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参松养心胶囊对心房颤动患者 P 波离散度及血清炎性因子水平的影响 *

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摘要 目的:探讨参松养心胶囊对心房颤动(AF)患者 P 波离散度(Pd)及血清炎性因子水平的影响,为临床用药提供依据。**方法:**将西安交通大学第一附属医院 2016 年 3 月-2018 年 1 月收治的 AF 患者纳入本研究,共 148 例。所有患者根据不同的治疗方式分为对照组和观察组。对照组(n=74)接受常规治疗,观察组(n=74)在对照组基础上加用参松养心胶囊,两组均治疗 8 周。比较两组患者治疗后的临床疗效,观察并比较两组患者治疗前及治疗后的 Pd、最大 P 波时限(Pmax)变化情况,检测两组患者治疗前及治疗后的血清炎性因子水平,记录不良反应发生情况。**结果:**观察组总有效率为 89.19%(66/74),高于对照组的 70.27%(52/74)($P<0.05$)。两组患者治疗后的 Pmax、Pd 均明显降低,且观察组患者治疗后的 Pmax、Pd 均明显低于对照组($P<0.05$)。两组患者治疗后的血清炎性因子水平均明显降低,且与对照组相比,观察组患者治疗后的血清肿瘤坏死因子- α (TNF- α)、高敏 C 反应蛋白(hs-CRP)、白介素-6(IL-6)水平均降低($P<0.05$)。两组不良反应发生情况比较无统计学差异($P>0.05$)。**结论:**参松养心胶囊治疗 AF 患者安全有效,能明显减轻炎症反应,改善患者心功能。

关键词:参松养心胶囊;心房颤动;P 波离散度;炎性因子;疗效

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Effect of Shensong Yangxin Capsule on P Wave Dispersion and Serum Inflammatory Factors in Patients with Atrial Fibrillation*

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ABSTRACT Objective: To investigate the effect of Shensong Yangxin Capsule on the levels of P wave dispersion (Pd) and serum inflammatory factors in patients with atrial fibrillation (AF), and to provide a basis for clinical medication. **Methods:** 148 cases of AF patients who received treatment in the First Affiliated Hospital of Xi'an Jiao Tong University from March 2016 to January 2018 were included in the study. There were 148 cases. All patients were divided into control group and observation group according to different treatment methods. The control group (n=74) received routine treatment, while the observation group (n=74) was additionally treated with Shensong Yangxin Capsule on the basis of the control group. The two groups were treated for 8 weeks. The efficacy of the two groups was compared after treatment. The changes of Pd, maximum P wave time (Pmax) of the two groups were observed before and after treatment. The levels of serum inflammatory factors of the two groups were detected before and after treatment. The adverse reactions of the two groups were recorded. **Results:** The total effective rate of the observation group was 89.19%(66/74), which was significantly higher than 70.27%(52/74) of the control group ($P<0.05$). The Pmax and Pd of the two groups were significantly lower after treatment, and the Pmax and Pd in the observation group were significantly lower than those in the control group ($P<0.05$). And compared with the control group, the levels of serum inflammatory factors in the two groups were significantly lower after treatment. And the levels of serum tumor necrosis factor- α (TNF- α), high sensitive C reactive protein (hs-CRP), interleukin-6 (IL-6) in the observation group were significantly lower ($P<0.05$). There was no significant difference in the incidence of adverse reactions between the two groups ($P>0.05$). **Conclusion:** Shensong Yangxin Capsule is safe and effective in the treatment of AF patients. It can obviously reduce inflammatory reaction and improve cardiac function of patients.

Key words: Shensong Yangxin Capsule; Atrial fibrillation; P wave dispersion; Inflammatory factors; Curative effect

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前言

心房颤动 (Atrial fibrillation, AF) 多发于器质性心血管疾病, 是临床常见的一种心脏疾病, 患者表现为心跳较快且心率不齐, 同时心房的收缩功能减退^[1-3]。AF 发病率随年龄增加而增高, 可引发心力衰竭、脑血栓等严重的心脑系统并发症, 严重威胁着人们的健康^[4-6]。AF 的治疗通常分为抗栓治疗、节律控制、室率控制三类, 但西医尚无明确的根治性疗法。有报道表明^[7-9], 临床治疗 AF 常用的射频消融术在治疗后的复发率为 11%~29%, 而常用的抗心律失常药物均有不同程度的不良反应。近年来, 中医药在 AF 治疗中的应用越来越多, 而参松养心胶囊正是其中较为常用的一种^[10-12]。本研究采用参松养心胶囊对 AF 患者进行治疗, 观察其对患者 P 波离散度 (P wave dispersion, Pd) 及血清炎症因子水平, 旨在探讨参松养心胶囊的作用机制, 为临床用药提供依据。报道如下。

1 资料与方法

1.1 一般资料

选择 2016 年 3 月 -2018 年 1 月期间在西安交通大学第一附属医院接受治疗的 148 例 AF 患者作为研究对象。纳入标准^[13]: ①患者均通过听诊或脉诊, 并结合临床症状确定为异常, 且经心电图确诊为 AF; ②既往未使用抗心律失常药物; ③基础疾病为冠心病、瓣膜病及肺心病; ④患者对本研究知情同意且签署同意书。排除标准: ①严重肝肾功能不全者; ②存在免疫系统疾病或恶性肿瘤者; ③心功能 NYHA 分级 III~IV 级; ④精神失常者; ⑤合并感染或非感染炎症性疾病者。所有患者根据治疗方式的不同分为对照组 (n=74) 和观察组 (n=74)。对照组男 41 例, 女 33 例, 年龄 42~77 岁, 平均 (57.44±6.87) 岁, AF 类型: 阵发性 21 例, 持续性 16 例, 永久性 37 例; 基础疾病: 冠心病 27 例, 瓣膜病 18 例, 肺心病 29 例。观察组男 43 例, 女 31 例, 年龄 40~79 岁, 平均 (59.23±7.15) 岁, AF 类型: 阵发性 22 例, 持续性 17 例, 永久性 35 例; 基础疾病: 冠心病 24 例, 瓣膜病 19 例, 肺心病 31 例。两组 AF 类型、年龄、基础疾病、性别等比较无统计学差异 ($P>0.05$), 均衡可比。西安交通大学第一附属医院伦理委员会已审批本研究。

1.2 治疗方法

对照组给予常规治疗, 主要包括控制心率、抗凝、抗血小板

等, 并对基础疾病进行相应的对症治疗。观察组在对照组的基础上联合应用参松养心胶囊 (国药准字: Z20103032, 生产厂家: 北京以岭药业有限公司, 规格: 0.4 g) 进行治疗, 其成分包括甘松、赤芍、桑寄生、山茱萸、麦冬、人参、丹参、土鳖虫、南五味子、龙骨、酸枣仁 (炒)、黄连, 患者按 3 次/d, 1.6 g/次口服治疗。两组治疗时间均为 8 周。

1.3 观察指标及评价标准

两组患者在治疗后进行疗效评价, 评价分为 3 个等级: 显效: 患者心率及生命体征基本恢复正常或有明显改善, 心悸、胸闷、气短、乏力等症状消失; 有效: 患者心率及生命体征明显改善, 心悸、胸闷、气短、乏力等症状明显减轻或偶有发作; 无效: 患者心率及生命体征、临床症状无明显改善或加重。总有效率 = 显效率 + 有效率。分别于治疗前及治疗后对患者 Pd 进行测定, 所有患者均在安静状态下, 取平卧位记录 12 导联心电图。参数设定: 电压 10 mm/mV, 走纸速度 25 mm/s。每个导联随机取图形清晰的 3 个 P 波时限, P 波时限为 P 波偏离 P 波等电位线的起点至终点的时限, 计算平均值作为最后结果。记录最大 P 波时限 (Pmax) 和最小 P 波时限 (Pmin), 计算 Pd, Pd = Pmax - Pmin。分别于治疗前及治疗后对患者血清炎症因子进行检测: 于清晨取患者空腹静脉血 3 mL, 抗凝离心 10 min (3000 r/min) 分离血清置于 -20℃ 冰箱保存。血清肿瘤坏死因子- α (Tumor necrosis factor- α , TNF- α) 及白介素-6 (Interleukins-6, IL-6) 采用酶联免疫吸附法测定, 高敏 C 反应蛋白 (High sensitive-C reactive protein, hs-CRP) 采用免疫透射比浊法测定, TNF- α 、IL-6 试剂盒购自康肽生物北京有限公司, hs-CRP 试剂盒购自美国 Rapidbio 公司。观察两组治疗期间的不良反应发生情况。

1.4 统计学方法

采用 SPSS24.0 进行统计分析。Pmax、Pd 指标、炎症因子水平等计量资料以 ($\bar{x} \pm s$) 的形式表示, 实施 t 检验, 计数资料以率表示, 实施 χ^2 检验, 检验水准 $\alpha=0.05$ 。

2 结果

2.1 两组患者治疗后疗效评价

观察组总有效率为 89.19% (66/74), 高于对照组的 70.27% (52/74), 差异有统计学意义 ($P<0.05$), 详见表 1。

表 1 两组患者疗效比较[n(%)]

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

Groups	n	Excellence	Effective	Invalid	Total effective rate
Control group	74	18 (24.23)	34 (45.94)	22 (29.73)	52 (70.27)
Observation group	74	26 (35.14)	40 (54.05)	8 (10.81)	66 (89.19)
χ^2					8.194
P					0.004

2.2 两组患者治疗前后心电图指标 Pmax、Pd 比较

治疗前两组患者 Pmax、Pd 比较无统计学差异 ($P>0.05$)。两组患者治疗后的 Pmax、Pd 均明显降低, 且观察组患者 Pmax、

Pd 与对照组比较明显更低 ($P<0.05$), 详见表 2。

2.3 两组患者治疗前后血清炎症因子比较

治疗前两组患者的血清炎症因子水平比较无统计学差异

($P>0.05$)。治疗后两组患者 TNF- α 、IL-6、hs-CRP 水平均明显降低,且观察组血清 hs-CRP、TNF- α 、IL-6 水平与对照组比较明显

表 2 两组患者 Pmax、Pd 变化情况比较($\bar{x}\pm s$)Table 2 Comparison of changes in Pmax and Pd between the two groups($\bar{x}\pm s$)

Groups	n	Pmax(ms)		Pd(ms)	
		Before treatment	After treatment	Before treatment	After treatment
Control group	74	118.92 $\pm$ 6.35	109.32 $\pm$ 4.51*	50.31 $\pm$ 9.22	37.73 $\pm$ 7.31*
Observation group	74	120.58 $\pm$ 6.89	102.87 $\pm$ 3.63*	49.86 $\pm$ 8.73	31.06 $\pm$ 6.98*
t		1.524	9.584	0.305	5.677
P		0.130	0.000	0.761	0.000

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

表 3 两组患者血清 hs-CRP、TNF- α 、IL-6 变化情况比较($\bar{x}\pm s$)Table 3 Comparison of serum hs-CRP, TNF- α and IL-6 levels between the two groups($\bar{x}\pm s$)

Groups	Times	hs-CRP(mg/L)	TNF- α (ng/L)	IL-6(ng/L)
Control group(n=74)	Before treatment	6.71 $\pm$ 1.42	23.02 $\pm$ 3.76	16.23 $\pm$ 3.55
	After treatment	5.58 $\pm$ 1.05*	19.13 $\pm$ 1.86*	12.95 $\pm$ 2.21*
Observation group(n=74)	Before treatment	6.62 $\pm$ 1.39	22.85 $\pm$ 3.54	15.96 $\pm$ 3.28
	After treatment	4.13 $\pm$ 0.97*#	16.72 $\pm$ 1.95*#	10.11 $\pm$ 2.05*#

Note: Compared with before treatment,* $P<0.05$; Compared with control group, # $P<0.05$.

2.4 两组不良反应发生情况分析

治疗过程中两组均无严重不良反应发生,观察组发生恶心/呕吐 2 例,不良反应发生率为 2.70%,对照组未出现不良反应,两组比较差异无统计学意义($\chi^2=2.027$, $P=0.154$)。

3 讨论

AF 是一种常见的心率失常,有文献报道表明^[14,15],AF 可导致心房电生理学甚至结构重构,使其发生的持续时间增长。Pd、Pmax 是近年来被用作评价药物对 AF 疗效及预测 AF 的敏感性指标,作为心房内局部传导的电生理参数,分别反映了心房内存在部位依从性的非匀质性电活动及心房传导变化,两者均能有效反映出心房出现的传导异常,AF 患者的 Pd、Pmax 与健康人群相比明显升高^[16-18]。我国传统医学将 AF 归于“心悸”、“脉结代”、“怔忡”等范畴,为本虚标实或虚实夹杂之证^[19]。外邪入侵、心络失养、气阴两虚、血行不畅、脉络瘀阻、清阳不升、心神不安等为其发病机制^[20,21]。本研究中观察组治疗后的 Pmax、Pd 均明显降低,且明显低于对照组,提示参松养心胶囊对 AF 具有较好的疗效。张军芳等人^[22,23]的研究表明,参松养心胶囊具有多途径、多靶点、多离子通道整合调节的作用,可对自主神经系统、心脏传导功能、多离子通道进行调节。参松养心胶囊全方具有益气养阴、清心安神、活血通络之功效。现代药理学研究^[24]也证实参松养心胶囊中的甘松可结合心肌细胞钾、钠离子通道中的特异蛋白,通过对钾离子外流的促进和钠离子内流的抑制,起到延长动作电位和膜抑制的作用;黄连对心肌动作电位时程具有延长作用;山萸肉可使心肌组织自律性降低;枣酸仁可镇静安神;人参皂苷等多种成分可调整血压、提高心率,有强心的功效。因此参松养心胶囊对 AF 有较好的疗效,对患者

Pmax、Pd 的降低作用明显。

同时有研究表明,炎症因子也是 AF 的致病因素之一,与健康者比较,AF 患者的心耳组织的炎症浸润、心肌纤维化和细胞凋亡均较高^[25,26]。炎症反应可诱发心房心肌炎,通过促使机体 TNF- α 、IL-6 的大量释放激活补体系统,刺激肝细胞对 hs-CRP 的释放,对心肌房细胞造成损伤,加速心房肌细胞的纤维化和坏死,进而引起心率失常的发生,AF 患者血清 hs-CRP、TNF- α 、IL-6 水平均异常升高^[27,28]。参松养心胶囊中许多成分的抗炎作用已经实验证实,如丹参与人参中的活性成分为人参皂苷和人参皂苷等,对小胶质细胞的激活有较为明显的抑制作用,同时在抗细胞凋亡方面作用明显,抗炎活性强;黄连碱可使炎症因子(如 TNF- α 、IL-1 等)的生成减少^[29]。本研究发现,治疗后观察组患者的血清 hs-CRP、TNF- α 、IL-6 水平均明显降低,且与对照组治疗后比较明显更低,同时观察组总有效率明显高于对照组,且未出现明显不良反应,证实参松养心胶囊治疗 AF 安全有效。参松养心胶囊可通过对炎症因子的调节,改善对 AF 患者的临床疗效。胡峻强等人^[30]采用参松养心胶囊对 72 例冠状动脉综合征合并心律失常患者进行治疗,也发现参松养心胶囊能明显降低患者体内的炎症因子水平,与本研究结果一致。

综上所述,参松养心胶囊治疗 AF 安全有效,能明显降低 AF 患者的 Pd,改善患者心功能,同时使患者炎症反应明显减轻。但参松养心胶囊通过降低炎症反应提高对 AF 疗效的具体作用机制仍需进一步的实验研究加以明确。

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