

doi: 10.13241/j.cnki.pmb.2023.24.032

补中益气汤联合低频脉冲电刺激促进产后盆底功能障碍的效果及血清松弛素、CTGF 和 MMP-1 水平的影响*

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摘要 目的:探讨补中益气汤联合低频脉冲电刺激促进产后盆底功能障碍的效果及血清松弛素(RLX)、结缔组织生长因子(CTGF)和基质金属蛋白酶-1(MMP-1)水平的影响。**方法:**选取我院 2022 年 4 月到 2023 年 4 月收治的 150 例产后盆底功能障碍患者作为研究对象,分为观察组与对照组,各组均 75 例。对照组患者采取低频脉冲电刺激治疗,观察组患者采取补中益气汤联合低频脉冲电刺激治疗,对比两组患者的临床疗效,治疗前后盆底表面肌电变化情况,并分别在治疗前后应用盆腔脏器脱垂-尿失禁性功能问卷(PISQ-12)、国际尿控协会盆腔脏器脱垂定量分析量表(POP-Q)、尿失禁问卷表简表(ICI-Q-SF)评估两组患者的性功能、盆腔脱垂程度及尿失禁情况,并对比治疗前后血清 RLX、CTGF 和 MMP-1 表达水平。**结果:**观察组总有效率 93.33%明显高于对照组 78.67%($P<0.05$);两组患者治疗前耐力收缩(II类肌)、持续收缩和快速收缩(I类肌)、前静息电位、后静息电位肌电水平对比无差异($P>0.05$),治疗后观察组快速收缩(I类肌)高于对照组($P<0.05$),静息电位与后静息电位低于对照组($P<0.05$);两组患者治疗前 PISQ-12、POP-Q 和 ICI-Q-SF 评分对比无明显差异($P>0.05$),治疗后两组患者 PISQ-12、ICI-Q-SF 评分升高,观察组较对照组高,POP-Q 评分均降低,观察组较对照组低($P<0.05$);两组患者治疗前 RLX、CTGF 和 MMP-1 表达水平对比无差异($P>0.05$),治疗后两组患者 RLX、CTGF 和 MMP-1 表达水平均降低,且观察组低于对照组($P<0.05$)。**结论:**补中益气汤联合低频脉冲电刺激可提升产后盆底功能障碍的临床疗效,改善盆底肌表面肌电变化,改善患者性功能、盆腔脱垂程度及尿失禁情况,且能够降低血清松弛素、CTGF 和 MMP-1 表达水平。

关键词:补中益气汤;盆底功能障碍;血清松弛素;低频脉冲电刺激;结缔组织生长因子;基质金属蛋白酶-1

中图分类号:R242;R711.5;Q683 **文献标识码:**A **文章编号:**1673-6273(2023)24-4760-05

Effect of Bu Zhong Yi Qi Tang Combined with Low-frequency Pulse Electrical Stimulation on Promoting Postpartum Pelvic Floor Dysfunction and the Influence of Serum Relaxin, CTGF and MMP-1 Levels*

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ABSTRACT Objective: To explore the effect of Bu Zhong Yi Qi Tang combined with low-frequency pulse electrical stimulation on promoting postpartum pelvic floor dysfunction and the influence of serum Relaxin (RLX), connective tissue growth factor (CTGF) and mechanism metalloproteinase-1 (MMP-1) levels. **Methods:** 150 patients with postpartum pelvic floor dysfunction admitted to our hospital from April 2022 to April 2023 were selected as the research subjects. They were divided into an observation group and a matched group using a lottery method, with 75 patients in each group. The patients in the matched group were treated with low-frequency pulse electrical stimulation, and the patients in the observation group were treated with Bu Zhong Yi Qi Tang combined with low-frequency pulse electrical stimulation. The clinical effects of the two groups were compared, and the changes of pelvic floor surface myoelectricity before and after treatment were compared. The pelvic organ prolapse Urinary incontinence sexual function questionnaire (PISQ-12), the International Association for Urinary Control pelvic organ prolapse quantitative analysis scale (POP-Q) Urinary incontinence questionnaire short form (ICI-Q-SF) was used to evaluate the sexual function, pelvic prolapse and Urinary incontinence of the two groups of patients, and the serum RLX, CTGF and MMP-1 expression levels were compared before and after treatment. **Results:** The total effective rate of 93.33% in the observation group was significantly higher than 78.67% in the matched group ($P<0.05$); There was no significant difference in the EMG levels of endurance contraction (Class II muscle), continuous contraction and rapid contraction (Class I muscle), anterior Resting potential and posterior Resting potential between the two groups before treatment ($P>0.05$). After treatment, the rapid contraction (Class I muscle) in the observation group was higher than that in the matched group ($P<0.05$), and the Resting potential and posterior Resting potential were lower than those in the matched group($P<0.05$); There was no significant difference in the PISQ-12, POP-Q, and ICI-Q-SF scores between the two groups of patients before treatment ($P>0.05$). After treatment, the PISQ-12, ICI-Q-SF scores of the two groups of

* 基金项目:陕西省重点研发计划项目(2023-YBSF-305)

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(收稿日期:2023-05-27 接受日期:2023-06-23)

patients increased, and the observation group was higher than the matched group, while the POP-Q scores decreased. The observation group was lower than the matched group ($P<0.05$); There was no significant difference in the expression levels of RLX, CTGF, and MMP-1 between the two groups of patients before treatment ($P>0.05$). After treatment, the expression levels of RLX, CTGF, and MMP-1 decreased in both groups of patients, and the observation group was lower than the matched group ($P<0.05$). **Conclusion:** Bu Zhong Yi Qi Tang combined with low-frequency pulse electrical stimulation can improve the clinical efficacy of postpartum pelvic floor dysfunction, improve the changes of pelvic floor muscle surface electromyography, improve patients' sexual function, pelvic prolapse and Urinary incontinence, and reduce the expression levels of serum Relaxin, CTGF and MMP-1.

Key words: Bu Zhong Yi Qi Tang; Low frequency pulse electrical stimulation; Pelvic floor dysfunction; Serum Relaxin; Connective tissue growth factor; Mechanism Metalloproteinase-1

Chinese Library Classification(CLC): R242; R711.5; Q683 **Document code:** A

Article ID: 1673-6273(2023)24-4760-05

前言

盆底功能障碍(Pelvic floor muscle dysfunction, PFD)多由产妇产在妊娠及分娩过程中盆底肌韧带受损导致,在发生 PFD 之后多存在性生活不满意、尿频、小腹坠胀等症状,严重者甚至会出现尿失禁、盆腔脏器脱垂等疾病,对患者的生活质量产生负面影响^[1,2]。当前临床上对 PFD 多采取电刺激、生物反馈治疗以及盆底肌肉锻炼等方式进行康复治疗,操作简单、安全性高,但是很多患者并不能够自主进行盆底肌收缩,不能够准确判断盆底肌收缩程度,影响 PFD 康复疗效^[3]。所以,改善 PFD 患者盆底功能,降低盆腔脏器脱垂和尿失禁等疾病的发生,成为临床研究的热点内容。随着中西医结合治疗在临床应用的开展,中西医互补的方式,不良反应发生率低,应用与 PFD 的治疗逐渐被越来越多的学者认可^[4]。中医中并无盆底功能障碍疾病名称,一般依照患者症状与体征将其归属于“魄门痛、肠风、脱肛、便秘、阴挺”等范畴,多以肾虚、气虚、体虚、中气不足为发病机理,所以需以补肾温阳、补中益气为主要原则^[5,6]。因此,为了改善 PFD 患者的临床疗效,本研究探讨补中益气汤联合低频脉冲电刺激促进产后盆底功能障碍的效果。

1 资料与方法

1.1 一般资料

选取我院 2022 年 4 月到 2023 年 4 月收治的 150 例产后盆底功能障碍患者作为研究对象,分为观察组与对照组,各 75 例。本研究经我院伦理委员会批准。对照组患者年龄为 25~38 岁,平均(27.37±3.63)岁;产后天数为 42~68 d,平均(46.36±4.73)d;盆底肌力:II 级 31 例,III 级 44 例;疾病类型:性功能障碍 18 例,子宫脱垂 36 例,尿失禁 21 例。观察组患者年龄为 23~35 岁,平均(27.38±3.13)岁;产后天数为 42~70 d,平均(46.93±4.17)d;盆底肌力:II 级 35 例,III 级 40 例;疾病类型:性功能障碍 21 例,子宫脱垂 35 例,尿失禁 29 例。两组患者一般资料对比无差异($P>0.05$)。

1.2 纳排标准

纳入标准:均符合《妇产科学》^[7]关于产后盆底功能障碍的诊断标准;产后 42~180 d;临床资料完整;初产妇;盆底肌力为 II~III 级;知情同意;

排除标准:合并神经肌肉病史或尿失禁史者;对本研究所用药物过敏者;多胎、过期妊娠过经产妇;合并胎盘早剥、胎位异常、先兆子痫等不良妊娠者;合并泌尿系统畸形或感染者。

1.3 方法

对照组:采取低频脉冲电刺激进行治疗。应用法国欧亚迪斯盆底神经肌肉刺激治疗仪(生产企业:西安木林森生物科技有限公司;注册证号:国械注进 20172211964;型号:PHENIX USB4),将探头放置到阴道中,机电转化为视觉信号之后,进行电流刺激,以患者耐受为宜。随后进行盆底肌的收缩和放松训练, I 类肌纤维刺激频率设置为 9~32Hz, II 类设置为 20~80 Hz,每周治疗 2 次,每次 30 min。完成后将康复期放置在患者的阴道内,实施收缩阴道肌肉夹持训练,每周 2 次,每次 30 min。治疗时间为 8 周。

观察组:在对照组基础上增加补中益气汤治疗,药方为:黄芪、益母草各 15 g,党参、枳壳、当归各 12 g,白术、炙甘草 9 g,陈皮、柴胡、升麻各 6 g。此为 1 剂药量,每日 1 剂,用水煎服,分早晚两次服用,共治疗 8 周。

1.4 观察指标与疗效判定标准

1.4.1 观察指标 (1)盆底表面肌电评估:评估之前嘱咐患者将膀胱排空,露出会阴后将探头放置在阴道内,应用生物反馈训练系统测试盆底肌相关肌电参数变化。

(2)分别在治疗前及治疗 8 周之后应用盆腔脏器脱垂-尿失禁性功能问卷(PISQ-12)^[8]评估患者性功能水平,其中共包括 12 个题目,总分为 48 分,分数预告代表性功能水平越好。应用国际尿控协会盆腔脏器脱垂定量分析量表(POP-Q)^[9]评估患者盆腔脏器脱垂程度,1 分为脱垂最远处在处女膜之内,且与处女膜距离在 1 cm 以上;2 分为脱垂最远处在处女膜的边缘 1 cm 之外;3 分为脱垂最远处在处女膜的边缘 1~2 cm;4 分为阴道几乎完全或完全脱垂。应用尿失禁问卷表简表(Urinary incontinence Questionnaire, ICI-Q-SF)^[10]评价患者尿失禁情况,总分为 21 分,分数越高代表尿失禁情况越严重。

(3)分别在治疗前及治疗 8 周之后抽取两组患者清晨空腹静脉血 10 min,以 3000 r/min 的速度离心 15 min,离心半径为 10 cm,离心后取上层清液,防止在零下 80℃ 的冰箱中保存待检。应用酶联免疫吸附试验法检测血清松弛素(RLX)、结缔组织生长因子(CTGF)和基质金属蛋白酶-1(MMP-1)表达水平,检测步骤严格依照北京奥森生物技术有限公司提供的试剂盒说明书进行。

1.4.2 疗效判定标准 治疗后患者盆底肌力改善 2 级以上,盆底功能相关体征与症状基本消失为显效;盆底肌力改善 1 级以上,盆底功能相关体征与症状缓解为有效;未达到上述标准为无效。总有效率=(显效人数+有效人数)/总人数×100%^[11]。

1.5 统计学方法

采取 SPSS 23.0 分析,计数资料以(n%)表示,进行 χ^2 检

验;计量资料用($\bar{x} \pm s$)表示,采用 t 检验;以 $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 临床疗效对比

观察组总有效率较对照组高($P < 0.05$),如表 1。

表 1 临床疗效对比(n,%)
Table 1 Comparison of Clinical Efficacy (n,%)

Groups	n	Apparent effect	Effective	Invalid	Total effective rate
Observers group	75	39(52.00)	31(41.33)	5(6.67)	70(93.33)
Matched group	75	34(45.33)	25(33.33)	16(21.33)	59(78.67)
χ^2	-	-	-	-	6.700
P	-	-	-	-	0.010

表 2 盆底表面肌电变化对比($\bar{x} \pm s, \mu V$)
Table 2 Comparison of changes in surface electromyography of pelvic floor($\bar{x} \pm s, \mu V$)

Groups	n	Endurance contraction (Class II muscle)		Continuous contraction		Rapid contraction (Class I muscle)		Anterior Resting potential		Posterior Resting potential	
		Before	After	Before	After	Before	After	Before	After	Before	After
		treatment	treatment	treatment	treatment	treatment	treatment	treatment	treatment	treatment	treatment
Observers group	75	17.38±	19.35±	23.53±	25.62±	36.36±	42.82±	8.53±	3.82±	9.25±	3.67±
		5.53	3.63	6.47	7.75	12.53	8.37*	2.51	1.76*	3.26	1.23*
Matched group	75	17.62±	19.53±	24.46±	24.63±	37.83±	37.93±	8.84±	5.62±	9.37±	5.52±
		5.74	4.84	7.15	8.12	12.93	9.84	2.36	1.83*	2.37	1.55*
t		0.261	0.258	0.835	0.764	0.707	3.278	0.779	6.140	0.258	8.097
P		0.794	0.797	0.405	0.446	0.481	<0.001	0.437	<0.001	0.797	<0.001

Note: Compared with Before treatment, * $P < 0.05$, the same below.

2.3 性功能、盆腔脱垂程度及尿失禁情况对比

两组患者治疗前 PISQ-12、POP-Q 和 ICI-Q-SF 评分对比无差异($P > 0.05$),治疗后两组患者 PISQ-12、ICI-Q-SF 评分升高,

2.2 盆底表面肌电变化对比

两组患者治疗前耐力收缩(II类肌)、持续收缩和快速收缩(I类肌)、前静息电位、后静息电位肌电水平对比无明显差异($P > 0.05$),治疗后观察组快速收缩(I类肌)高于对照组($P < 0.05$),静息电位与后静息电位低于对照组($P < 0.05$),如表 2。

观察组较对照组高,POP-Q 评分均降低,观察组较对照组低($P < 0.05$),如表 3。

表 3 性功能、盆腔脱垂程度及尿失禁情况对比($\bar{x} \pm s$,分)
Table 3 Comparison of sexual function, degree of pelvic prolapse and urinary incontinence($\bar{x} \pm s$, points)

Groups	n	PISQ-12		POP-Q		ICI-Q-SF	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Observers group	75	24.37± 4.21	42.13± 5.32*	1.91± 0.17	0.62± 0.12*	27.61± 6.37	69.12± 7.12*
Matched group	75	23.94± 3.21	33.68± 6.12*	1.84± 0.31	0.92± 0.25*	28.47± 5.25	61.21± 8.93*
t	-	0.703	9.024	1.715	9.369	0.902	5.998
P	-	0.483	<0.001	0.088	<0.001	0.369	<0.001

2.4 血清 RLX、CTGF 和 MMP-1 表达水平对比

两组患者治疗前 RLX、CTGF 和 MMP-1 表达水平对比无差异($P > 0.05$),治疗后均降低,且观察组较对照组低($P < 0.05$),如表 4。

3 讨论

低频脉冲电刺激主要是利用电刺激的形式,激活和唤醒肌肉的收缩能力,加速血液循环后,加强新陈代谢水平,避免进一步损伤盆底肌肉和萎缩过程^[12]。研究发现^[13],低频脉冲电刺激能

够明显提升阴道、尿道口等位置的肌肉收缩功能。该方法作为盆底功能障碍的常见治疗方式,逐渐被广泛应用到临床。而在祖国医学中,多认为产妇在生产之后会出现中气不足的情况,此为气虚。而生产史用力太过会导致元气大损、阴血亏虚,此为血虚^[14]。气血双虚导致的盆底功能障碍的发生。因此,治疗盆底功能障碍需以补中益气为主要原则^[15]。补中益气方作为金元李东垣所创的经典组方,也是补中益气、益气升阳的代表方剂,可治疗清阳下陷、中气不足之证^[16]。

本文作者通过设立不同分组的方式进行研究。最终显示,

表 4 血清 RLX、CTGF 和 MMP-1 表达水平对比($\bar{x} \pm s$)Table 4 Comparison of serum RLX, CTGF, and MMP-1 expression levels($\bar{x} \pm s$)

Groups	n	RLX($\rho/\text{ng} \cdot \text{L}^{-1}$)		CTGF($\mu\text{g}/\text{L}$)		MMP-1($\mu\text{g}/\text{L}$)	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Observers group	75	59.47± 11.25	49.21± 8.93*	58.84± 5.21	42.68± 7.12*	9.44± 2.31	5.32± 1.02*
Matched group	75	59.21± 12.37	52.12± 6.12*	58.37± 6.21	49.63± 5.52*	9.41± 2.37	7.02± 2.23*
t	-	0.135	3.207	0.502	6.681	0.079	6.004
P	-	0.893	0.002	0.616	<0.001	0.937	<0.001

采取补中益气汤联合低频脉冲电刺激可改善盆底功能障碍的临床疗效,与 Wagner B 等^[17]研究相符。Wagner B 等研究发现,对盆底功能障碍患者采取电刺激联合中医治疗可改善患者临床症状,提升盆底肌力。这是因为,通过低频电刺激治疗能够利用低频脉冲电流兴奋肌肉神经阻滞,改善局部血液循环,让休眠的神经细胞觉醒,从而增强肌肉收缩能力^[18]。另外增加补中益气汤治疗,全方以益母草、黄芪为君药,益母草可活血调经、清热解毒、利尿消肿;黄芪可补气、解毒排脓,对于气虚乏力、自汗、盗汗、久泻脱肛、失眠多梦等病症有一定的调理效果。《日华子本草》中有云:黄芪可助气壮筋骨,长肉补血。以枳壳、党参、当归为臣,枳壳可理气宽中、行滞消胀;党参可补中益气、健脾益肺、养血生津;当归可补血活血、调经止痛^[19]。并以白术、柴胡、陈皮、升麻为辅,白术可利尿消肿、固表止汗、燥湿健脾;柴胡可疏肝解郁、升举阳气;陈皮可理气健脾,调中;升麻可补中益气、益气升阳^[20]。并以甘草调和诸药,诸药共奏补中益气、气血双补之效。本研究结果表明,补中益气汤联合低频脉冲电刺激可改善盆底肌表面肌电变化。这也说明了,该治疗方法可改善患者神经肌肉兴奋性,提升肌肉收缩能力,加快盆底肌静脉回流,与张丽玲等^[21]研究相符。张丽玲等研究相符,补中益气汤作为经典组方,通过对患者的气血双补效果,对盆底功能障碍的治疗具有显著效果,可提升患者盆底肌力。这是因为,补中益气汤的中药成分的配伍,可共奏补中益气、升阳举陷的效果,多适合中气下陷等病症^[22]。现代药理学研究发现^[23],黄芪的主要成分可增加白细胞计数,改善网状内皮系统吞噬功能,进而提高吞噬细胞功能,还能够提升细胞免疫和体液免疫来改善毛细血管通透性,改善结缔组织之中筋膜和韧带胶原蛋白含量,进而维持盆底肌组织的营养,改善肌力水平;本研究结果显示,治疗后两组患者 PISQ-12、ICI-Q-SF 评分升高,观察组较对照组高,POP-Q 评分降低,观察组较对照组低($P<0.05$)。提示在电刺激治疗基础上增加补中益气汤能够改善患者性功能,减轻盆腔脱垂程度及尿失禁情况,与郭青戈等^[24]研究相符;盆底韧带、筋膜、肌肉的交错及相互作用来支撑盆底肌,而韧带、筋膜构成结缔组织与平滑肌,其中的成纤维细胞在细胞外基质生成。细胞外基质主要成分是胶原蛋白,扩张力高,影响盆底肌结构稳定性。胶原蛋白含量会影响结缔组织张力,其水平减少后会降低弹性水平,对盆底支持作用降低,继而引发盆底功能障碍和脏器脱垂。研究显示^[25],盆底功能障碍的发生与发展与细胞外基质的重构与代谢异常具有一定关系,而且很多细胞因子共同参与细胞外基质的重构过程。CTGF 可增加细胞的增殖速度,促进胶原蛋白合成,同时参与了细胞外基质相关基因的发展,促进结缔组织增生,细胞外基质水平提升。因此,CTGF 水平升高,也是诱导盆底功能障碍发生与发展的重要过程^[26]。血清

MMP-1 水平若升高,可能导致盆底结缔组织病理性变化^[27]。RLX 是由黄体所产生的妊娠相关技术,可作用与松弛盆腔韧带,能够抑制职工恩个平滑肌瘦多,待分娩之后会下降到孕前水平。研究发现^[28],RLX 水平升高会使盆底支持组织作用产生影响,继而导致盆底功能异常。本研究显示,治疗后两组患者 RLX、CTGF 和 MMP-1 表达水平均降低,且观察组低于对照组($P<0.05$)。提示补中益气汤联合低频脉冲电刺激能够通过改善盆底肌支撑程度,从根源上提升对盆底功能障碍的治疗效果,与 Groenendijk IM 等^[29]研究相符。Groenendijk IM 等通过对补中益气汤的药理学研究发现,补中益气汤可促进盆底肌收缩平衡,提高环核苷酸调节功能,改善子宫兴奋性与收缩能力。另外,补中益气汤还能够促进结缔组织细胞增殖和分裂,进一步改善 RLX、CTGF 和 MMP-1 表达水平^[30]。

综上,补中益气汤联合低频脉冲电刺激可提升疗效,改善盆底肌表面肌电变化,改善患者性功能、盆腔脱垂程度及尿失禁情况,且能够降低血清松弛素、CTGF 和 MMP-1 表达水平,值得临床应用推广。

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