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电针腧穴联合当飞利肝宁治疗非酒精性脂肪性肝炎的临床研究

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摘要 目的:探讨电针腧穴联合当飞利肝宁治疗非酒精性脂肪性肝炎(nonalcoholic steatohepatitis, NASH)的临床疗效及其安全性。**方法:**选择符合 2010 年非酒精性脂肪性肝病诊疗指南^[1]诊断标准的 80 例非酒精性脂肪性肝炎患者,随机分为联合组(电针联合当飞利肝宁治疗组)和对照组(护肝宁治疗组)各 40 例,两组患者均在纠正不良生活方式、控制饮食(BMI<24)、适量有氧运动等的基础上给予相应的治疗,对照组仅服用护肝宁,3 次/d,联合组服用当飞利肝宁及电针腧穴治疗。观察和比较两组的疗效、血清转氨酶、血脂水平、脂肪肝程度变化和不良反应的发生情况。**结果:**联合组和对照组的治疗总有效率分别为 90.0%和 62.5%,两组总有效率比较有显著性差异($P<0.05$)。治疗后,联合组患者的血清转氨酶、血脂水平均较对照组显著降低($P<0.05$)。治疗中两组均未发现明显不良反应。**结论:**电针腧穴联合当飞利肝宁对非酒精性脂肪性肝炎有较好的治疗效果,具有很高的临床应用价值。

关键词:非酒精性脂肪性肝炎;电针;当飞利肝宁;临床疗效

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Clinical Research on the Electro-acupuncture Combined with Dangfei Liganning Capsule in the Treatment of Nonalcoholic Fatty Liver Disease

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ABSTRACT Objective: To investigate the efficacy and safety of electro-acupuncture combined with Dangfei Liganning Capsule in the treatment of Nonalcoholic Fatty Liver Disease (NASH). **Methods:** Eighty patients who were diagnosed as NASH according to 2010 nonalcoholic fatty liver disease diagnosis and treatment guideline were randomly divided into the combination group (electro-acupuncture combined with Dangfei Liganning Capsule) and control group (Hugan Ning). The patients in both groups were treated by correcting unhealthy lifestyles, dietary control (BMI<24), moderate aerobic exercise on the basis of the corresponding treatment. The control group was given Hugan Ning, 3 times/d, while the combination group was given Dangfei Liganning Capsule with electro-acupuncture acupoints. The changes of ALT, GGT levels, the severity of fatty liver and the adverse reaction were observed and compared. **Results:** The total effective rate of combination group and control group were respectively 90.0% and 62.5% ($P<0.05$). The aminotransferase and blood fat of combination group were decreased significantly than those of the control group ($P<0.05$). No significant adverse reaction was found. **Conclusion:** Electro-acupuncture combined with Dangfei Liganning Capsule may obtain a favorable effect on nonalcoholic fatty liver disease and was of great clinical value.

Key words: Nonalcoholic Fatty Liver Disease; electro-acupuncture; Dangfei Liganning Capsule; Clinical efficacy

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前言

非酒精性脂肪性肝病 (nonalcoholic fatty liver disease, NAFLD)是一种与遗传因素和胰岛素抵抗相关的代谢应激性肝

损伤,排除过量饮酒和其他明确的损肝因素,以弥漫性肝细胞大泡性脂肪变为主要病理特征的临床病理综合征,可由单纯肝细胞脂肪变性逐渐衍变为单纯性脂肪肝、非酒精性脂肪性肝炎(NASH)、肝硬化和肝细胞癌^[2-4],其发病率与生活水平提高和膳食结构改变密切相关。如何有效治疗 NAFLD 及阻断其衍变进程已成为临床医学关注的焦点。本研究针对 NASH 治疗方法进行了探索,应用电针联合当飞利肝宁治疗肝功能异常的 NASH 患者 80 例,探讨该联合治疗方案的临床应用价值。

1 资料和方法

1.1 一般资料

选择 2010 年 10 月至 2012 年 10 月间我院就诊的符合中

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华医学会肝脏病学分会脂肪肝和酒精性肝病学会 2010 年 1 月修订的《非酒精性脂肪性肝病诊疗指南》^[1] 诊断标准的 NASH 患者 80 例, 随机分为联合组和对对照组各 40 例。其中男性 42 例, 女性 38 例, 年龄 35~60 岁, 中位年龄 51.5 岁, 病程 2~20 年。入组标准: 血清转氨酶 ALT 和 / 或 AST 增高, 血总胆固醇及甘油三酯增高, 肝脏影像学表现符合弥漫性脂肪肝诊断标准, 且无其他原因可解释^[5]。排除标准: ① 乙醇摄入量: 男性 $\geq 140\text{g/W}$, 女性 $>70\text{g/W}$; ② 病毒性肝炎、药物性肝病、全胃肠外营养、肝豆状核变性、自身免疫性肝病等可致脂肪肝的特定疾病; ③ 治疗前 3 个月内使用降脂药物、降血糖药物、熊去氧胆酸及维生素 E 等。两组患者的性别、年龄、体重、症状、血生化指标及脂肪肝程度、病程等方面无显著差异, 具有可比性。

1.2 方法

两组患者均在纠正不良生活方式、控制饮食(BMI <24)、适量有氧运动等基础上进行相应治疗。对照组服用护肝宁(通化斯威药业股份有限公司, 国药准字 Z20055664, 每粒 0.3 g)1.5 g 餐后口服, 3 次 / d; 联合组予以当飞利肝宁(江西心正药业有限公司, 国药准字 Z20050170, 每粒 0.45 g)0.9 g 餐后口服, 3 次 / d, 同时给予智能电针仪电针治疗。针灸治疗以疏肝健脾益肾, 祛瘀化痰行浊为原则, 取穴为: 日月、期门、肝俞、内关、脾俞、中脘、足三里、丰隆、气海、血海。局部常规消毒, 采用 0.35 mm $\times$ 40 mm 毫针, 得气后行平补平泻手法, 接 G6805-II 型电针仪, 频率 0.83/1.67Hz, 疏密波, 强度以患者耐受为度, 30 min/次, 5 次 / 周, 治疗期间每周复诊一次, 记录病情变化。治疗周期为 12 周, 疗程结束时, 对比治疗前后主要症状、肝功能、血脂及

彩超检查脂肪肝程度的变化。

1.3 观察指标

观察治疗前后临床症状及体征变化, 记录血清转氨酶谷丙转氨酶(ALT)、谷草转氨酶(AST)肝功能、血脂甘油三酯(TG)、胆固醇(TC)数据变化, 以彩超检查脂肪肝程度并参照《非酒精性脂肪性肝病诊疗指南》中 NASH 诊断标准, 分为无脂肪肝、轻、中、重度脂肪肝。同时观察药物不良反应。

1.4 疗效判断标准

无效: 症状、体征、血脂、肝功能, 彩超检查较治疗前无明显改善; 有效: 症状、体征、血脂、肝功能, 彩超检查较治疗前有所改善(脂肪肝由重度恢复到中度或中度恢复到轻度); 治愈: 症状体征消失, 血脂和肝功能结果正常, 彩超恢复正常(肝脏体积复常、肝区光点回声均匀、血管走行清楚); 以治愈、有效计算临床有效率。

1.5 统计学分析

计量资料的比较采用 t 检验, 计数资料的比较采用 χ^2 检验, 以 $P<0.05$ 为差异有显著性。

2 结果

2.1 两组临床疗效的比较

如表 1 所示, 联合组 40 例患者 8 例治愈, 29 例显效, 3 例无效, 治疗总有效率为 90%, 而对对照组 40 例患者 4 例治愈, 21 例显效, 15 例无效, 治疗总有效率为 62.5%, 联合组治疗总有效率明显高于对照组, 两者间差异有统计学意义($P<0.05$), 见表 1。

表 1 两组患者治疗后疗效情况表[例(%)]

Table 1 Comparison of clinical efficacy of patients in the two groups($\bar{X} \pm S$)

Group	Cure	Improve	Invalid	Total efficiency (%)
Combination group	8 (17.5)	29 (72.5)	3 (10.0)	90.0*
Control group	4 (10)	21 (52.5)	15 (37.5)	62.5

注: * $P<0.05$ 与对照组比较。

Note: * $P<0.05$ compared with control group.

2.2 两组治疗前后血清转氨酶(ALT、AST)、血脂(TG、TC)水平的比较

如表 2 所示, 治疗前, 联合组与对照组血清转氨酶与血脂水平比较均无明显差异($P>0.05$); 治疗后, 联合组与对照组血清转氨酶、血脂较同组治疗前均显著降低, 差异具有统计学意义($P<0.05$), 血清转氨酶 $P<0.05$ 联合组患者的血清谷丙转氨酶

(ALT)、谷草转氨酶(AST)水平均显著低于对照组($P<0.05$), 甘油三酯(TG)、胆固醇(TC)较对照组显著下降($P<0.05$)。

2.3 两组不良反应的发生情况

治疗中个别患者服药后感轻微的恶心、腹胀, 改为餐后口服后症状消失。

表 2 两组治疗前后肝功能、血脂水平的比较($\bar{X} \pm S$)

Table 2 Comparison of the liver function, lipid level before and after treatment between two groups($\bar{X} \pm S$)

Group	n		ALT(IU/L)	AST(IU/L)	TG(mmol/L)	TC(mmol/L)
Control group	40	Before treatment	67.34 $\pm$ 19.1	20.11 $\pm$ 4.31	2.6 $\pm$ 1.6	5.5 $\pm$ 1.2
		After treatment	53.8 $\pm$ 11.5	16.68 $\pm$ 5.25	2.01 $\pm$ 1.1	5.1 $\pm$ 1.1
Combination group	40	Before treatment	61.84 $\pm$ 19.2	19.95 $\pm$ 5.11	2.7 $\pm$ 1.65	5.5 $\pm$ 1.3
		After treatment	32.70 $\pm$ 13.65 *	11.43 $\pm$ 4.33*	1.6 $\pm$ 1.0*	4.5 $\pm$ 0.8 *

注: * $P<0.05$ 与对照组治疗后比较。

Note: * $P<0.05$ compared with control group.

3 讨论

非酒精性脂肪性肝炎 (nonalcoholic steatohepatitis, NASH) 是 NAFLD 漫长病程中的一个阶段, 可进一步发展成肝纤维化、肝硬化^[6,7], 其发病机制复杂, 国内外学者多认为其发生、发展与胰岛素抵抗、脂代谢紊乱、氧化应激、脂质过氧化损伤和细胞因子异常等因素有关。目前, 对于此类患者, 最基础的治疗为运动与饮食控制^[8-14], 在此基础上寻求一种有效治疗方法已成为当前的研究热点^[15]。

根据非酒精性脂肪性肝炎的发病特点, 可将其归属于中医学中的“胁痛”、“血瘀”、“积聚”、“痰浊”、“瘕瘕”等范畴。中医认为该病的发生多因饮食不节、嗜食肥甘厚味及情志抑郁、肝气郁结而致, 使肝失疏泄、脾失健运、湿热内蕴、瘀血阻滞, 肝胆失于调达, 气血运行不畅而致。饮食、情志、外邪等为非酒精性脂肪肝的主要发病因素, 病位在肝胆, 病机则在胆汁郁而不畅致气机不畅, 这是脂肪肝发生发展的基本病机, 无论是在疾病初期或是久病不愈者皆可见胆郁证, “从胆论治”应贯穿始终。故在针灸取穴时重点把握疏肝利胆、清热利湿、健脾和胃、活血化瘀四法一体的治疗法则。电针取穴中, 肝俞属足太阳膀胱经, 为肝的背俞穴, 该穴内应肝脏, 为肝气压在背部输注、转输之处, 是治疗肝病的重要穴; 日月为人体足少阳胆经上的一个要穴, 能养肝补脾、疏肝利胆; 期门属肝经, 肝之募穴, 能健脾疏肝, 理气活血; 脾俞能健脾利湿; 内关能理气行滞, 足三里能够调理阴阳, 具有健脾化湿和疏肝解郁的功效; 丰隆、气海、血海能理气活血行滞, 诸穴合用, 可以联合起到疏肝利胆、活血行滞、健脾化湿功效, 并可以标本兼治。

当飞利肝宁的主要成分为当药和水飞蓟的提取物, 其中含有龙胆苦甙、龙胆碱、牙桑苦甙、当归甙及水飞蓟素齐墩果酸等重要保肝成分, 广泛用于各类肝病治疗, 在临床护肝治疗中起到清热解毒、祛湿利胆的作用^[16]。动物实验表明, 当飞利肝宁可减轻高脂血症脂肪肝大鼠模型肝细胞脂肪变性及肝脏炎症反应程度, 明显降低血清转氨酶水平^[17]。该药中的当药能提升肝细胞处理脂质的能力, 促进胆固醇转化、排泄, 具有选择性降低血脂的作用^[18]; 水飞蓟素具有抗脂质过氧化、维持细胞膜的稳定性、促进肝细胞再生及抗肝纤维化等作用^[19,20]。临床研究发现该类药物可改善 NAFLD 的临床症状, 肝功能及肝细胞脂肪变程度^[21-24]。

本研究结果显示, 电针腧穴联合当飞利肝宁能显著提高 NASH 患者的临床有效率, 治疗后患者的血清 AST、ALT、TG、TC 水平明显降低, 且较护肝宁单独治疗的患者更低。个别患者空腹服用当飞利肝宁有轻微的胃肠道反应, 改为餐后服用后症状消失。因此, 电针腧穴联合当飞利肝宁是一种对非酒精性脂肪性肝炎较为理想的联合治疗方案, 但由于本研究病例观察时间较短, 尚需追踪观察病例作更进一步的研究探讨。

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