doi: 10.13241/j.cnki.pmb.2020.12.032

盆底康复治疗仪结合中医辨证治疗产后盆底功能障碍性疾病的临床研究 *

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摘要 目的:评价盆底康复治疗仪结合中医辨证分型施治产后盆底功能障碍性疾病(PFD)的临床疗效,为中西医结合治疗产后 PFD 提供临床依据。**方法:**连续选择 2017 年 6 月至 2018 年 6 月入我院诊断产后 PFD 的患者共 115 例作为观察组,根据中医辨证分型将其分为气虚型 60 例和肾虚型 55 例,两组患者均给予盆底康复治疗仪进行产后康复,气虚型患者给予补中益气汤加减,肾虚型患者给予大补元煎加减,另选择 50 例仅进行盆底康复治疗仪干预作为对照组,疗程为产后 12 周。比较两组治疗前后盆底功能障碍问卷(PFDI20)评分、国际尿失禁咨询委员会尿失禁问卷表简表(ICI-Q-SF)评分、盆腔器官脱垂 POP-Q 量表评分、盆底肌力分级及中医症候积分的变化,临床疗效以及中医证候疗效。**结果:**对照组和观察组患者治疗后 PFDI20、ICI-Q-SF 和 POP-Q 评分均较治疗前明显降低($P<0.05$),盆底肌力明显增加($P<0.05$),中医症候积分明显降低($P<0.05$);与对照组比较,观察组改善更明显($P<0.05$),但气虚型和肾虚型患者比较改善程度不明显($P>0.05$)。与对照组比较,观察组临床疗效和中医证候疗效明显提高($P<0.05$),但是气虚型和肾虚型患者临床疗效和中医证候疗效比较差异无统计学意义($P>0.05$)。**结论:**盆底康复治疗仪结合中医辨证分型施治产后 PFD 有较好的安全性和有效性。

关键词:盆底康复治疗仪;中医辨证分型;盆底功能障碍性疾病

中图分类号:R711.5;R271 **文献标识码:**A **文章编号:**1673-6273(2020)12-2346-05

Clinical Study of Pelvic Floor Rehabilitation Therapeutic Apparatus Combined with TCM Syndrome Differentiation in Treatment of Postpartum Pelvic Floor Dysfunction*

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ABSTRACT Objective: To evaluate the clinical efficacy of pelvic floor rehabilitation therapeutic apparatus combined with TCM syndrome differentiation in treatment of postpartum pelvic floor dysfunction (PFD), in order to bring evidences and inform standardized plan for PFD with integrated traditional Chinese and Western medicine treatment. **Methods:** A total of 115 consecutives as PFD from June 2017 to June 2018 were enrolled as observation group, 60 cases of Qi deficiency type and other 55 cases of Kidney deficiency type by TCM syndrome differentiation; they all received pelvic floor rehabilitation therapeutic apparatus, and they of Qi deficiency type got Buzhong Yiqi Decoction, they of Kidney deficiency type adopted Dabu Yuan Decoction; other 50 patients only received pelvic floor rehabilitation therapeutic apparatus intervention as control group, the course was 12 weeks. Then to compare scores of Pelvic floor distress inventory-short form 20 (PFDI-20), International urinary incontinence Advisory Committee urinary incontinence questionnaire form (ICI-Q-SF) and pelvic organ prolapse quantitive examination (POP-Q), Pelvic floor muscle strength classification, clinical effect, TCM symptom score and TCM syndrome effect. **Results:** The scores of PFDI-20, ICI-Q-SF and POP-Q in control and observation groups after treatment were all significantly lower than before ($P<0.05$). What's more, the pelvic floor muscle strength in the two groups after treatment were both higher, TCM symptom scores were lower, too ($P<0.05$). Compared with control group, the improvements of above indicators in observation group were more higher ($P<0.05$), but the improvements in patients with Qi deficiency and kidney deficiency were no differences ($P>0.05$). Furtherly, the clinical effect and TCM syndrome effect in observation group were more than control group ($P<0.05$), while there were no differences between Qi deficiency and kidney deficiency patients($P>0.05$). **Conclusion:** It is better safety and efficacy of pelvic floor rehabilitation therapeutic apparatus combined with TCM syndrome differentiation in treatment of postpartum PFD.

* 基金项目:2017-2020 年浦东新区卫计委项目(PWZzb2017-04);2017-2019 年上海市妇幼健康中医专项建设项目

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(收稿日期:2020-01-23 接受日期:2020-02-18)

Key words: Pelvic floor rehabilitation therapeutic apparatus; TCM syndrome differentiation; Pelvic floor dysfunction
Chinese Library Classification(CLC): R711.5; R271 Document code: A
Article ID: 1673-6273(2020)12-2346-05

前言

盆底功能障碍性疾病(pelvic floor dysfunction，PFD)是指盆底支持结构缺陷、损伤及功能障碍造成的一类疾病综合征，主要以压力性尿失禁、盆腔器官脱垂、性功能障碍、粪失禁、便秘以及慢性盆腔疼痛为临床表现[1,2]。PFD 的发病率很高，已成为影响妇女身心健康和生活质量的重要公共卫生疾病之一[3,4]。报道指出，约 43～76%的产后 PFD 患者需要采用手术治疗[5,6]，但对于临床症状较轻的患者可通过中西医结合的方式治疗[7,8]，具有见效快、安全、可靠的优点。

妊娠和分娩过程是 PFD 发病的关键因素，产后恰好是预防和治疗 PFD 的关键有利时机[9,10]。目前防治产后 PFD 的主要方法有盆底功能重建和中医康复治疗，其中生物反馈治疗、电刺激、肌肉训练等方法，操作简便，不会对患者有新的损伤，且安全有效，易于接受[11-13]。中医通过辩证施治，调整机体功能，中西医结合综合治疗可进一步提高疗效[14,15]。因此，该研究旨在评价盆底康复治疗仪结合中医辨证分型施治产后 PFD 的临床疗效，为中西医结合治疗产后 PFD 提供可靠的临床依据，形成中西医结合治疗产后 PFD 的标准化诊疗方案。

1 对象与方法

1.1 对象资料

连续选择 2017 年 6 月至 2018 年 6 月入我院建卡产检、分娩和产后随访的孕产妇，其中诊断产后 PFD 患者共 115 例作为观察组。纳入标准：1.均为单活胎，符合产后 PFD 诊断标准，无产前 PFD；2.年龄 18~50 岁；3.能根据分组要求完成规定治疗和随访；4.取得患者的知情同意权，临床资料完善。排除标准：1.产后恶露未净或月经期，禁止使用阴道内器械进行康复治疗；2.产妇有精神或心理障碍，痴呆、癫痫等神经系统疾病；3.合并恶性肿瘤、泌尿生殖道活动性感染、安装心脏起搏器、伤口感染或有手术瘢痕裂开风险患者；4.严重心、肺、肝、肾等脏器功能障碍；5.同时参与其他研究。

根据中医辨证分型可分为气虚型 60 例和肾虚型 55 例，气虚型[4]辨证为：子宫下脱，尿意频数、尿量不多，面色苍白，少气懒言、体倦乏力，头晕眼花，心悸气短，小腹沉坠；舌质淡，苔白，脉虚弱无力。肾虚型[4]辨证为：子宫下脱，头晕耳鸣，腰膝酸软，小腹下坠，小便频数、甚至小便自出；舌质淡红，苔薄，脉沉弱。气虚型患者年龄 25～42 岁，平均(34.6±6.8)岁；体质量指数(BMI)21.6～25.7 kg/m^2，平均(22.8±1.2)kg/m^2；孕周 38.5~40 周，平均(39.2±0.8)周；初产妇 40 例，经产妇 20 例，阴道分娩 50 例，剖宫产 10 例。肾虚型患者年龄 23～45 岁，平均(35.7±7.2)岁；BMI 21.8～25.6 kg/m^2，平均(23.2±1.5)kg/m^2；孕周 38.4~40.5 周，平均(39.3±0.7)周；初产妇 35 例，经产妇 20 例，阴道分娩 40 例，剖宫产 15 例。

另选择 50 例仅进行盆底康复治疗仪干预作为对照组，年龄 25～48 岁，平均(36.6±7.5)岁；BMI 22.2～28.9 kg/m^2，平均(24.5±2.3)kg/m^2；孕周 38.2~40.1 周，平均(39.1±0.8)周；初产妇 34 例，经产妇 16 例，阴道分娩 36 例，剖宫产 14 例。三组患者的一般临床资料比较无差异($P>0.05$)。

1.2 研究方法

产后 PFD 的中西医结合治疗方案共分产前、产时、产褥期和产后恢复期四个阶段进行，在各期均进行常规宣教；助产过程严格遵守产科规范，注重保护盆底组织；产后 42 天内为产褥期，密切观察泌尿道、消化道恢复情况，对出现尿潴留、尿失禁、粪失禁等异常情况及时对症处理，指导产妇逐步适应盆底肌锻炼；产后 42 天至 12 周为产后恢复期，产妇定期进行门诊随访，进行产后盆底功能评估，指导患者采用 kegel 训练法进行盆底肌锻炼，具体为：作收缩肛门和阴道的动作，每次收紧不少于 3s 后放松，连续做 15～30 min，每日 2～3 次，或每日做 150～200 次，6～8 周为 1 个疗程。

对照组和观察组患者均给予盆底康复治疗仪进行产后康复，气虚型患者给予补中益气汤加减，肾虚型患者给予大补元煎加减，疗程为产褥期和产后恢复期共 12 周。盆底康复治疗仪根据操作说明进行，每周治疗 2 次，每次 30 min，8 次为 1 个疗程，连续治疗 3 个疗程。气虚型以健脾益气为治法，方药为补中益气汤加减，具体组方为：党参 10 g、黄芪 15 g、陈皮 6 g、白术 9 g、当归 10 g、升麻 6 g、柴胡 6 g、益母草 15 g、炙甘草 9 g、枳壳 10 g，易感冒者可加大黄芪用量、加桔梗、防风益气固表，汗出量多者加浮小麦、五味子敛肺止汗；小腹坠胀者加桔梗升阳举陷；小便频数或遗尿者加乌药、益智、山药温肾固精缩尿，畏寒怕冷、夜尿频多者可加淫羊藿、巴戟天、肉苁蓉、仙茅温而不燥；口干口苦、腰膝酸软、潮热盗汗者加黄柏、知母、女贞子、旱莲草、生地、枣皮清热滋肾；尿频、尿急、尿灼感甚或尿痛者加萹蓄、瞿麦、蒲公英、白花蛇舌草利水通淋、清热解毒。每日一剂，煎药 400 mL，分早晚 2 次温服。

肾虚型以温补肾阳为治法，方药为大补元煎加减，具体组方为：党参 30 g、山药 30 g、熟地 24 g、杜仲 15 g、当归 12 g、山茱萸 12 g、枸杞子 12 g、炙甘草 6 g，夹杂血虚者可加生地和玄参各 20 g，夹杂阳虚者加肉桂 6 g，肉苁蓉 20 g。每日一剂，煎药 400 mL，分早晚 2 次温服。

1.3 观察指标和评价方法

观察指标有盆底功能障碍问卷 (Pelvic floor distress inventory-short form 20，PFDI-20)评分、国际尿失禁咨询委员会尿失禁问卷表简表(International urinary incontinence Advisory Committee urinary incontinence questionnaire form，ICI-Q-SF)评分和盆腔器官脱垂量表(pelvic organ prolapse quantitive examination，POP-Q)评分，盆底肌力分级，临床疗效，中医症候积分以及中医证候疗效。

PFDI-20[5]涵盖近 3 个月的膀胱、肠道和盆腔症状，分别为 POPDI-6、CRADI-8 和 UDI-6 三项，每项设置 0～4 分，总分 0～80 分，分数越高，表明症状越重。ICI-Q-SF[6]涉及近 4 周的尿失禁及严重程度、日常生活、性生活、情绪以及其他泌尿系症状共

5 个方面，各项评分相加总分 0～100 分，分数越高，表明症状越重。POP-Q[7]以处女膜为参照，阴道前壁、后壁和顶部 6 个点为指示点，以 6 点相对于处女膜的位置变化为尺度，对脱垂作出量化，记录阴道全长(tvl)、生殖道裂孔(gh)长度、会引体(pb)长度。并以此进行分度，其中 0 度为无脱垂，Aa、Ap、Ba 和 Bp 均为 -3 cm，C 点在 tvl 和 -(tvl-2 cm)之间；I 度为脱垂最远处在处女膜内，距离处女膜大于 1 cm；II 度为脱垂最远处在处女膜边缘 1 cm 内，不论在处女膜内或外；III 度为脱垂最远处在处女膜外，距离处女膜边缘大于 1 cm，但小于 +(tvl-2 cm)；IV 度为阴道完全或几乎完全脱垂，脱垂最远处大于或等于 +(tvl-2 cm)。

盆底肌力采用盆底康复治疗仪检测盆底肌阴道最大压力和肌纤维肌力等级[8]，临床疗效[9]分为显效、有效和无效 3 种，其中显效定义为：主观症状消失，症状问卷及生活质量问卷明显改善(评分改变≥ 70%)，中医临床症状、体征明显改善，证候积分减少≥ 70%；客观体征恢复，盆底肌力测定 IV 级，或改善 2 级及以上，子宫脱垂程度降低 1 度或以上，尿失禁改善 2 度或以上；辅助检查指标正常。有效定义为主观症状缓解，症状问卷及生活质量问卷改善(评分改变≥ 30%)，中医临床症状、体征好转，证候积分减少≥ 30%；客观体征恢复，盆底肌力测定改善 1 级，子宫脱垂程度降低，POP-Q 评分减少，尿失禁改善 1 度，辅助检查指标改善。无效定义为主观症状无缓解或加重，症状问卷及生活质量问卷改善(评分改变 <30%)，中医临床症状、体征好转，证候积分减少 <30%；客观体征无改变，盆底肌力测定未见改善，子宫脱垂程度未见降低，POP-Q 评分未见减少，尿失禁未见改善，辅助检查指标未见改善。

中医证候疗效[9]分为临床痊愈、显效、有效和无效 4 种，其中临床痊愈定义为中医临床症状、体征消失或基本消失，证候积分减少≥ 90%；显效定义为中医临床症状、体征明显改善，证候积分减少≥ 70%；有效定义为中医临床症状、体征均有好转，证候积分减少≥ 30%；无效定义为中医临床症状、体征均无明显改善，甚或加重，证候积分减少不足 30%。

中医症候包括尿失禁、盆腔器官脱垂、性功能障碍、粪失禁、便秘和慢性盆腔疼痛共 6 个项目，每个项目设置 1～4 分，总分 6～24 分，总分越高，表明症状越重。证候疗效＝[(治疗前－治疗后)积分 / 治疗前积分]×100%。

1.4 统计学方法

采用 SPSS20.0 软件进行统计分析，计量资料以均数± 标准差表示，治疗前后比较采用配对 t 检验，计数资料以例数或(%)表示，比较用 χ^2 检验；$P<0.05$ 认为差异有统计学意义。

2 结果

2.1 治疗前后各调查问卷评分的比较

对照组和观察组治疗后 PFDI20、ICI-Q-SF 和 POP-Q 评分均较治疗前明显降低，差异有统计学意义($P<0.05$)；与对照组比较，观察组改善更明显($P<0.05$)，但气虚型和肾虚型患者比较改善程度不明显($P>0.05$)。见表 1。

表 1 治疗前后各调查问卷评分的比较(分)

Table 1 Comparison of questionnaire scores before and after treatment(score)

	Control group(n=50)			Qi deficiency type(n=60)			Kidney deficiency type(n=55)		
	PFDI20	ICI-Q-SF	POP-Q	PFDI20	ICI-Q-SF	POP-Q	PFDI20	ICI-Q-SF	POP-Q
Before	55.2±13.6	81.9±15.7	2.7±0.7	54.6±12.3	78.9±16.7	2.9±0.6	51.8±13.4	82.5±18.5	2.6±0.4
After	39.8±8.9	56.9±14.5	1.6±0.5	33.5±9.7	45.6±12.2	1.1±0.2	30.9±8.5	49.7±13.3	0.8±0.2
t	10.235	19.658	5.006	15.623	25.624	5.625	13.527	21.329	5.327
P	0.000	0.000	0.013	0.000	0.000	0.004	0.000	0.000	0.009

2.2 治疗前后盆底肌力和中医症候积分的比较

对照组和观察组治疗后盆底肌Ⅰ类和Ⅱ类肌纤维肌力等级均明显增加，差异有统计学意义($P<0.05$)。两组治疗后中医症候积分均较前明显降低，差异有统计学意义($P<0.05$)。与对照组比较，观察组改善更明显($P<0.05$)，但气虚型和肾虚型患者比较改善程度不明显($P>0.05$)。见表 2。

表 2 治疗前后盆底肌力和中医症候积分的比较

Table 2 Comparison of pelvic floor muscle strength and TCM syndrome score before and after treatment

	Control group(n=50)			Qi deficiency type(n=60)			Kidney deficiency type(n=55)		
	Class I muscle fiber strength	Class II muscle fiber strength	TCM syndrome score	Class I muscle fiber strength	Class II muscle fiber strength	TCM syndrome score	Class I muscle fiber strength	Class II muscle fiber strength	TCM syndrome score
Before	2.5±0.3	2.4±0.4	15.9±4.5	2.6±0.3	2.2±0.3	15.5±4.6	2.4±0.3	2.3±0.3	16.2±4.8
After	3.1±0.4	2.9±0.5	13.3±3.9	3.8±0.5	3.4±0.5	10.2±3.5	3.6±0.5	3.5±0.5	10.8±3.4
t	5.126	5.203	5.316	5.659	5.525	5.728	5.427	5.607	5.627
P	0.009	0.011	0.003	0.002	0.004	0.000	0.006	0.007	0.008

2.3 临床疗效

与对照组比较，观察组临床疗效明显提高($P<0.05$)，但是气虚型和肾虚型患者临床疗效比较差异无统计学意义 ($P>0.05$)。各组均未见明显不良反应，所有患者均能坚持完成规定

疗程的治疗。见表 3。

2.4 中医证候疗效

与对照组比较,观察组临床疗效明显提高(P<0.05),但是气虚型和肾虚型患者临床疗效比较差异无统计学意义 (P>0.05),见表 4。

表 3 临床疗效[例(%)]

Table 3 Clinical efficacy[n(%)]

Groups	N	Markedly effective	Effective	Ineffective	Total effective
Control group	50	20(40.0)	15(30.0)	15(30.0)	35(70.0)
Qi deficiency type	60	33(55.0)	20(33.3)	7(11.7)	53(88.3)
Kidney deficiency type	55	27(49.1)	20(36.4)	8(14.5)	47(85.5)
χ^2					6.895
P					0.032

表 4 中医证候疗效[例(%)]

Table 4 Therapeutic effect of TCM Syndromes [n(%)]

Groups	N	Clinical cured	Markedly effective	Effective	Ineffective	Total effective
Control group	50	12(24.0)	17(34.0)	8(16.0)	13(26.0)	37(74.0)
Qi deficiency type	60	20(33.3)	26(43.3)	8(13.3)	6(10.0)	54(90.0)
Kidney deficiency type	55	16(29.1)	23(41.8)	10(18.2)	6(10.9)	49(89.1)
χ^2						6.586
P						0.037

3 讨论

近年来,随着"二胎"政策的开放,女性妊娠及分娩次数增加,产后 PFD 的发病率进一步上升,由于社会大众对本病的认识不足,不知道怎样预防及治疗,常常导致病情延误,病程长,错失了最佳治疗时间,难以根治,又多复发,给患者的精神造成严重负担,影响正常的生活和工作[16,17]。

产后盆底康复训练能促进妊娠和分娩过程损伤的神经和肌肉得到恢复,从而改善远期盆底状况,降低因解剖结构改变和年龄增长发生的 PFD[18-21]。研究表明[22-25],孕期盆底训练可以降低初产妇产后 3 个月的 PFD 发生率,产后康复可明显降低产后 6~12 个月 PFD 发生率。中医将 PFD 归为"阴挺",认为中气不足、体虚、气虚、肾虚为其发病气机。中医辨证在盆底康复训练的基础上进一步调节体质,增强机体抵抗力,能够进一步改善临床疗效。补中益气汤首见于《内外伤辨惑论》,方中黄芪、党参、白术入肺、脾两经,起补益肺脾之气;升麻、柴胡清轻升散之性,可升阳举陷,助已虚之脾、肺二气升清散精、通调水道;陈皮辛温,可助肺脾二脏恢复水之上中二源之职;当归补血和血,以防气病及血;甘草补脾益肺[23-26]。补中益气汤在盆底康复训练的基础上进一步发挥补中益气、升阳举陷之功效,临床中多用于脾胃虚弱,中气下陷,久泻、脱肛,子宫脱垂等症[24-26]。临证加减,更具针对性。大补元煎方根据张景岳的经效良方改制,全方共奏肝肾双补、益气养血之功效,在经期异常、带下病、产后恶露、阴挺、不孕症、卵巢早衰等妇科疾病中应用较为广泛[27-29]。方中熟地滋补肾阴,配以当归滋阴养血;合枸杞子、山茱萸滋补肝肾,填精补血;杜仲补肝肾而温下元;党参伍与山药、甘草,共奏益气健脾,广生化之源之功;党参、当归配伍益气补血[30-32]。大补元煎方在盆底康复训练的基础上进一步发挥滋肝肾,益气血,调冲任,使得肾气旺盛,气血充足,冲任调和[33-35]。

综上所述,盆底康复治疗仪结合中医辨证分型施治产后 PFD 有较好的安全性和有效性,值得临床推广应用。

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