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基于心脾同治理论观察扶正养心汤对焦虑性失眠患者的临床疗效*

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摘要 目的:观察扶正养心汤治疗心脾两虚型焦虑性失眠患者的临床疗效,探索扶正养心汤治疗心脾两虚型焦虑性失眠的可能性机制。**方法:**在中医情志病门诊就诊患者中,选取的心脾两虚型焦虑性失眠患者 50 例,按照随机数表法分为观察组和对照组各 25 例,对照组给予艾司唑仑片,1 mg,1 次/d,观察组在对照基础上加服扶正养心汤,2 次/d,共 14 天,分别在治疗前后,比较两组患者 WBC、IL-6、IgA 表达水平以及生活质量评分(SF-36)、匹兹堡睡眠质量量表(PSQI)评分、焦虑自测量表(SAS)评分、中医证候积分及治疗后总有效率。**结果:**治疗后,组内相比,两组患者 WBC、IL-6、IgA 表达水平均较前下降($P<0.05$),两组患者 PSQI 评分、SAS 评分均较治疗前降低($P<0.05$),SF-36 评分较前升高($P<0.05$),观察组中医证候积分降低($P<0.05$),对照组中医证候积分降低无统计学差异($P>0.05$);组间相比,观察组 WBC、IL-6、IgA 较对照组降低更明显($P<0.05$),SF-36 较对照组提升更为明显($P<0.05$),PSQI 评分和 SAS 评分降低更明显($P<0.05$),且总有效率更高($P<0.05$)。**结论:**扶正养心汤可改善心脾两虚型焦虑性失眠患者睡眠质量、临床症状和生活质量;相较于单纯使用艾司唑仑,疗效更佳。可能与扶正养心汤可降低患者 WBC、IL-6、IgA 水平相关。

关键词:扶正养心汤;失眠;焦虑;心脾两虚

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Observation of the Clinical Effect of Fu Zheng Yang Xin Decoction on Anxiety Insomnia Patients Based on the Theory of Heart and Spleen Simultaneous Treatment*

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ABSTRACT Objective: To observe the clinical effect of Fu Zheng Yang Xin Decoction in treating anxiety insomnia with deficiency of both heart and spleen, and to explore the possibility mechanism of Fu Zheng Yang Xin Decoction to treat anxiety insomnia with deficiency of both heart and spleen. **Methods:** Among the patients in the traditional Chinese medicine (TCM) emotional diseases clinic, 50 patients with anxiety insomnia due to deficiency of both heart and spleen were selected, and divided them into observation group and control group by random number table method, 25 cases in each group. The control group was given estazolam tablets, 1 mg, 1 time/d, the observation group was given Fu Zheng Yang Xin Decoction on the basis of the control, 2 times/d, in a total of 14 days. Before and after the treatment, WBC, IL-6, IgA expression level, quality of life score (SF-36), the score by the Pittsburgh Sleep Quality Index (PSQI), Self-Rating Anxiety Scale (SAS) score, TCM syndrome score, and total efficiency of the two groups of patients were compared. **Results:** Post-treatment, compared within the group, the expression levels of WBC, IL-6 and IgA in the two groups were all decreased ($P<0.05$), and the PSQI and SAS scores of the two groups were decreased compared with those pretherapy ($P<0.05$). The SF-36 score was higher than before ($P<0.05$). Compared with the control group, the WBC, IL-6 and IgA of the observation group decreased more significantly than the control group ($P<0.05$), and the SF-36 increased more obviously than the control group ($P<0.05$), the PSQI score and SAS score decreased more significantly ($P<0.05$), and the total effective rate was higher ($P<0.05$). **Conclusion:** Fuzheng Yangxin Decoction can improve sleep quality, clinical symptoms and quality of life in patients with anxiety insomnia due to deficiency of both the heart and spleen. Compared with estazolam alone, the effect is better. It may be related to that Fuzheng Yangxin Decoction can reduce the levels of WBC, IL-6 and IgA in patients.

Key words: Fu Zheng Yang Xin Decoction; Insomnia; Neurasthenia; Deficiency of Heart and Spleen

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前言

临床上单纯失眠较少见,多是与其他的躯体疾病并发。近年来随着我国社会水平的不断提高,人们生活节奏加快,竞争压力不断增加,使得人们多处于担心、紧张、焦躁不安的情况,其中焦虑性失眠是因患者长期处于紧张或焦虑状态下而引起的睡眠障碍^[1],失眠与焦虑可相互影响,早期症状隐匿,如若患者不能得到及时诊断和治疗,常引起严重精神疾病^[2]。本病尽管西药对症治疗,能有效改善睡眠质量,但是部分患者担心服用精神类药物“成瘾”或者出现副作用,因此,患者依从性不佳,临床疗效受限^[3,4]。在临床,中西医结合诊疗本病时,需要考虑患者与环境、患者“脏腑”功能之间的整体性^[5]。中医认为本病属于中医的不寐、郁证范畴,病因包括情绪失常、饮食失节、病后体虚、劳逸失调、年长阳衰等,病机为思虑过度,耗伤心血,心失所养,故心脾两虚证为多发证型^[6],临床表现为心神失养、心血亏虚、入睡困难、阳不入阴、早醒易醒、焦躁不安、心烦多梦,白天则乏力疲劳、头昏脑胀、注意力不集中甚至记忆力减退、精神不足、认知功能减退,病情日久则更耗阴血,形成恶性循环,严重影响患者的生活质量,因此临床上需给予积极治疗^[7-9]。本院中医情志门诊建立以来,坚持以中医“整体观”整体观中的心脾同治为理论依据,由归脾汤化裁出扶正养心汤治疗本病,具有补益心脾、养血安神的功效,本研究通过临床试验观察扶正养心汤联合艾司唑仑治疗心脾两虚型焦虑性失眠的临床疗效,结果报道如下。

1 临床资料

1.1 一般资料

选自2021年10月至2022年4月就诊于我院中医情志病门诊的心脾两虚型焦虑性失眠患者50例。按随机数表法分为观察组和对照组各25例,其中观察组男7例,女18例,平均年龄 41.64 ± 16.25 岁。对照组男9例,女16例,平均年龄 48.88 ± 18.01 岁。两组患者基线资料比较(性别: $\chi^2=0.368, P=0.544$;年龄: $t=-1.493, P=0.142$),差异均无统计学意义。

1.2 诊断标准

西医诊断参考《沈渔邨精神病学》^[7]中焦虑性失眠诊断标准;中医诊断及证型参考《中医内科学》^[10]中不寐心脾两虚型的证候标准。

1.3 纳入与排除标准

纳入标准:①同时符合上述中、西医诊断标准者;②年龄18~75岁者;③近2周内未使用抗焦虑及镇静安神药物者;④同意参加并签署知情同意书者(本研究已通过本院临床伦理委员会审查)。

排除标准:①因其他疾病引起失眠患者;②怀孕及哺乳期患者;③合并其他精神类疾病或长期服用精神类药物的患者;④合并严重心、肺、肝、肾等功能损伤的患者;⑤研究人员认为不适合纳入者。

1.4 方法

1.4.1 治疗方法 对照组每晚睡前30 min口服艾司唑仑1 mg(准字:H32020699,1 mg/片,常州四药制药有限公司);观察组艾司唑仑的服用方法同对照组,同时增加扶正养心汤,口服,组

成:党参10 g,黄芪10 g,白术10 g,当归10 g,甘草10 g,茯神10 g,远志10 g,酸枣仁10 g,五味子10 g,白芍10 g,山药15 g,枸杞子15 g水煎分早晚2次,饭后1 h温服;疗程均为14天。

1.5 观察指标

(1)对比两组患者治疗前后的WBC、IL-6、IgA水平 治疗前后1 d抽取患者的静脉血3 mL,在3500 r/min下离心5 min,使用激光染色法检测WBC水平,使用酶联免疫吸附法检测两组的IL-6水平,所有操作均按照试剂盒要求进行,使用全自动特定蛋白分析仪及其试剂盒,用乳胶增强散射比浊法检测IgA水平,所有操作均严格按照仪器操作要求进行。

(2)对比两组治疗前后PSQI、SAS评分比较^[11,12] 两组患者均在治疗前后1 d使用匹兹堡睡眠质量量表(Pittsburgh Sleep Quality Index, PSQI)评分、焦虑自测量表(Self-Rating Anxiety Scale, SAS)评分评定,PSQI量表的分值范围在0~21分,分值越低,睡眠质量越好;SAS分值范围在0~100分,分值越高,患者的焦虑程度越重。

(3)对比两组治疗前后中医证候积分^[13] 心脾两虚证型,主症:心悸、乏力、纳差、便溏4项进行评分,分为无症状、轻、中、重度4个等级,对应记0、1、2、3分;次症:面色无华、少气懒言2项同主症记分,舌质、脉象是否正常记0、2分,各项得分相加为总分。

(4)对比两组治疗前后的生活质量(SF-36)评分^[14] 量表的分值范围在0~100分,分值越高,患者的生活质量水平越好。

(5)对比两组治疗疗效 参考PSQI评分减分率来评定临床疗效^[15],减分率=治疗前后总分差/治疗前总分 $\times 100\%$ 。痊愈:PSQI减分率 $>75\%$,症状完全消失;显效: $75\% \geq$ PSQI减分率 $>50\%$,症状(失眠、早醒、心悸、乏力、面色无华、少气、纳差、便溏)明显改善;有效: $50\% \geq$ PSQI减分率 $>25\%$,症状稍有改善;无效:PSQI减分率 $\leq 25\%$,症状无改善。

1.6 统计学处理

采用SPSS 24.0统计软件进行数据分析。计量资料用“均数 $\pm$ 标准差($\bar{x} \pm s$)”表示。同组治疗前后数据比较采用配对t检验或Wilcoxon检验,两组数据比较采用两个独立样本t检验或秩和检验;两组临床疗效分布比较采用Mann-Whitney U检验。采用双侧检验,显著性水准为 $\alpha=0.05$ 。

2 结果

2.1 对比两组患者治疗前后的WBC、IL-6、IgA水平

两组患者治疗后WBC、IL-6、IgA水平均较治疗前下降($P<0.05$),组间比,观察组降低更为明显($P<0.05$)。

2.2 两组治疗前后PSQI、SAS评分比较

治疗后,组内相比,PSQI、SAS评分均较治疗前下降($P<0.05$);组间相比,观察组PSQI、SAS评分更低($P<0.05$)。

2.3 两组治疗前后中医证候积分比较

治疗后,组内相比,观察组中医证候积分降低($P<0.05$);组间相比,观察组中医证候积分更低($P<0.05$),见表3。

2.4 两组患者治疗前后SF-36评分比较

治疗后,组内比,观察组SF-36较治疗前明显提升($P<0.05$);组间相比,观察组SF-36较前降低更为明显($P<0.05$)。

表 1 两组患者治疗前后的 WBC、IL-6、IgA 水平比较($\bar{x} \pm s$)Table 1 Comparison of WBC, IL-6, and IgA levels in the two groups($\bar{x} \pm s$)

Groups	n	WBC($10^9/L$)		IL-6(ng/L)		IgA(g/L)	
		Pretherapy	Post-treatment	Pretherapy	Post-treatment	Pretherapy	Post-treatment
Observation group	25	12.68 $\pm$ 5.15	5.83 $\pm$ 1.95	54.42 $\pm$ 8.57	31.52 $\pm$ 3.15	2.57 $\pm$ 0.29	2.49 $\pm$ 0.27
Control group	25	13.15 $\pm$ 3.66	7.54 $\pm$ 2.73 ^{##}	52.71 $\pm$ 6.82	36.26 $\pm$ 5.23 ^{##}	2.48 $\pm$ 0.21	1.49 $\pm$ 0.18 ^{##}

Note: Compared with Pretherapy, * $P < 0.05$; Compared with control group, [#] $P < 0.05$, the same below.

表 2 两组患者 PSQI、SAS 评分比较($\bar{x} \pm s$, 分)Table 2 Comparison of PSQI and SAS scores between the two groups of patients($\bar{x} \pm s$, score)

Groups	n	PSQI		SAS	
		Pretherapy	Post-treatment	Pretherapy	Post-treatment
Observation group	25	13.91 $\pm$ 1.47	7.22 $\pm$ 1.76 ^{##}	76.61 $\pm$ 5.63	35.27 $\pm$ 3.16 ^{##}
Control group	25	14.26 $\pm$ 1.56	10.24 $\pm$ 1.25 [*]	75.17 $\pm$ 5.22	50.39 $\pm$ 5.24 [*]

表 3 两组患者中医证候积分比较($\bar{x} \pm s$, 分)Table 3 Comparison of cumulative scores of TCM syndrome between two groups of patients($\bar{x} \pm s$, score)

Groups	n	Pretherapy	Post-treatment
Observation group	25	17.93 $\pm$ 2.79	10.16 $\pm$ 2.37 ^{##}
Control group	25	16.15 $\pm$ 2.85	15.33 $\pm$ 1.66 [*]

表 4 两组患者 SF-36 评分情况比较($\bar{x} \pm s$, 分)Table 4 Comparison of SF-36 scores in two groups($\bar{x} \pm s$, score)

Groups	Physiological functions		Body pain		Social function		Dynamic		Emotional function		Total score	
	Prethera- py	Post-treat ment	Prethera- py	Post-treat ment	Prethera- py	Post-treat ment	Prethera- py	Post-treat ment	Prethera- py	Post-treat ment	Prethera- py	Post-treat ment
Observa- tion group	11.14 $\pm$ 2.34	24.67 $\pm$ 1.85 ^{##}	12.21 $\pm$ 2.33	25.89 $\pm$ 4.56 ^{##}	14.21 $\pm$ 2.76	23.78 $\pm$ 3.09 ^{##}	13.32 $\pm$ 1.89	24.45 $\pm$ 2.99 ^{##}	11.33 $\pm$ 1.78	23.88 $\pm$ 3.24 ^{##}	59.05 $\pm$ 10.78	88.73 $\pm$ 8.29 ^{##}
Control group	11.23 $\pm$ 2.43	19.45 $\pm$ 2.14 [*]	12.45 $\pm$ 2.67	20.34 $\pm$ 3.89 [*]	12.35 $\pm$ 2.89	18.25 $\pm$ 2.34 [*]	13.45 $\pm$ 2.12	19.45 $\pm$ 2.09 [*]	11.42 $\pm$ 1.89	18.78 $\pm$ 2.99 [*]	60.15 $\pm$ 11.28	85.56 $\pm$ 8.77 [*]

2.5 两组治疗疗效比较

($P < 0.05$), 见表 5。

两组临床疗效比较, 治疗组临床疗效显著优于对照组

表 5 两组患者疗效对比(例)

Table 5 Comparison of treatment effect between two groups of patients(n)

Groups	n	Cure	Significant effect	Effecicay	Invalid	Z	P
Observation group	25	2	17	5	1	-2.740	0.006
Control group	25	0	10	11	4		

3 讨论

睡眠是机体巩固记忆、记忆复原的一个重要环节, 其是维持机体的正常活动的必要修整过程, 我国成年人中失眠发生率已达 38%^[16,17]。《景岳全书》"心为时扰则神动, 神动则不静, 是以不寐也", 表明不寐多是因心神不安引起的阴不敛阳, 阳不入阴, 神不守舍, 难以入睡。其中病因是是劳倦伤脾、饮食不节或

思虑过度引起的脾气亏虚, 因此临床上需给予补益心脾、养心安神的的治疗方法。而失眠是严重精神疾病最主要的危险因素之一, 研究表明, 焦虑与失眠可相互影响, 加重病情^[19,20]。目前, 焦虑性失眠的治疗仍以精神类西药为主, 虽然疗效确切, 但停药后症状容易反复, 并且患者存在睡眠改善这种"单一"临床疗效, 其他症状改变不明显, 例如胃肠道功能紊乱、心悸、血压波动等症状, 因此, 临床治疗本病可考虑多脏器联合方案治疗

本病^[21-23]。

本文结果表明,治疗后,组内相比,两组患者 PSQI 评分、SAS 评分均较治疗前降低,SF-36 评分较前升高,观察组中医证候积分降低,对照组中医证候积分降低无统计学差异;组间相比,SF-36 较对照组提升更为明显,PSQI 评分和 SAS 评分降低更明显,且总有效率更高,表明与单纯应用艾司唑仑相比,加用扶正养心汤可提高焦虑失眠患者的生活质量,改善患者的焦虑情绪、临床症状,本文结果与庄雪^[24]等研究结果相似。主要是由于中医将焦虑失眠归于“不寐”、“脏燥”、“郁病”等范畴,“忧思伤脾”为主要病因,脾虚心血生化不足,心失所养为病机,病位在心,与脾胃密切相关。张仲景提出“心脾同治”,强调“补母救子”的五行相生理论,启发现代临床研究,例如,“调脾护心法”“补血安神法”均为中医心脾同治法防治本病的具体实践。而扶正养心汤是我院中医情志病门诊多年防治失眠的基础方,针对焦虑性失眠患者的心脾协作关系失调而立。方中党参、黄芪补益脾气为君药,白术甘温补气,与黄芪相配伍、加强益气健脾之功;当归与白芍配伍,柔肝养血,增强君药益气之功,均为臣药;茯神、远志、酸枣仁养心安神佐药;山药、枸杞子,五味子滋养脾肾为使药;全方健脾养血宁心,心脾同治^[25,26]。现代药理学研究发现,本方中药物所含药物成分(酸枣仁总皂苷、白术内酯、远志皂苷等)的作用靶点与 JAK-STAT 通路介导的 IL1B、TNF、OD1、TP53 高表达密切相关,通过 JAK-STAT 通路能抑制情绪应激性失眠^[27,28],除此之外,白术、当归、白芍有效成分抑制 p38MAPK 信号通路在皮层记忆区的激活,下调 CYP1A2、NR3C1 蛋白的表达,降低交感神经亢奋水平等。IL-6 表达升高会促进失眠症的疾病进展,白细胞减少会导致患者出现乏力、头晕、食欲减退、肢体酸软、精神萎靡等症状,白细胞严重减少时会导致患者出现认知功能障碍、慢性失眠等情况,焦虑性失眠会对患者的免疫系统产生影响,而免疫系统改变会导致患者功能改变,甚至参与焦虑性失眠的发生、发展,此类患者多存在免疫功能抑制的情况。炎症因子不仅调节免疫,而且调节睡眠,是近几年失眠研究的热点之一,IgA 是免疫系统中的一个重要指标^[29,30]。因此本文选择其作为观察指标,研究扶正养心汤对这些血清指标的影响,探索扶正养心汤对失眠的可能影响机制,本文结果表明,治疗后两组患者 WBC、IL-6、IgA 表达水平均较前下降,同时治疗观察组 WBC、IL-6、IgA 较对照组降低更明显,表明扶正养心汤改善心脾两虚型焦虑性失眠患者的临床疗效可能与其可降低患者的血清 WBC、IL-6、IgA 水平有关。

总之,扶正养心汤可改善心脾两虚型焦虑性失眠患者睡眠质量、临床症状和生活质量;相较于单纯使用艾司唑仑,疗效更佳。可能与扶正养心汤可降低患者 WBC、IL-6、IgA 水平相关,进一步验证心脾同治理论可为临床防治本病提供参考。本研究仍存在一定的不足之处,所选样本量不足,随访时间较短,有待进一步延长随访时间,增加样本量进行深入分析。

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