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中药联合克罗米芬治疗排卵障碍性不孕的临床效果

朱 怡 吴 旭[△] 杨 蓉 顾培君 徐 妍

(上海市第七人民医院妇产科 上海 200137)

摘要 目的:探讨中西医结合治疗排卵障碍性不孕的临床效果。**方法:**112例排卵障碍性不孕患者随机分为观察组与对照组,每组各56例,对照组患者给予克罗米芬治疗,观察组患者在克罗米芬治疗的基础上加用补肾活血促排卵类中药内服治疗,对两组患者治疗后的妊娠率、临床疗效进行比较分析。**结果:**观察组患者治疗后妊娠率为62.5%,高于对照组患者(41.1%),总有效率为89.3%,高于对照组患者(73.2%),差异有统计学意义($P<0.05$)。观察组患者治疗后的中医证候积分、FSH、LH、雌二醇水平均高于对照组,子宫内膜厚度及优势卵泡直径均大于对照组,差异均有统计学意义($P<0.05$)。**结论:**菟丝子、全当归等组成的补肾活血方能明显改善排卵障碍性不孕患者的临床表现及中医证候积分,调节不孕患者FSH、LH、雌二醇、睾酮水平,促进子宫内膜生长及卵泡的发育,提高妊娠率。

关键词: 中西医结合;排卵障碍性不孕;临床疗效

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The Clinical Efficacy of Combination of Traditional Chinese Medicine and Western Medicine in the Treatment of Anovulatory Infertility

ZHU Yi, WU Xu[△], YANG Rong, GU Pei-jun, XU Yan

(The gynaecology and obstetrics of seventh people's hospital of Shanghai, Shanghai, 200137, China)

ABSTRACT Objective: To explore the clinical efficacy of combination of traditional Chinese medicine and Western medicine in the treatment of anovulatory infertility. **Methods:** 112 patients of anovulatory infertility were randomly divided into the observation group and the control group, each group with 56 cases. The patients in the control group were treated with clomiphene while the patients in the observation group were treated with Chinese traditional medicine on basis of clomiphene. The clinical curative effect of the two groups was compared. **Results:** The pregnancy rate in the observation group was 62.5%, higher than that of the control group (41.1%) and the total effective rate in the observation group was 89.3%, higher than that in the control group (73.2%). The levels of symptom integral, FSH, LH, estradiol in the observation group were higher than those in the control group, and the endometrial thickness, dominant follicle diameter were greater than those of the control group ($P<0.05$). **Conclusion:** The Chinese traditional medicine, such as tusizi and quandanggui, can significantly improve the treatment efficacy in patients with anovulatory infertility. It can increase the levels of FSH, LH, estradiol and testosterone, promote the growth of endometrium and ovarian follicles development, and increase the pregnancy rate.

Key words: Chinese traditional and Western medicine; Anovulatory infertility; Clinical efficacy

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前言

不孕症是指以育龄期女子婚后或未次妊娠后,夫妇同居2年以上,男方生殖功能正常,以未避孕而不受孕为主要表现的疾病。研究显示,育龄妇女不孕症的发生率为8%~17%^[1,2],且不孕症的发病率有逐年增高的趋势,这可能与晚婚晚育、人工流产、性传播疾病等相关^[3,4]。研究表明,排卵功能障碍是引起女性不孕的主要原因之一,占全部不孕症患者的25%~30%^[5-7]。中医药作为我国的传统医学,对治疗排卵障碍性不孕具有独特优势。我院自2009年6月至2012年6月采用中西医结合方法治疗排卵障碍性不孕患者56例,取得了较好的疗效,现将结果报

道如下。

1 资料与方法

1.1 临床资料

病例来源于2009年6月至2012年6月我院中西医结合门诊收治的排卵障碍性不孕患者,其诊断标准参照《中药新药治疗女性不孕症的临床研究指导原则》。病例入选标准包括:

(1)导致不孕症的原因为排卵功能障碍;(2)35岁以下1年,35岁以上6个月未避孕者且未能怀孕的患者;(3)中医辨证分型属肾虚血瘀型不孕症;(4)治疗期间,夫妇应保持正常性生活;(5)签署知情同意书并自愿参加本研究。病例排除标准包括:(1)因先天性生理缺陷、畸形或遗传因素所导致的不孕症患者;(2)因男性生殖功能异常所导致的不孕症患者;(3)合并有子宫内膜异位症、子宫肌瘤、子宫腺病、子宫发育不良、卵巢早衰等疾病的患者;(4)合并有严重心血管、肝、肾、造血系统

作者简介:朱怡(1972-),女,主治医师,本科,主要研究方向:不孕症、宫颈疾病

[△]通讯作者:吴旭, E-mail:15920497434@yeah.net

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等原发性疾病及精神性疾病患者。

1.2 治疗方法

采用随机对照方法,将 112 例排卵障碍性不孕患者分为观察组与对照组,每组各 56 例,对照组患者给予克罗米芬治疗(枸橼酸氯米芬胶囊,上海衡山药业有限公司,国药准字 H31021107),口服,每日 50 mg,自月经周期的第 5 天开始服药,每天一次,连用 5 天。3 个月经周期为一个疗程,坚持治疗 2 个疗程。观察组患者在西药治疗的基础上加用中药内服治疗,中药的配方包括菟丝子 15 g、全当归 15 g、川断 15 g、枸杞子 15 g、赤芍 12 g、鸡血藤 15 g、益母草 15 g、女贞子 10 g、白芍 10 g、泽兰 15 g、蒲黄 10 g、锁阳 10 g、川牛膝 15 g 等,水煎服,每日两次,早晚各一次,每日 1 剂。自月经周期第 5 天开始服药,连续服药 14 天。三个月经周期为一个疗程,坚持治疗 1-2 个疗程。所有患者均于疗程结束后进行随访 1-2 年。

1.3 观察指标

参照相关标准,对两组患者治疗后的妊娠率、临床疗效进行比较分析,并根据中医证候积分表及疗效判定标准对两组患者治疗前后中医证候积分的比较^[8,9]。采用全自动免疫发光分析系统测定两组患者治疗前后卵泡刺激素(FSH)、黄体生成素(LH)、雌二醇、睾酮水平,应用彩色多普勒超声诊断仪进行治

疗前后子宫内膜厚度及优势卵巢直径的检测。

1.4 临床疗效判定标准

临床疗效判定标准参照《中医病证诊断疗效标准》及《中药新药临床研究指导原则》进行判定,分为痊愈、显效、有效、无效。其中痊愈指的是:恢复排卵或妊娠,连续 3 个月经周期恢复正常,其他临床症状消失。显效:恢复排卵或妊娠,月经周期恢复 28±7 天,经量比治疗前增加 1/3,其他临床症状消失或减轻。有效:已恢复排卵但未妊娠,治疗后月经周期、经量较治疗前明显改善,其他临床症状较治疗前减轻。无效:治疗后月经周期、经量较治疗前无改善,未恢复排卵且未妊娠。

1.5 统计学分析

采用 SPSS18.0 统计学软件进行数据的处理,采用 t 检验进行计量资料的比较,采用秩和检验进行等级资料的比较,采用 X² 检验进行计数资料的比较,以 P<0.05 为差异有统计学意义。

2 结果

2.1 两组患者治疗后妊娠率比较

对两组患者治疗后妊娠率进行比较后发现,观察组患者治疗后妊娠 35 例,妊娠率 62.5%,高于对照组患者治疗后的妊娠率(23/56,41.1%),差异有统计学意义(P<0.05)。

表 1 两组患者治疗后妊娠率比较

Table 1 The pregnancy rate of two groups after treatment

Groups	n	Pregnancy	Non-pregnancy	The pregnancy rate (%)	X ²	P
Observation group	56	35	21	62.5	5.149	0.037
Control group	56	23	33	41.1		

2.2 两组患者中医证候疗效比较

观察组患者治疗后痊愈 14 例,显效 21 例,总有效率 89.3%,高于对照组患者治疗后的总有效率(41/56,73.2%),差

异有统计学意义(P<0.05),见表 2。两组患者治疗后的中医证候积分均高于治疗前,且观察组患者治疗后的中医证候积分高于对照组,差异有统计学意义(P<0.05),见表 3。

表 2 两组患者中医证候疗效比较(n,%)

Table 2 The curative effect of traditional Chinese medicine on two groups of patients

Groups	n	recovery	Excellent	Valid	Invalid	Total effective rate (%)
Observation group	56	14(25.0)	21(37.5)	15(26.8)	6(10.7)	89.3
Control group	56	8(14.3)	15(26.8)	18(32.1)	15(26.8)	73.2

表 3 两组患者治疗前后中医证候积分比较

Table 3 The traditional Chinese medicine symptom score of the two groups before and after treatment

Groups	n	Before treatment	After treatment
Observation group	56	19.5±5.46	7.82±3.65*#
Control group	56	18.9±4.58	12.4±5.08*

注:与治疗前相比:*P<0.05,与对照组相比:#P<0.05。

Note: compared with Before treatment, *P<0.05, compared with the Control group, #P<0.05。

2.3 两组患者治疗前后性激素、子宫内膜厚度及优势卵泡直径比较

对两组患者治疗前后卵泡刺激素(FSH)、促黄体生成素

(LH)、雌二醇(estradiol)、睾酮(testosterone)、子宫内膜厚度(endometrial thickness)及优势卵泡直径(advantages of follicle diameter)进行比较后发现,与治疗前相比,两组患者治疗后 FSH、

LH、雌二醇、睾酮水平及子宫内膜厚度、优势卵泡直径均有显著性升高,且观察组患者治疗后 FSH、LH、雌二醇水平均高于

对照组,子宫内膜厚度及优势卵泡直径均大于对照组,差异有统计学意义($P<0.05$),见表 4。

表 4 两组患者治疗前后性激素、子宫内膜厚度及优势卵泡直径比较

Table 4 The level of sex hormone, endometrial thickness and dominant follicle diameter of the two groups before and after treatment

Index	Observation group		Control group	
	Before treatment	After treatment	Before treatment	After treatment
FSH(mIU/ml)	8.80± 1.01	9.32± 1.02* [#]	9.01± 1.29	9.87± 1.08*
LH(mIU/ml)	10.52± 3.20	18.40± 4.15* [#]	11.29± 4.29	15.47± 3.60*
Estradiol (pg/ml)	66.85± 12.52	86.47± 11.08* [#]	68.50± 10.29	78.54± 11.26*
Testosterone (nmol/L)	1.18± 0.18	1.27± 0.11*	1.15± 0.22	1.26± 0.17*
Endometrial thickness (mm)	7.45± 2.21	9.52± 2.08* [#]	7.53± 1.39	8.14± 1.11*
Dominant follicle diameter (mm)	12.54± 3.20	20.45± 5.02* [#]	12.79± 4.05	17.50± 3.66*

注:与治疗前相比:* $P<0.05$,与对照组相比:[#] $P<0.05$ 。

3 讨论

卵巢功能障碍是影响女性的生殖功能、性别特征及心理变化的重要因素,是引起育龄妇女不孕症的主要原因之一,其发病机制较为复杂^[10,11]。卵巢功能障碍可导致排卵功能障碍、多囊卵巢综合征、高催乳素血症、黄素化卵泡不破裂综合征、卵巢早衰等多种疾病^[12-14]。因卵巢功能障碍引起的排卵功能障碍是造成育龄期妇女不孕的主要原因之一,排卵功能障碍不仅可以引起不孕,还可导致月经不调、闭经、子宫内膜增生症等内分泌代谢障碍性疾病,严重威胁着女性患者的身心健康^[15,16]。

临床上常用克罗米芬及促性腺激素来治疗排卵障碍性不孕,但研究发现克罗米芬虽能提高患者的排卵率,但妊娠率往往不能同时提高,且克罗米芬是通过外源性激素的替代而起作用,无法从根本上调节人体的内分泌代谢,远期效果不甚理想^[17-19]。中医药做为我国的传统医学,在治疗女性排卵障碍性不孕症方面有其独特的优势。中医学认为肾虚是引起排卵障碍性不孕各证型的主要因素之一^[20],补肾活血方是治疗排卵障碍不孕的有效方剂^[21-22]。本研究发现,以菟丝子、全当归、川断、枸杞子、赤芍、鸡血藤、益母草、女贞子、白芍等组成的补肾活血方剂能明显改善排卵障碍性患者的临床表现及中医证候积分,调节不孕患者 FSH、LH、雌二醇、睾酮水平,促进子宫内膜生长及卵泡的发育,提高妊娠率。这可能与上述药物能补肾活血、调经助卵、平衡阴阳、流畅气血、协调脏腑等功能有关。

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