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心血管疾病专题

参松养心胶囊对持续性心房颤动经射频消融术后患者左心功能及生活质量的影响

张国伟，陈守强，张梦贺，左瑶瑶，陈莹，李妍，邢钰尉，赵义凤

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作者单位：250000　济南，山东中医药大学第一临床医学院(张国伟、陈莹、李妍、邢钰尉)；山东中医药大学第二附属医院心血管病科(陈守强、张梦贺、左瑶瑶、赵义凤)

通信作者：张梦贺，E-mail: zhangmenghezmh@163.com

【摘　要】 目的　观察参松养心胶囊对持续性心房颤动经射频消融术后患者窦性心律维持、左心功能及生活质量的影响。**方法**　选取2019年5月—2021年6月在山东中医药大学第二附属医院心血管病科行射频消融术转窦性心律的持续性心房颤动患者60例，随机数字表法分成常规组和联合组，各30例。常规组患者术后给予基础方案治疗，联合组在常规组的基础上服用参松养心胶囊，3个月为1个疗程，治疗2个疗程。每个疗程结束后，监测患者动态心电图、心脏彩色超声指标并统计心房颤动特异生活质量量表(AFEQT)评分，比较2组患者窦性心率维持、左心房内径(LAD)、左心室射血分数(LVEF)，以及不良反应发生情况。**结果**　术后6个月，联合组总有效率高于常规组(90.0% vs. 83.3%，$\chi^2=6.825$，$P=0.033$)。术后3个月，2组AFEQT量表总分及4个维度得分(症状维度、日常活动维度、治疗焦虑维度、治疗满意维度)均高于治疗前($P<0.05$)，且联合组在治疗焦虑维度方面得分高于常规组($P<0.05$)；术后6个月，2组AFEQT量表总分及4个维度得分均高于术前($P<0.05$)，且联合组均高于常规组($t/P=10.311/<0.001$，$6.139/<0.001$，$5.763/<0.001$，$3.076/0.005$，$4.899/<0.001$)。2组术后3个月、6个月窦性心律维持率比较差异无统计学意义($P>0.05$)。术后3个月，联合组左心房内径小于术前，且明显小于常规组($t/P=4.187/<0.001$)，2组LVEF均高于术前($P<0.05$)，而组间比较差异无统计学意义($P>0.05$)；术后6个月，2组左心房内径均小于术前，LEVF均高于术前($P<0.05$)，联合组LVEF明显高于常规组($t/P=2.142/0.036$)，而2组左心房内径比较差异无统计学意义($P>0.05$)。**结论**　持续性心房颤动患者射频消融术后经参松养心胶囊治疗可减少左心房内径、提高LVEF及改善患者生活质量。

【关键词】 心房颤动，持续性；射频消融术后；参松养心胶囊；左心功能；生活质量

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Effect of *Shensongyangxin* capsule on left ventricular function and quality of life in patients with persistent atrial fibrillation after radiofrequency ablation

*Zhang Guowei**, *Chen Shouqiang*, *Zhang Menghe*, *Zuo Yaoyao*, *Chen Ying*, *Li Yan*, *Xing Yuwei*, *Zhao Yifeng*. * *The First Clinical Medical College of Shandong University of Traditional Chinese Medicine*, *Shandong Province*, *Jinan* 250000, *China*

Corresponding author: *Zhang Menghe*, *E-mail*: *zhangmenghezmh@163.com*

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【Abstract】 Objective　To observe the effect of *Shensongyangxin* capsule on sinus rhythm maintenance, left ventricular function and quality of life in patients with persistent atrial fibrillation after radiofrequency ablation. **Methods**　From May 2019 to June 2021, 60 patients with persistent atrial fibrillation who underwent radiofrequency ablation and converted to sinus rhythm in the Cardiovascular Department of the Second Affiliated Hospital of Shandong University of Traditional Chinese Medicine were selected. They were randomly divided into the conventional group and the combined group, with 30 patients in each group. The patients in the conventional group were treated with basic scheme after operation, and the patients in the combined group were treated with *Shensongyangxin* capsule on the basis of the conventional group. Three months was one course of treatment, and two courses of treatment. At the end of each course of treatment, the patients' dynamic electrocardiogram and cardiac color ultrasound indexes were monitored and the scores of atrial fibrillation specific quality of life scale (AFEQT) were

counted. Sinus heart rate maintenance, left atrial diameter, left ventricular ejection fraction (LVEF) and adverse reactions were compared between the two groups. **Results** Six months after operation, the total effective rate of the combined group was higher than that of the conventional group (90.0% vs.83.3%, $\chi^2 = 6.825$, $P = 0.033$). Three months after operation, the total score of the AFEQT scale and the scores of four dimensions (symptom dimension, daily activity dimension, treatment anxiety dimension, treatment satisfaction dimension) of the two groups were higher than those before treatment ($P < 0.05$), and the scores of the combined group in the treatment anxiety dimension were higher than those of the conventional group ($P < 0.05$). Six months after operation, the total score and four-dimension scores of the AFEQT scale in both groups were higher than those before operation ($P < 0.05$), and those in the combined group were higher than those in the conventional group ($t/P = 10.311/ < 0.001$, $6.139/ < 0.001$, $5.763/ < 0.001$, $3.076/0.005$, $4.899/ < 0.001$). There was no significant difference in the maintenance rate of sinus rhythm between the two groups at 3 and 6 months after operation ($P > 0.05$). Three months after operation, the left atrial diameter in the combined group was smaller than that before operation, and significantly smaller than that in the conventional group ($t/P = 4.187/ < 0.001$). LVEF in both groups was higher than that before operation ($P < 0.05$), but there was no significant difference between the two groups ($P > 0.05$). Six months after operation, the left atrial diameter in both groups was smaller than that before operation, and LEVF was higher than that before operation ($P < 0.05$). LVEF in the combined group was significantly higher than that in the conventional group ($t/P = 2.142/0.036$), but there was no significant difference in the left atrial diameter between the two groups ($P > 0.05$). **Conclusion** *Shensongyangxin* capsule can reduce the left atrial diameter, improve LVEF and improve the quality of life of patients with persistent atrial fibrillation after radiofrequency ablation.

【Key words】 Atrial fibrillation, persistent; Post-radiofrequency ablation; *Shensongyangxin* capsule; Left ventricular function; Quality of life

心房颤动(atrial fibrillation, AF)简称房颤,是最常见的心律失常之一,长期房颤可导致进行性心力衰竭、心脏性猝死、脑卒中等各种并发症[1]。房颤治疗的主要原则为控制易患因素、转复和维持窦性心律、预防复发、控制心室率及预防栓塞并发症[2]。现阶段,房颤的治疗以药物和射频消融为主,而药物治疗存在复发率高及不良反应多等诸多缺点,如普罗帕酮虽维持窦性心律作用较优但会降低患者心功能,对老年人并不适用;且长时间应用抗心律失常药物后,窦性心律维持效果逐渐下降;因此,射频消融术治疗房颤明显优于单纯抗心律失常药物治疗[3]。既往用药经验证明,参松养心胶囊多用于室性早搏及改善心功能的治疗[4],而对于持续性房颤射频消融术后的复发、心功能及患者生活质量影响的报道仍鲜见。现观察参松养心胶囊对持续性房颤经射频消融术后患者左心功能及生活质量的影响,报道如下。

1　资料与方法

1.1　临床资料　选取2019年5月—2021年6月在山东中医药大学第二附属医院心血管病科经射频消融术转窦性心律的持续性房颤患者60例,随机数字表法分为常规组和联合组,各30例。2组患者在性别、年龄、基础病、病程、心功能分级、吸烟史、饮酒史、治疗史、CHA2DS2评分、抗凝药选择、家族遗传史等比较,差异无统计学意义($P > 0.05$),具有可比性,见表1。本研究经医院医学伦理委员会批准(2020-029-01),患者或家属知情同意并签署知情同意书。

表1　常规组与联合组患者临床资料比较

Tab. 1　Comparison of clinical data between conventional group and combined group

项　目	常规组($n=30$)	联合组($n=30$)	t/χ^2 值	P 值
性别(男/女)	23/7	23/7	<0.001	1.000
年龄($\bar{x}\pm s$,岁)	62.22±11.93	61.57±10.23	0.323	0.850
基础病[例(%)]				
高血压	21(70.0)	20(66.7)	0.770	0.781
2型糖尿病	10(33.3)	11(36.7)	0.073	0.787
高脂血症	4(13.3)	7(23.3)	1.002	0.371
冠心病	18(60.0)	12(40.0)	2.400	0.121
病程($\bar{x}\pm s$,年)	2.12±0.23	2.10±0.21	0.027	0.979
心功能分级[例(%)]			0.267	0.606
Ⅰ级	14(46.7)	16(53.3)		
Ⅱ级	16(53.3)	14(46.7)		
吸烟史[例(%)]	6(20.0)	4(13.3)	0.480	0.731
饮酒史[例(%)]	11(36.7)	7(23.3)	1.270	0.260
治疗史[例(%)]				
长期抗AF药物史	14(46.7)	12(40.0)	0.271	0.602
药物转律史	5(16.7)	6(20.0)	0.111	0.739
电复律史	1(3.3)	2(6.7)	<0.001	1.000
CHA2DS2评分($\bar{x}\pm s$,分)	2.67±0.33	2.70±0.32	0.073	0.942
口服抗凝药[例(%)]				
华法林	6(20.0)	9(30.0)	0.800	0.371
新型抗凝药物	3(10.0)	6(23.3)	1.176	0.472

1.2　病例选择标准　(1)纳入标准:①年龄18~75岁;②明确诊断为持续性心房颤动;③持续性房颤病史<5年;④首次行射频消融术治疗。(2)排除标准:

①心肌病及瓣膜性房颤; ②NYHA 心功能分级Ⅳ级或 LVEF <40%, 左心房内径 >50 mm; ③中度至重度左心室肥厚(壁厚 >1.5 cm); ④急性冠状动脉综合征、需植入支架、近半年内有心脏手术史或既往行导管射频消融治疗者; ⑤房颤病史≥5 年; ⑥甲状腺功能亢进者; ⑦需安装起搏器的缓慢性心律失常者; ⑧存在左心房/左心耳血栓或严重止血与凝血功能障碍者; ⑨严重肝、肾功能不全(ALT≥3 ULN, eGFR <50 ml · min^{-1} · 1.73 m^{-2}) 者; ⑩患有神经精神系统疾病者; ⑪已知对参松养心胶囊成分过敏者; ⑫妊娠期及哺乳期妇女; ⑬正在参加其他临床研究者。

1.3　治疗方法　2 组患者进行射频消融后, 均参照中华医学会"心房颤动: 目前的认识和治疗建议—2021"指南推荐的基础方案进行治疗: 如口服抗凝药物、胺碘酮等抗心律失常等术后常规治疗。联合组在此基础上, 术后 48 h 之内予参松养心胶囊(北京以岭药业有限公司) 1.6 g/次, 餐后约 30 min 服用, 每天 3 次。3 个月为 1 疗程, 2 组均治疗 2 个疗程。

1.4　观测指标与方法

1.4.1　生活质量评估: 在治疗前、每个疗程结束时, 患者根据自身情况填写 AFEQT 量表对生活质量进行评估[5], 该量表 20 个条目, 4 个维度; 症状维度(4 个条目)、日常活动维度(8 个条目)、治疗焦虑维度(6 个条目)、治疗满意维度(2 个条目); 量表总分与各维度总分均为 100 分, 分值越高说明房颤对患者的生活质量各方面影响越小, 恢复情况越好。

1.4.2　房颤复发: 术后 3 个月、6 个月, 以 12 导联动态心电图仪(PI200D-B 动态心电记录盒, 上海群天通用电器有限公司) 对患者进行持续 24 h 动态心电图监测以判定是否复发, 动态心电图记录到的房颤、房扑、房速发作持续时间≥30 s 即视为房颤复发[6]。

1.4.3　心功能检测: 治疗前及术后 3 个月、6 个月分别用心脏彩色超声(GE E95) 记录患者左心房内径、LVEF 以判定心功能。

1.4.4　不良反应及安全性: 记录术后用药期间出现的不良反应, 如胃胀、恶心、头晕、腹泻、皮疹等。

1.5　疗效评价标准　2 组疗效判定参考《中药新药临床研究指导原则》[7]。显效: 心悸症状消失, 生活质量明显改善, 动态心电图示心房颤动发作基本控制或频发转为偶发; 有效: 心悸症状大部分消失, 生活质量有所改善, 动态心电图示房颤发作较治疗前减少 50% 以上, 持续时间较治疗前缩短 50% 以上, 或频发转为多发, 或多发转为偶发; 无效: 心悸症状、生活质量、动态心电图无变化或加重。总有效率 =(显效 + 有效) / 总例数 ×100%。

1.6　统计学方法　采用 SPSS 21.0 软件分析处理数据。计数资料以频数或率(%) 表示, 组间比较采用 χ^2 检验; 正态分布的计量资料以 $\bar{x} \pm s$ 表示, 组间比较采用独立样本 t 检验, 多时点比较采用 F 检验。$P<0.05$ 为差异具有统计学意义。

2　结　果

2.1　2 组临床疗效比较　术后 6 个月, 联合组总有效率为 90.0%, 高于常规组的 83.3%, 差异有统计学意义($P<0.05$), 见表 2。

表 2　常规组与联合组持续性房颤患者临床疗效比较　[例 (%)]

Tab. 2　Comparison of clinical efficacy between the conventional group and the combined group in patients with persistent atrial fibrillation

组　别	例数	显效	有效	无效	总有效率(%)
常规组	30	11(36.7)	14(46.6)	5(16.7)	83.3
联合组	30	21(70.0)	6(20.0)	3(10.0)	90.0
U/χ^2 值			$U=306.000$		$\chi^2=6.825$
P 值			0.018		0.033

2.2　2 组治疗前后 AFEQT 量表评分比较　术后 3 个月, 2 组 AFEQT 量表总分及 4 个维度得分均高于术前, 且联合组在治疗焦虑维度方面得分高于常规组($P<0.05$); 术后 6 个月, 2 组 AFEQT 量表总分及 4 个维度得分均高于术前, 且联合组均高于常规组(P 均 <0.01), 见表 3。

2.3　2 组窦性心律维持率比较　术后 3 个月、6 个月, 2 组患者窦性心律维持率比较, 差异无统计学意义($P>0.05$), 见表 4。

表 4　常规组与联合组患者窦性心律维持率比较　[例(%)]

Tab. 4　Comparison of sinus rhythm maintenance rate between conventional group and combined group

组　别	例数	术后 3 个月	术后 6 个月	χ^2 值	P 值
常规组	30	23(76.67)	25(83.33)	0.417	0.519
联合组	30	26(86.67)	27(90.00)	0.162	0.688
χ^2/P 值		0.445/0.507	0.144/0.706		

2.4　2 组治疗前后心功能指标比较　术后 3 个月, 联合组左心房内径小于术前, 且明显小于常规组($P<0.01$); 2 组 LVEF 均高于术前($P<0.05$)。术后 6 个月, 2 组左心房内径均小于术前($P<0.05$), 但组间比

表 3　常规组与联合组持续性房颤患者治疗前后 AFEQT 量表评分比较　($\bar{x} \pm s$, 分)

Tab. 3　Comparison of AFEQT scores of patients with persistent atrial fibrillation in the conventional group and the combined group before and after treatment

组　别	时间	AFEQT 量表总分	症状维度	日常活动维度	治疗焦虑维度	治疗满意维度
常规组	治疗前	49.15 ± 5.04	50.32 ± 10.68	50.64 ± 8.94	46.37 ± 5.12	37.15 ± 7.32
(n = 30)	术后 3 个月	64.96 ± 6.16	73.08 ± 8.94	58.49 ± 6.78	62.87 ± 3.57	72.42 ± 21.35
	术后 6 个月	61.75 ± 6.16	68.59 ± 10.84	56.57 ± 6.78	64.10 ± 6.36	57.70 ± 20.54
联合组	治疗前	49.37 ± 6.77	50.76 ± 9.47	52.08 ± 10.70	44.41 ± 4.88	35.59 ± 14.95
(n = 30)	术后 3 个月	64.48 ± 5.23	70.45 ± 8.83	62.68 ± 7.42	68.16 ± 9.26	74.49 ± 12.63
	术后 6 个月	73.65 ± 6.45	80.30 ± 6.47	69.13 ± 9.26	75.25 ± 4.72	87.11 ± 10.77
F/P 常规组内值		154.204 / < 0.001	53.153 / < 0.001	7.399 / 0.002	46.657 / < 0.001	29.219 / < 0.001
F/P 联合组内值		226.200 / 0.001	95.518 / < 0.001	22.945 / < 0.001	36.757 / 0.001	200.952 / < 0.001
t/P 术后 3 个月组间值		0.586 / 0.560	0.951 / 0.350	1.967 / 0.540	0.615 / 0.048	0.320 / 0.751
t/P 术后 6 个月组间值		10.311 / < 0.001	6.139 / < 0.001	5.763 / < 0.001	3.076 / 0.005	4.899 / < 0.001

较差异无统计学意义($P > 0.05$)；2 组 LVEF 均高于术前，且联合组 LVEF 高于常规组($P < 0.05$)，见表 5。

表 5　常规组与联合组持续性房颤患者治疗前后左心房内径、LVEF 比较　($\bar{x} \pm s$)

Tab. 5　Comparison of left atrial diameter and LVEF before and after treatment in patients with persistent atrial fibrillation in the conventional group and the combined group

组　别	时间	左心房内径(mm)	LVEF(%)
常规组	治疗前	42.33 ± 5.05	63.73 ± 6.88
(n = 30)	术后 3 个月	41.67 ± 4.78	66.73 ± 5.04
	术后 6 个月	38.47 ± 6.27	66.87 ± 5.06
联合组	治疗前	40.20 ± 5.86	63.27 ± 4.03
(n = 30)	术后 3 个月	36.80 ± 4.21	66.87 ± 4.52
	术后 6 个月	36.00 ± 5.13	69.33 ± 3.76
F/P 常规组内值		4.389 / 0.015	3.762 / 0.027
F/P 联合组内值		5.709 / 0.005	16.900 / < 0.001
t/P 术后 3 个月组间值		4.187 / < 0.001	0.108 / 0.914
t/P 术后 6 个月组间值		1.668 / 0.101	2.142 / 0.036

2.5　2 组不良反应发生情况比较　2 组患者均未出现药物过敏、肝肾功能损害，也未出现胃胀、头晕等不良反应现象。

3　讨　论

射频消融术目前已成为治疗房颤的主要治疗手段之一，在维持窦性心律、减少复发、提高生活质量等方面明显优于抗心律失常药物的治疗[8-10]。但对于持续性房颤患者窦性心律的维持率较低，我国大部分持续性房颤患者只接受单次治疗，总体复发率仍较高，使患者的生活质量难以保证；且根据房颤管理指南推荐，存在抗凝适应证的患者术后无论是否存在复发，仍应继续进行抗凝治疗[11]，而在临床中，术后停药率达 29.2% ~53.2%[12-13]；加之术后空白期内存在复发率高的特点[14]，因此术后维持窦性心律、提高生活水平、术后抗凝仍是持续性房颤患者术后值得关注的问题；而参松养心胶囊以脉络学说为理论基础，温清并用，通补兼施，使心络通利、心神安宁、心脉通畅，进而纠正机体功能失调。

射频消融后左心房发生逆重构从而使得左心房容积变小，间接提高 LVEF。左心房发生逆重构的原因主要考虑以下两点，一是由于折返环的减少，二是由于射频消融产生疤痕的收缩效应[15]。左心房容积减小使左心房无规律的颤动比例大大减少，延缓左心房纤维化进展[16]，进而恢复有效的血流动力学，使左心功能明显改善，LVEF 随之提高[17-18]。参松养心胶囊减小左心房容积、提高左心功能，可能是因其可降低 TGF-β_1、MMP-9、TIMP-1 及Ⅰ型、Ⅲ型胶原蛋白的表达，从而抑制左心房纤维化进展[19]；并可延长动作电位和阻断 Ca^{2+} 通道、抑制 Ca^{2+} 内流，从而改善心肌血供，减缓心脏重构[20]；再者参松养心胶囊可降低心肌耗氧量并保证心肌细胞正常的生理活动，又可抵抗外界不良刺激积极调节神经内分泌分子，从而提高 LVEF[21]，改善左心功能。

射频消融术后房颤患者生活质量可明显提高[22-23]，但焦虑情绪的缓解控制欠佳。已有研究证实，房颤患者的精神心理障碍比例明显高于正常人[24]。而参松养心胶囊改善焦虑状态与其能恢复自主神经系统平衡，改善交感及副交感神经紊乱症候群，且该药物中的山茱萸、甘松及酸枣仁具有中枢镇静效果等有关[25-26]；加之其能平衡 ET-1/NO 和 TXA2/PGI2 及抑制 VEGF 和 eNOS 的表达，从而改善心肌微循环灌注，改善心肌内皮功能障碍[27]；还能激活能量代谢的关键调节因子—AMP 活化蛋白激酶，以增强心肌细胞能量供给[28]，最终通过调节神经系统、心脏结构及改善微循环、增强能量供给等提高术后患者的生活

水平[29-30]。

研究证实，参松养心胶囊和西药抗心律失常作用类似[31]，但能显著改善患者心悸、乏力等症状，减少心律失常发作次数。参松养心胶囊通过动物实验证实可调节心肌细胞的 Na^+、K^+、Ca^{2+} 等多离子通道，降低心房纤维化从而达到抗心律失常的作用[32-33]。其可通过阻滞肺静脉肌袖心肌细胞(PVC)的多种离子通道以减少微折返的形成，延长 PVC 不同复极阶段的动作电位时程，从而避免触发房颤的发作。因而参松养心胶囊是一种可通过多种途径降低心肌细胞的自律性以协调维持窦性心律的抗心律失常药物，可进一步降低射频消融术后房颤的复发，但本研究中并未观察到此现象，可能原因为：(1) 入组患者心肌细胞纤维化程度低，左心房内低电压区较少，本研究中大多数患者在接受肺静脉隔离 + 左心房顶部线性消融后即可转为窦性心律，CAFE 电位消融及转子消融使应用率较低；(2) 样本量小，随访仅有 6 个月，未进一步随访。增长随访时间，增加样本量，有可能会观察到参松养心胶囊可明显提高术后窦性心律维持率。

综上所述，持续性房颤患者接受射频消融术后，在常规治疗的基础上加服参松养心胶囊会使患者获益更多，进一步证实了此药物更多的适用范围，提示其在多种心律失常疾病中有潜在应用价值。

利益冲突：所有作者声明无利益冲突

作者贡献声明

张国伟：资料收集整理，实施研究过程，分析试验数据，进行统计学分析，论文撰写，论文修改；陈守强、张梦贺：提出研究思路，课题设计，论文审核；左瑶瑶：分析试验数据，论文审核；陈莹、李妍、邢钰尉、赵义凤：实施研究过程，资料收集整理

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