

doi: 10.13241/j.cnki.pmb.2021.15.027

加味补中益气汤治疗肥胖型多囊卵巢综合征患者的疗效 及对子宫内膜容受性和糖脂代谢的影响*

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摘要 目的:探讨加味补中益气汤治疗肥胖型多囊卵巢综合征(PCOS)患者的疗效及对子宫内膜容受性和糖脂代谢的影响。方法:选择2018年3月~2020年5月期间我院收治的肥胖型PCOS患者280例,采用抽签法分为观察组140例和对照组140例。对照组给予二甲双胍片治疗,观察组给予加味补中益气汤治疗,对比两组疗效、体质量指数(BMI)、腰臀比、性激素指标[雌二醇(E2)、促黄体生成激素(LH)、卵泡刺激素(FSH)]、子宫内膜容受性指标[子宫内膜厚度、子宫内膜螺旋动脉搏动指数(PI)与阻力指数(RI)]、糖脂代谢指标[总胆固醇(TC)、低密度脂蛋白(LDL-C)、甘油三酯(TG)、高密度脂蛋白(HDL-C)、空腹血糖(FPG)]。结果:观察组的临床总有效率为92.14%(129/140),高于对照组的80.71%(113/140)($P<0.05$)。治疗3个月经周期后,两组BMI、腰臀比、PI、RI、LH、FSH、TC、LDL-C、TG、FPG均下降,且观察组低于对照组($P<0.05$)。治疗3个月经周期后,两组子宫内膜厚度、HDL-C、E2升高,且观察组高于对照组($P<0.05$)。结论:加味补中益气汤治疗肥胖型PCOS患者,可降低患者体质量,调节性激素、子宫内膜容受性和糖脂代谢水平,具有较好的疗效。

关键词: 加味补中益气汤; 多囊卵巢综合征; 疗效; 子宫内膜容受性; 糖脂代谢

中图分类号: R711.75; R243 **文献标识码:** A **文章编号:** 1673-6273(2021)15-2931-04

Efficacy of Jiawei Buzhong Yiqi Decoction on Obese Polycystic Ovary Syndrome and Its Influence on Endometrial Receptivity and Glucose and Lipid Metabolism*

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ABSTRACT Objective: To investigate the efficacy of Jiawei Buzhong Yiqi decoction on obese polycystic ovary syndrome (PCOS) and its influence on endometrial receptivity and glucose and lipid metabolism. **Methods:** 280 cases of obese PCOS in our hospital from March 2018 to May 2020 were selected, they were divided into observation group (140 cases) and control group (140 cases) by drawing lots. The control group was treated with metformin tablets, while the observation group was treated with Jiawei Buzhong Yiqi decoction. The efficacy, body mass index (BMI), waist hip ratio, sex hormone indexes [estradiol (E2), luteinizing hormone (LH), follicle stimulating hormone (FSH)], endometrial receptivity indexes [endometrial thickness, endometrial spiral artery pulsatility index (PI) and resistance index (RI)], glucose and lipid metabolism indexes [total cholesterol (TC), low density lipoprotein (LDL-C), triglyceride (TG), high-density lipoprotein (HDL-C), fasting plasma glucose (FPG)] were compared between the two groups. **Results:** The clinical total effective rate of the observation group was 92.14% (129 / 140), which was higher than 80.71% (113/140) of the control group ($P<0.05$). 3 menstrual cycles after treatment, BMI, waist hip ratio, PI, RI, LH, FSH, TC, LDL-C, TG and FPG of the two groups decreased, and the observation group was lower than the control group ($P<0.05$). 3 menstrual cycles after treatment, endometrial thickness, HDL-C and E2 in the two groups increased, and the observation group was higher than the control group ($P<0.05$). **Conclusion:** In the treatment of obese PCOS patients, Jiawei Buzhong Yiqi decoction can reduce body weight, regulate sex hormone, endometrial receptivity and glucose and lipid metabolism, and which has a good curative effect.

Key words: Jiawei Buzhong Yiqi decoction; Obese polycystic ovary syndrome; Efficacy; Endometrial receptivity; Glucose and lipid metabolism

Chinese Library Classification(CLC): R711.75; R243 **Document code:** A

Article ID: 1673-6273(2021)15-2931-04

* 基金项目:成都中医药大学附属医院 / 四川省中医院科技发展基金项目(18ZX02);

四川省高等学校人文社会科学重点研究基地 " 四川中医药文化协同发展研究中心 "2020 年度项目(2020WH036);

四川省科技厅苗子工程项目(2018105)

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(收稿日期:2020-12-27 接受日期:2021-01-21)

前言

多囊卵巢综合征(PCOS)主要由下丘脑-垂体-卵巢轴系功能失调引起^[1],该病不仅对女性生殖内分泌功能造成影响,还可诱发子宫内膜癌、糖尿病、心血管疾病等较严重的远期并发症^[2]。相关数据分析显示^[3],我国PCOS发病率高达4%~18%,且近年来PCOS发病率逐渐上升。肥胖是指体内脂肪细胞数目增多或体积增大,肥胖与PCOS紧密关联,并与PCOS相互交织作用,形成恶性循环^[4]。国内一项PCOS流行病学调查显示PCOS中肥胖的患病率高达75%^[5]。现临床有关肥胖型PCOS发病机制尚未完全阐明,且一直未能有统一、有效的治疗方案,多以降低雄激素、调节月经周期、针对胰岛素抵抗以及促排卵的治疗为主,但不少患者易出现卵巢过度刺激综合征、耐药等^[6]。中医药治疗本病,具有独特的优势,中医学认为:"妇人身体肥胖、不能受孕者乃脾土之内病也","脾为生痰之源",可见肥胖型PCOS的主要病机为脾虚为本、痰湿血瘀为标^[7]。鉴于此,本研究采用加味补中益气汤治疗肥胖型PCOS,疗效明确。

1 资料与方法

1.1 临床资料

纳入标准:(1)参考《中华妇产科学》^[8]、《中药新药临床研究指导原则》^[9],辨证分型为肾虚痰湿证;(2)肥胖诊断标准参考亚太地区相关会议标准:腰臀比 ≥ 0.8 、BMI $\geq 24 \text{ kg/m}^2$ 为肥胖;(3)B超检查显示卵巢存在多个囊肿;(4)均对本研究知情且签署同意书。排除标准:(1)先天性的生殖器官发育畸形或器质性疾病导致月经异常者;(2)经性激素测定已进入围绝经期者或卵巢早衰者;(3)入组前1个月曾服用影响内分泌激素类药物者;(4)对本次研究用药存在禁忌者;(5)患有生殖器官或其他恶性肿瘤者;(6)合并甲状腺功能异常者。脱落和剔除标准:(1)受试过程中发生并发症或严重不良反应者;(2)未严格按试验方案规定用药坚持治疗者。我院伦理学委员会已批准本研究。选择2018年3月~2020年5月我院收治的280例肥胖型PCOS患者,采用抽签法分为两组(分别命名为对照组和观察组),其中对照组140例,年龄24~35(29.86 $\pm$ 2.35)岁;病程1~5(3.06 $\pm$ 0.87)年;体质量指数(Body mass index, BMI)24~29(27.81 $\pm$ 1.24)kg/m²。观察组140例,年龄25~35(29.34 $\pm$ 1.97)岁;病程1~5(3.11 $\pm$ 0.93)年;BMI 24~30(27.74 $\pm$ 1.31)kg/m²。两组一般资料对比无差异($P>0.05$)。

1.2 方法

两组均指导其合理膳食,适量运动,给予枸橼酸氯米芬胶囊(国药准字H31021107,上海衡山药业有限公司,规格:50mg),在月经周期第5d口服,50mg/次,1次/d。在此基础上,对照组患者予以盐酸二甲双胍片治疗(国药准字H31022081,上海上药信谊药厂有限公司,规格:0.25g),用法:从第1个月经周期的第1d开始嘱患者口服,0.5g/次,1次/d,总疗程为3个月经周期。观察组给予加味补中益气汤,汤方主要由人参、当归、陈皮、黄芪、白术、半夏各10g,柴胡3g,升麻6g,茯苓15g组成。煎煮3次,所得300mL混合浓缩药液,分早中晚三次温服,具体服药时间为自然月经周期第一天或撤药性出血第1d开始口服,总疗程为3个月经周期。

1.3 观察指标

(1)统计两组治疗3个月经周期后的临床疗效。参照《中药新药临床研究指导原则》^[9]并结合《中华妇产科学》^[8]有关内容拟定:总有效率=痊愈率+显效率+有效率,其中治疗后各症状消失或基本消失,证候积分减少 $\geq 95\%$ 为痊愈;70% $\leq$ 证候积分减少 $<95\%$,治疗后症状明显减轻为显效;30% $\leq$ 证候积分减少 $<70\%$,治疗后症状有所改善为有效;治疗后证候积分减少 $<30\%$,症状无减轻或加重为无效。(2)记录两组治疗前、治疗3个月经周期后的BMI和腰臀比。(3)治疗前、治疗3个月经周期后采用盆腔B超分别监测子宫内膜容受性指标,包括子宫内膜厚度、子宫内膜螺旋动脉搏动指数(PI)与阻力指数(RI)。(4)治疗前、治疗3个月经周期后采集患者晨起空腹静脉血5mL,采用电化学发光免疫法及配套试剂盒(试剂盒购自上海化工生物科技发展有限公司)测定雌二醇(E2)、促黄体生成激素(LH)、卵泡刺激素(FSH)含量。采用日立公司生产的7080全自动生化分析仪检测血脂指标:总胆固醇(TC)、低密度脂蛋白(LDL-C)、甘油三酯(TG)、高密度脂蛋白(HDL-C)。采用血糖检测仪[罗氏诊断产品(上海)有限公司]对空腹血糖(FPG)水平进行检测。

1.4 统计学方法

采用SPSS21.0统计软件处理数据,计量资料以($\bar{x} \pm s$)表示,组内数据采用成组t检验,采用配对t检验处理组间数据;以率表示计数资料,采用卡方检验,检验水准为 $\alpha=0.05$ 。

2 结果

2.1 临床疗效比较

治疗3个月经周期后,对照组痊愈21率,显效43例,有效49例,无效27例,总有效率为80.71%(113/140)。观察组痊愈32率,显效56例,有效41例,无效11例,总有效率为92.14%(129/140)。与对照组相比,观察组的临床总有效率较高($\chi^2=7.795$, $P=0.005$)。

2.2 BMI和腰臀比较

两组治疗3个月经周期后BMI和腰臀比均下降,且观察组较对照组低($P<0.05$),详见表1。

2.3 子宫内膜容受性指标对比

治疗3个月经周期后,两组PI、RI均下降,且观察组较对照组低($P<0.05$),治疗3个月经周期后,两组子宫内膜厚度增加,且观察组较对照组高($P<0.05$),详见表2。

2.4 性激素指标对比

治疗3个月经周期后,两组LH、FSH均下降,且观察组较对照组低($P<0.05$),治疗3个月经周期后,两组E2升高,且观察组较对照组高($P<0.05$),详见表3。

2.5 糖脂代谢指标对比

治疗3个月经周期后,两组HDL-C升高,且观察组高于对照组($P<0.05$),两组LDL-C、TC、TG、FPG均下降,且观察组低于对照组($P<0.05$),治疗3个月经周期后,详见表4。

3 讨论

PCOS是临床妇科最为常见的内分泌疾病,是临床妇女不孕不育的主要病因之一^[10]。肥胖除了可降低女性生殖能力外,还会加大自然流产的风险,影响妊娠结局^[11]。肥胖型PCOS患

表 1 两组 BMI 和腰臀比比比较($\bar{x} \pm s$)Table 1 Comparison of BMI and waist hip ratio between the two groups($\bar{x} \pm s$)

Groups	BMI(kg/m ²)		Waist hip ratio	
	Before treatment	3 menstrual cycles after treatment	Before treatment	3 menstrual cycles after treatment
Control group(n=140)	27.81± 1.24	25.23± 1.12 ^a	0.93± 0.12	0.81± 0.15 ^a
Observation group(n=140)	27.74± 1.31	23.69± 1.28 ^a	0.94± 0.13	0.72± 0.14 ^a
t	0.459	10.713	0.669	5.190
P	0.646	0.000	0.504	0.000

Note: compared with before treatment, ^aP<0.05.表 2 两组子宫内膜容受性指标对比($\bar{x} \pm s$)Table 2 Comparison of endometrial receptivity between the two groups($\bar{x} \pm s$)

Groups	Endometrial thickness(mm)		PI		RI	
	Before treatment	3 menstrual cycles after treatment	Before treatment	3 menstrual cycles after treatment	Before treatment	3 menstrual cycles after treatment
Control group(n=140)	7.33± 0.58	8.95± 0.61 ^a	2.26± 0.37	1.69± 0.33 ^a	0.76± 0.13	0.61± 0.14 ^a
Observation group(n=140)	7.39± 0.62	10.66± 0.78 ^a	2.29± 0.28	1.27± 0.26 ^a	0.81± 0.16	0.45± 0.13 ^a
t	0.836	20.433	0.765	11.829	2.870	9.909
P	0.404	0.000	0.445	0.000	0.040	0.000

Note: compared with before treatment, ^aP<0.05.表 3 两组性激素指标对比($\bar{x} \pm s$)Table 3 Comparison of sex hormone indexes between the two groups($\bar{x} \pm s$)

Groups	E ₂ (ng/L)		LH(U/L)		FSH(U/L)	
	Before treatment	3 menstrual cycles after treatment	Before treatment	3 menstrual cycles after treatment	Before treatment	3 menstrual cycles after treatment
Control group(n=140)	85.87± 8.72	164.21± 12.66 ^a	12.68± 1.21	9.12± 1.17 ^a	5.73± 0.82	4.87± 0.79 ^a
Observation group(n=140)	85.71± 9.83	192.58± 10.47 ^a	12.62± 1.25	7.31± 1.28 ^a	5.79± 0.96	3.23± 0.85 ^a
t	0.148	20.433	0.408	12.350	0.562	16.722
P	0.882	0.000	0.604	0.000	0.574	0.000

Note: compared with before treatment, ^aP<0.05.表 4 两组糖脂代谢指标对比($\bar{x} \pm s$)Table 4 Comparison of glucose and lipid metabolism indexes between the two groups($\bar{x} \pm s$)

Groups	Time points	TC(mmol/L)	LDL-C(mmol/L)	TG(mmol/L)	HDL-C(mmol/L)	FPG(mmol/L)
Control group (n=140)	Before treatment	4.71± 0.73	2.81± 0.39	1.57± 0.24	1.38± 0.12	8.69± 0.58
	3 menstrual cycles after treatment	3.59± 0.69 ^a	1.97± 0.34 ^a	1.25± 0.18 ^a	1.82± 0.25 ^a	7.38± 0.53 ^a
Observation group (n=140)	Before treatment	4.75± 0.62	2.86± 0.42	1.61± 0.27	1.42± 0.13	8.73± 0.64
	3 menstrual cycles after treatment	2.47± 0.46 ^{ab}	1.42± 0.28 ^{ab}	0.92± 0.15 ^{ab}	2.06± 0.12 ^{ab}	6.24± 0.61 ^{ab}

Note: compared with before treatment, ^aP<0.05; compared with the control group, ^bP<0.05.

者中,肥胖加重人体生殖内分泌紊乱的途径主要表现为以下几点:脂肪细胞可以储存各种脂溶性的类固醇,因此肥胖者的类固醇较多;游离脂肪酸可直接刺激胰岛素 β 细胞分泌胰岛素,加重胰岛素抵抗;高雄激素水平亦能促进内脏脂肪的沉积,影响脂肪细胞功能而加重腹型肥胖^[12-14]。由上可见,肥胖与 PCOS

可互为因果,遏制肥胖与 PCOS 的恶性循环对于改善肥胖型 PCOS 的生殖情况及远期健康具有积极的意义。随着研究的深入,学者们发现肥胖型 PCOS 常伴有糖脂代谢异常,致使体内产生过多的雄激素^[15,16],而当雄激素分泌过多时又可对 LH、E₂、FSH 等性激素指标产生干扰作用^[17,18],故对于肥胖型 PCOS 患

者,在关注促排卵和恢复排卵的前提下,对患者糖脂代谢、性激素的调节亦应给予关注。

二甲双胍是临床治疗肥胖型 PCOS 的常用药物,具有改善血脂、血糖的作用,同时二甲双胍的促排卵为渐进式,可有效恢复患者卵巢功能,但其存在恢复月经与促排卵效果不显著等不足之处^[19,20]。根据中医理论,肥人多痰,痰湿脂膜壅塞胞宫,冲任阻滞,发为月经稀发、闭经,因而肥胖型 PCOS 的病因主要归结于痰湿蕴结,故中医治疗主张以健脾化痰为宜^[21]。加味补中益气汤由补中益气汤和二陈汤化裁而成,方中主要成分有人参、当归、陈皮、黄芪、白术、半夏、柴胡、升麻、茯苓,方中当归养血和血,柴胡、升麻提举下陷之阳气,茯苓、半夏、陈皮燥湿利滞,以祛痰湿之壅滞,黄芪、人参、白术补中健脾,诸药配伍,共奏强脾利湿之效^[22]。本次研究中,观察组的临床总有效率高于对照组,提示加味补中益气汤治疗肥胖型 PCOS 患者具有较好的疗效,中西医结合治疗从不同的作用机制出发,既重视机体的完整统一,又可调节机体内分泌功能,使脏腑协调,达到较好的治疗效果。

子宫内膜容受性是指子宫内膜对胚胎的接受能力,以往的研究结果显示,临床上不孕患者存在子宫内膜容受性下降的情况^[23,24]。子宫内膜厚度随月经周期呈周期性变化,内膜厚度适当易于胚胎着床^[25]。PI、RI 则可反映子宫动脉血流阻力,两指标越高,提示内膜血流信号缺乏或者无血流,子宫内膜容受性不良^[26]。E2、LH、FSH 均是由脑垂体前叶的嗜碱性细胞分泌的糖蛋白激素,当发生 PCOS 等病理变化时,雄性激素增多造成 E2 相对不足,同时可引起 LH/FSH 较高,对卵巢发育或排卵进行抑制,最终导致 PCOS 不孕^[27,28]。本次研究结果中,肥胖型 PCOS 患者经加味补中益气汤治疗后,体重得到有效控制,性激素、子宫内膜容受性和糖脂代谢水平的改善效果均优于二甲双胍治疗者。现代药理研究结果证实,加味补中益气汤可通过促进胰岛素的生物合成,促进胰岛素的释放,改善 BMI 及腰臀比,其还可通过祛除痰湿的作用改善机体的代谢状态,进而提高子宫内膜容受性^[29,30]。

综上所述,加味补中益气汤治疗肥胖型 PCOS 患者,可降低患者体质量,调节性激素、子宫内膜容受性和糖脂代谢水平,具有较好的疗效。

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