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针刺联合明目地黄丸对干眼症患者眼表功能、生活质量和血清炎症因子的影响*

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摘要 目的:探讨针刺联合明目地黄丸对干眼症患者眼表功能、生活质量和血清炎症因子的影响。方法:选择我院 2019 年 5 月~2020 年 12 月期间收治的干眼症患者 84 例。依据随机数字表法将患者分为对照组(n=42,常规西医治疗)和研究组(n=42,在对照组基础上联合针刺与明目地黄丸治疗),两组均治疗 8 周。对比两组治疗 8 周后的疗效,对比两组治疗前、治疗 8 周后的眼表功能、生活质量及血清炎症因子变化情况。结果:治疗 8 周后,研究组的临床总有效率较对照组高($P<0.05$)。治疗 8 周后,两组眼表疾病指数(OSDI)、角膜荧光素染色(FL)评分较治疗前下降,且研究组低于对照组($P<0.05$),治疗 8 周后,两组 Schirmer I 试验结果(SIT)、泪膜破裂时间(BUT)较治疗前升高或延长,且研究组高或长于对照组($P<0.05$)。治疗 8 周后,两组转化生长因子- β (TGF- β)、肿瘤坏死因子- α (TNF- α)和白介素-1(IL-1)较治疗前下降,且研究组低于对照组($P<0.05$)。治疗 8 周后,两组 SF-36 各维度评分较治疗前升高,且研究组高于对照组($P<0.05$)。结论:干眼症患者经针刺联合明目地黄丸治疗后,症状得到显著改善,可有效提高患者生活质量,其主要作用机制可能与调节机体炎症反应有关。

关键词: 针刺;明目地黄丸;干眼症;眼表功能;生活质量;炎症因子

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Effects of Acupuncture Combined with Mingmu Dihuang Pill on Ocular Surface Function, Quality of Life and Serum Inflammatory Factors in Patients with Dry Eye*

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ABSTRACT Objective: To explore the effect of acupuncture combined with Mingmu Dihuang Pills on ocular surface function, quality of life and serum inflammatory factors in patients with dry eye. **Methods:** 84 patients with dry eye in our hospital from May 2019 to December 2020 were selected. According to the random number table method, the patients were divided into control group (n=42, conventional western medicine treatment) and study group (n=42, acupuncture combined with Mingmu Dihuang Pill treatment on the basis of control group), both groups were treated for 8 weeks. The curative effect of the two groups at 8 weeks after treatment was compared, and the changes of ocular surface function, quality of life and serum inflammatory factors before and 8 weeks after treatment were compared. **Results:** 8 weeks after treatment, the total effective rate of the study group was higher than that of the control group ($P<0.05$). 8 weeks after treatment, ocular surface disease index (OSDI) and corneal fluorescein staining (FL) scores of the two groups decreased compared with those before treatment, and the study group was lower than the control group ($P<0.05$). 8 weeks after treatment, Schirmer I test results (SIT), tear film break-up time (BUT) of the two groups increased or prolonged compared with those before treatment, and the study group was higher or longer than the control group ($P<0.05$). 8 weeks after treatment, the transforming growth factor- β (TGF- β), tumor necrosis factor- α (TNF- α) and interleukin-1 (IL-1) of the two groups decreased compared with those before treatment, and the study group was lower than the control group ($P<0.05$). 8 weeks after treatment, SF-36 dimensions scores of the two groups were higher than those before treatment, and the study group was higher than the control group ($P<0.05$). **Conclusion:** After acupuncture combined with Mingmu Dihuang Pill, the symptoms of patients with dry eye can be significantly improved, which can effectively improve the quality of life of patients. Its main mechanism may be related to the regulation of inflammatory reaction.

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前言

干眼症是指由各种原因造成的机体泪液量或者质的异常,使结膜和角膜得不到正常滋润,进而出现眼痒、异物感、眼睛干涩、易疲惫以及分泌物黏稠等一系列眼部症状的疾病^[1]。近年来,随着空气污染加重,空气质量下降,加上电子产品的普及,用眼时间增长,导致干眼症的发病率逐年升高^[2]。干眼症若未能给予及时的治疗,可引起角膜病变,影响患者视力。目前西医主要采用人工泪液替代治疗,虽能缓解眼部不适症状,改善眼表的润滑度,但远期疗效不稳定,无法达到根治目的^[3,4]。中医认为干眼症属于“神水将枯”“白涩症”等范畴,主要病因为津液生成减少、脏腑功能失调,治疗应以生津润燥、养阴益气、疏肝明目为主^[5]。明目地黄丸主要功效为滋肾、养肝、明目,可有效改善眼睛干涩、流泪、视物不清等症状^[6],针刺则可通过行气通络、活血养血以恢复眼部津液的输布^[7]。本研究选取部分干眼症患者,给予针刺联合明目地黄丸治疗,疗效较好,整理如下。

1 资料与方法

1.1 一般资料

选择我院 2019 年 5 月~2020 年 12 月期间收治的干眼症患者 84 例。依据随机数字表法将患者分为对照组和研究组,其中对照组 42 例,女 16 例,男 26 例,年龄 35~68 岁,平均(49.82±4.37)岁,病程 6~20 个月,平均(13.59±2.73)个月。研究组 42 例,女 18 例,男 24 例,年龄 37~67 岁,平均(46.69±5.26)岁,病程 7~22 个月,平均(13.76±2.56)个月。两组基线资料比较无差异($P>0.05$)。研究方案经过我院伦理学委员会批准。诊断标准:西医诊断标准:符合《干眼临床诊疗专家共识(2013 年)》中干眼症的诊断标准^[8]:(1)主观症状包括眼部异物感、干涩,其他症状:痒感、烧灼感、红痛、畏光、易视疲劳、粘丝状分泌物、视物模糊等;(2)Schirmer I 试验结果(SIT)<5 mm/5 min 或泪膜破裂时间(BUT)<5 s;(3)SIT 5-10 mm/5 min 或 BUT 5-10 s;并且角膜荧光素染色(FL)阳性。眼部特异检查同时满足(1)(2)或(1)(3)即可诊断为干眼症。中医诊断标准:参照《中医病证诊断疗效标准》^[9]中神水将枯的诊断依据:(1)目珠干燥失却莹润光泽,白睛微红,有皱褶等症状;(2)泪液分泌量测定,多次 SIT 试验结果<5 mm/5 min,虎红染色试验阳性,荧光素试验染色阳性。中医证候分为肺阴不足型:口干鼻燥,大便干,舌红少津等;阴虚湿热型:疼痛、畏光、视力模糊等;气阴两虚型:干涩、眼疲劳,口干唇燥裂等。纳入、排除标准:纳入标准:(1)知情本研究,签署同意书;(2)年龄 18~75 岁。排除标准:(1)妊娠或哺乳期妇女;(2)干燥症综合患者;(3)有精神障碍,严重的造血系统疾病、心、肝、肾脏及全身营养状况不良者;(4)半年内行眼科手术者;(5)合并其他眼病,如葡萄膜炎、青光眼、眼底出血、结膜炎及视神经疾病等;(6)眼部结构改变,如角膜溃疡、结膜瘢痕化、泪腺开口处闭锁、眼睑畸形、副泪腺完全萎缩等;(7)对艾灸或本研究相关药物过敏者;(8)过去 2 周内使用其他

干眼药物治疗者。

1.2 治疗方法

对照组采取玻璃酸钠滴眼液(国药准字:J20130012,参天制药(中国)有限公司,规格:5 mL/瓶/盒)治疗,外用,1~2 滴/次,3 次/d,持续治疗 8 周。研究组患者在对照组的基础上联合针刺与明目地黄丸治疗,其中玻璃酸钠滴眼液治疗同对照组,明目地黄丸(湖北瑞华制药有限责任公司,国药准字 Z20174048,规格:每 8 丸相当于原生药 3 克),口服,9 g/次,2 次/d,持续治疗 8 周。针刺治疗方案如下:针刺丝竹空、睛明、攒竹、太阳、瞳子髎进行治疗。使用苏州医疗器械厂生产的无菌针灸针(规格:40 mm×0.25 mm),由同一医师施治。其中睛明穴指切直刺缓慢进针,至患者眼部有明显酸胀感,不行手法。丝竹空、攒竹、瞳子髎平刺 15 mm,行平补平泻法,睛明、太阳直刺 15 mm,得气后留针 30 min,3 次/周,持续治疗 8 周。

1.3 疗效判定依据^[7]

治疗 8 周后,参照国家中医药管理局制定的中医疗效判定标准。其中临床症状消失,SIT 多次测定>10 mm/5 min 为治愈;SIT 多次测定泪液分泌量有所增加,症状减轻为好转;SIT 多次测定泪液分泌量未增加,症状体征无好转为未愈。总有效率=治愈率+好转率。

1.4 观察指标

(1)观察两组患者治疗前、治疗 8 周后的眼部症状指标:眼表疾病指数(OSDI)^[10]、BUT、角膜荧光素染色(FL)评分^[11]、SIT。其中 SIT:采用泪液测试专用滤纸(规格 5 mm×40 mm),轻放于下睑缘结膜囊内,闭合眼睑,5min 后测量睑缘外被泪液浸润滤纸的长度。BUT、FL:BUT 是指最后一次瞬目后睁眼至角膜出现第一个黑斑的时间;FL 评分标准:无染色 0 分,染色少于 5 个点 1 分,3 分为出现丝状、块状染色,2 分为染色介于 1 和 3 分。OSDI:观察视疲劳、畏光、刺痛、异物感、视力下降等症状,总分 100 分,分数越高,眼表问题越严重。(2)采集两组治疗前、治疗 8 周后的血清 20 μL,取上清液待测(离心方法:5500 r/min 离心 12 min,离心半径 14cm)。血清转化生长因子-β(TGF-β)、肿瘤坏死因子-α(TNF-α)和白介素-1(IL-1)水平采用酶联免疫吸附法检测,根据试剂盒(德国 r-Biopharm 公司生产)步骤进行。(3)治疗前、治疗 8 周后采用健康状况调查简表(SF-36)^[12]对患者生活质量进行评价,SF-36 从生理机能、生理职能、精神健康、躯体疼痛、健康状况、社会功能、活力、情感职能等 8 个维度进行测评,每个维度各为 100 分,总分越高表示生活质量越高。

1.5 统计学方法

采用 SPSS26.0 进行数据分析。计数资料用率(%)表示,采用卡方检验,计量资料以($\bar{x} \pm s$)表示,行 t 检验。检验水准 $\alpha=0.05$ 。

2 结果

2.1 疗效比较

治疗 8 周后研究组临床总有效率 92.86%(39/42)较对照组 71.43%(30/42)高($P<0.05$),具体如表 1 所示。

表 1 两组疗效比较 [例(%)]

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

Groups	Cure	Become better	Invalid	Total effective rate
Control group (n=42)	9(21.43)	21(50.00)	12(28.57)	30(71.43)
Study group (n=42)	16(38.10)	23(54.76)	3(7.14)	39(92.86)
χ^2				6.574
P				0.010

2.2 两组眼表功能指标对比

治疗前,两组 OSDI、BUT、FL、SIT 组间比较无差异($P>0.05$),
治疗 8 周后,两组 OSDI、FL 评分下降,且研究组的下降程度高

于对照组($P<0.05$),治疗 8 周后,两组 BUT、SIT 升高,且研究
组的升高程度高于对照组($P<0.05$),详见表 2。

表 2 两组眼表功能指标对比($\bar{x} \pm s$)Table 2 Comparison of ocular surface function between the two groups($\bar{x} \pm s$)

Groups	OSDI(score)		BUT(s)		FL(score)		SIT(mm/5 min)	
	Before treatment	8 weeks after treatment	Before treatment	8 weeks after treatment	Before treatment	8 weeks after treatment	Before treatment	8 weeks after treatment
Control group (n=42)	36.87 $\pm$ 3.22	21.71 $\pm$ 4.26 ^a	5.68 $\pm$ 1.71	8.02 $\pm$ 1.57 ^a	6.23 $\pm$ 0.97	4.11 $\pm$ 0.89 ^a	4.34 $\pm$ 0.92	6.62 $\pm$ 0.88 ^a
Study group (n=42)	36.56 $\pm$ 4.20	14.60 $\pm$ 3.17 ^a	5.61 $\pm$ 1.54	10.11 $\pm$ 1.47 ^a	6.18 $\pm$ 0.86	3.13 $\pm$ 0.75 ^a	4.47 $\pm$ 0.89	8.98 $\pm$ 0.74 ^a
t	0.380	8.678	0.197	6.298	0.250	5.457	0.658	13.302
P	0.705	0.000	0.844	0.000	0.803	0.000	0.512	0.000

Note: compared with before treatment in the same group, ^a $P<0.05$.

2.3 血清炎症因子指标对比

治疗前,两组 TGF- β 、TNF- α 、IL-1 比较无差异($P>0.05$),

治疗 8 周后,两组 TGF- β 、TNF- α 、IL-1 下降,且研究组下降程
度高于对照组($P<0.05$),详见表 3。

表 3 两组血清炎症因子指标对比($\bar{x} \pm s$)Table 3 Comparison of serum inflammatory factors between the two groups($\bar{x} \pm s$)

Groups	TGF- β (μ g/L)		TNF- α (μ g/L)		IL-1(pg/mL)	
	Before treatment	8 weeks after treatment	Before treatment	8 weeks after treatment	Before treatment	8 weeks after treatment
Control group (n=42)	25.34 $\pm$ 3.21	15.23 $\pm$ 3.64 ^a	19.25 $\pm$ 2.34	15.19 $\pm$ 2.38 ^a	0.31 $\pm$ 0.06	0.23 $\pm$ 0.04 ^a
Study group (n=42)	25.27 $\pm$ 4.78	9.10 $\pm$ 2.88 ^a	19.14 $\pm$ 3.45	11.52 $\pm$ 2.49 ^a	0.32 $\pm$ 0.05	0.15 $\pm$ 0.03 ^a
t	0.079	8.559	0.171	6.905	0.830	10.369
P	0.937	0.000	0.865	0.000	0.409	0.000

Note: compared with before treatment in the same group, ^a $P<0.05$.

2.4 两组 SF-36 各维度评分对比

治疗前,两组 SF-36 各维度评分比较无差异($P>0.05$),治
疗 8 周后,两组 SF-36 各维度评分升高,且研究组升高程度高
于对照组($P<0.05$),详见表 4。

3 讨论

干眼症病因很多,个人用眼习惯、环境因素等引起的轻度
干眼症患者出现轻微的临床症状,并无明显的眼表损害,这些
症状可随着影响因素的改善而消失^[13]。然而针对局部或全身有
明确病因的干眼症,如过敏、睑缘炎、眼表化学及热烧伤时,其

发病机制就较为复杂^[14]。眼表、主泪腺组成的整体功能单位可
共同发挥调控泪膜形成、泪液分泌作用,当出现局部或全身有
明确病因的影响因素时,泪膜完整性和功能遭到破坏,致使眼
表和泪腺处于一种慢性炎症状态,同时涉及到性激素水平改
变、细胞凋亡、眼表面改变等机制的变化^[15,16]。尽管引起干眼症
的起始病因存在差异,但当干眼症一旦进入进展期时,炎症仍
是发病机制中最为关键的因素^[17,18]。故探寻有效的治疗方案成
为临床关注的焦点。过去对于干眼症的治疗,西医治疗主要从补
充人工泪液及保持泪液入手,玻璃酸钠滴眼液属于人工泪液的一
种,主要成分为透明质酸钠,润滑与保水较为显著,能增加泪

液分泌量,延长泪膜破裂时间,缓解临床症状^[19,20]。但随着泪道 排出和蒸发,作用时间短暂,效果欠佳。

表 4 两组 SF-36 各维度评分对比($\bar{x} \pm s$, 分)

Table 4 Comparison of SF-36 dimensions scores of the two groups($\bar{x} \pm s$, score)

Groups	Time points	Physiologi- cal function	Social function	Role emotional	Vitality	Health condition	Mental health	Somatic pain	Physiologi- cal enginery
Control group (n=42)	Before treatment	59.41± 6.45	64.85± 7.33	62.68± 8.36	68.21± 6.27	62.32± 7.41	61.77± 8.39	65.24± 7.78	64.01± 8.51
	8 weeks after treatment	71.35± 7.39 ^a	72.79± 6.25 ^a	73.04± 7.52 ^a	75.88± 6.19 ^a	72.39± 7.36 ^a	73.13± 8.26 ^a	77.36± 7.65 ^a	73.78± 7.31 ^a
Study group (n=42)	Before treatment	59.32± 7.23	64.24± 6.42	62.53± 9.09	68.39± 8.29	62.73± 6.19	61.35± 7.24	65.53± 7.64	64.47± 8.58
	8 weeks after treatment	84.45±	83.53±	81.62±	82.27±	83.82±	85.92±	83.49±	81.63±
		6.18 ^{ab}	7.37 ^{ab}	6.11 ^{ab}	7.06 ^{ab}	6.30 ^{ab}	8.09 ^{ab}	7.58 ^{ab}	6.42 ^{ab}

Note: compared with before treatment in the same group, ^a $P < 0.05$; compared with control group, ^b $P < 0.05$.

近年来,临床开始关注于中医治疗干眼症的效果。中医认为干眼症主要因目珠失润、脏腑功能失调、肝肾虚弱而引发,治宜益气养阴、生津润燥、疏肝明目、滋补肝肾为主^[21]。明目地黄丸可发挥养肝、滋肾、明目的功效,主要成分包括生地黄、熟地黄、淮山药、山茱萸、泽泻、牡丹皮、茯苓、当归、柴胡、五味子^[22]。原方以六味地黄丸(生地黄、熟地黄、淮山药、山茱萸、泽泻、牡丹皮、茯苓)为滋养肝肾之基础,更增当归、熟地黄、五味子益精养血;柴胡升散,疏肝解郁,全方补中有泻,升降得宜,共呈益精明目、补养肝肾的作用^[23,24]。现代药理学研究发现^[25],明目地黄丸能增强组织细胞代谢能力,有效改善局部微循环。历年来,我国中医常用针刺治疗眼部疾病,选取的穴位中,攒竹位于面部,眉头凹陷中,额切际处,常用于治疗近视、急性腰扭伤、泪囊炎等;睛明穴位于目内眦角稍上方凹陷处,主治目赤肿痛、目眩、近视等目疾;太阳穴能够缓解眼睛疲劳;丝竹空位于在眉梢凹陷处,配睛明、瞳子髎、攒竹主治目赤肿痛;瞳子髎主治目翳、目赤、目痛等目疾,可配合睛明、攒竹、丝竹空等治疗眼疾^[26]。本次研究中,治疗 8 周后,针刺联合明目地黄丸治疗干眼症患者,可有效提升临床治疗效果,增加泪液分泌量,延长泪膜破裂时间,促进症状改善,改善患者生活质量。针刺可以活血养血、行气通络,恢复眼部津液的正常输布,改善泪液分泌^[27]。配合明目地黄丸从根本上调节脏腑功能,补肝益肾,促进治疗效果提升,促进症状改善,减少日常工作生活的多种不便,提高其生活质量。免疫炎症是引起干眼病发病的机制,通常由细胞因子介导,其中 TNF- α 是一种促炎细胞因子,参与正常炎症反应和免疫;IL-1 是协调机体对创伤、感染和炎症的整体反应的生理性介质;TGF- β 通过干扰结膜上皮细胞的增殖、分化,并侵袭泪腺组织,加重眼表炎症反应^[28,29]。本研究结果显示,针刺联合明目地黄丸治疗可有效降低炎症因子水平。究其原因,针刺对炎症介质存在着双向良性调节作用,可抑制炎症细胞因子的合成,使炎症反应不致扩大,恢复机能同各结构、各组织之间的综合平衡^[30]。

综上所述,干眼症患者经针刺联合明目地黄丸治疗后,可促进临床症状改善,同时能降低机体炎症因子水平,提高患者生活质量,疗效可靠。

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