[22]。

本文结果表明,C 组的治疗有效率明显较 A 组、B 组高,A 组、B 组间对比无差异,表明单独应用,表明单独应用参松养心胶囊对胺碘酮心力衰竭后室性心律失常的疗效相当,而联合应用参松养心胶囊、胺碘酮较单一参用药,可提高疗效,主要是由于胺碘酮是抗心律失常药,会明显阻断钠、钙、钾离子通道,将各心肌细胞的动作电位时程、有效不应期延长,同时其具有抗心律失常药的特性,可抑制交感神经兴奋,抗肾上腺素兴奋^[23];参松养心胶囊具有疏通脉络、滋阴补气、宁心安神的作用,其是以生脉散为基础方,佐以安神定志、活血通络的药物,可改善心悸不安,在这之中人参可生津养血、补中益气;麦冬益气养阴;五味子收敛生津,三者共奏益气养阴复脉之效;外加赤芍、丹参、土鳖虫、甘松,活血通络,龙骨、酸枣仁可安神定志,君臣佐使,亦通亦补,从而改善心力衰竭后室性心律失常患者的疗效,胺碘酮联合应用参松养心胶囊,起到了协同作用,从而提高了治疗效果^[24]。

本研究结果发现,与治疗前相比,A、B、C 三组的 LVDs、LVDd 降低,LVEF、CO、SV 明显升高,且 C 组较 A、B 组比较有相同趋势;与治疗前相比,A、B、C 三组的室性心动过速数量、室性早搏数量、QTd 明显降低,QTc 升高,且 C 组较 A、B 组比较有相同趋势。表明二者联合会明显改善心力衰竭后室性心律

失常者的心功能及心率变异性。主要是由于心律失常会导致机体的心肌收缩力出现无节律情况,提高了心肌耗氧量,进而加重了心力衰竭症状,因此对于心力衰竭后室性心律失常需明显改善患者的心律失常情况^[25]。方中甘松所含成分缬草酮可结合特异蛋白。调节 K^+ 、 Na^+ 通道,促使 K^+ 外流,对 Na^+ 内流产生抑制作用,进而使得心肌细胞自律性降低,延长动作电位时间,进而控制心律失常^[26];人参皂苷可促进儿茶酚胺释放,降低 Na^+ - K^+ -ATP 酶活性,提高 Na^+ 含量进而正性肌力,且人参可增加心率,起到强心作用^[27];麦冬可明显改善实验动物缺氧能力,增加冠状动脉血流量,对心律失常起到作用;桑寄生可抑制 Na^+ - K^+ -ATP 酶活性,对心肌代谢起到改善作用,降低心脏自律性^[28];山茱萸使得动作电位时程延长,降低心肌细胞自律性;酸枣仁中总皂苷可抗心律失常,以上多种中药成分合用,改善患者的心肌缺血、心律失常情况;而胺碘酮中主要化学成分为含碘呋喃衍生物,可以阻断 K^+ 、 Na^+ 、 Ca^{2+} 通道,阻断 α 、 β ,对复极化进行抑制,延长电位时程,同时可降低传导性、自律性,联合用药可协同改善心功能。心率变异性可用于评估迷走神经、交感神经张力对心脏的支配成功程度,是预测心脏疾病心律失常、监测药物疗效的指标,用于判断心血管疾病的预后,本研究结果也表明二者联合明显提高心力衰竭后室性心律失常的心率变异性,表明二者疗效较好。

治疗过程中三组不良反应发生率无统计学意义,表明二者联合未明显增加治疗过程中的不良反应,临床中可用于心力衰竭后室性心律失常患者的治疗。

而临床中对于频发室性、室上性早搏患者,尤其是器质性心脏病的心率偏慢者、功能性早搏者,需首选参松养心胶囊,其心律失常作用较胺碘酮弱,而对于严重的心律失常患者,需尽快缓解患者的临床症状,及早控制疾病病情,可以有限的使用胺碘酮。二者联合可以结合二者优点,快速有效的改善心力衰

竭后室性心律失常的疗效。

总之,与单独应用参松养心胶囊、胺碘酮相比,参松养心胶囊与胺碘酮联合可提高疗效,且应用安全,可能与其可改善患者的心率变异性有关。

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