

# 麦芪降糖丸联合胰岛素对妊娠期糖尿病患者相关指标的影响<sup>△</sup>

翟悦静\*,朱思宇,左学军,朱慧芳<sup>#</sup>(廊坊卫生职业学院公共临床系/廊坊卫生职业学院附属医院,河北廊坊065001)

中图分类号 R714 文献标志码 A 文章编号 1001-0408(2016)15-2035-03

DOI 10.6039/j.issn.1001-0408.2016.15.06

**摘要** 目的:探讨麦芪降糖丸联合胰岛素对妊娠期糖尿病(GDM)患者相关指标的影响。方法:135例GDM患者随机分为对照组(69例)和观察组(66例)。对照组患者给予控制饮食,运动疗法,生物合成人胰岛素注射液,精蛋白生物合成人胰岛素注射液,按4:2:3:1的比例以4~6单位分别于三餐前及睡前注射,并根据血糖监测结果决定是否需要调整胰岛素剂量(每次增减2~4单位);观察组患者在对照组治疗的基础上给予麦芪降糖丸6g,口服,每日4次。两组疗程均为15d。观察两组患者分娩时的空腹血糖(FPG)、餐后2h血糖(2hPG)、糖化血红蛋白(HbA<sub>1c</sub>)、体质量指数(BMI),两组患者妊娠结局情况(子痫前期、早产、产褥感染、产后出血、新生儿窒息、低体质量儿、夜间低血糖)及不良反应发生情况。结果:观察组患者FPG、2hPG、HbA<sub>1c</sub>水平、BMI与子痫前期、早产、低体质量儿、新生儿窒息、夜间低血糖发生例数均显著低于对照组,差异均有统计学意义( $P<0.05$ );但两组患者产褥感染、产后出血发生例数比较,差异均无统计学意义( $P>0.05$ )。两组妊娠期妇女治疗期间均未见明显不良反应发生。结论:麦芪降糖丸联合胰岛素可有效降低GDM患者的血糖,且安全性较好。

**关键词** 麦芪降糖丸;胰岛素;妊娠期糖尿病;血糖;妊娠结局

## Effects of Maiqi Jiangtang Pill Combined with Insulin on Related Indicators in Maternal Gestational Diabetes

ZHAI Yuejing, ZHU Siyu, ZUO Xuejun, ZHU Huifang (Dept. of Public Clinic, Langfang Health Vocational College/Affiliated Hospital of Langfang Health Vocational College, Hebei Langfang 065001, China)

**ABSTRACT** OBJECTIVE: To investigate the effects of Maiqi jiangtang pill combined with insulin on related indicators in maternal gestational diabetes. METHODS: 135 GDM women were randomly divided into control group (69 cases) and observation group (66 cases). Control group was given diet controlling and exercise therapy, Novolin R insulin biosynthesis and protamine synthetic human insulin were injected before meals and bedtime from 4-6 units with the ratio of 4:2:3:1, and decided whether to adjust the insulin dose based on the blood glucose monitoring results (increase or decrease 2-4 units each times); observation group was additionally given 6 g Maiqi jiangtang pill, 4 times a day. The treatment course for both groups was 15 d. Fasting plasma glucose (FPG), 2 h postprandial glucose (2 h PG), glycosylated hemoglobin (HbA<sub>1c</sub>), body mass index (BMI), maternal pregnancy outcomes (preeclampsia, preterm labor, puerperal infection, postpartum hemorrhage, neonatal asphyxia, low-weight children and nocturnal hypoglycemia) and incidence of adverse reactions in 2 groups were observed. RESULTS: FPG, 2 h PG, HbA<sub>1c</sub>, BMI, preeclampsia, preterm labor, low-weight children, neonatal asphyxia and nocturnal hypoglycemia in observation group were significantly lower than control group, the differences were statistically significant ( $P<0.05$ ); there were no significant differences in the puerperal infection and postpartum hemorrhage between 2 groups ( $P>0.05$ ). And there were obvious adverse reactions between 2 groups during treatment. CONCLUSIONS: Maiqi jiangtang pill combined with insulin can effectively reduce the blood glucose of GDM women, with good safety.

**KEYWORDS** Maiqi jiangtang pill; Insulin; Gestational diabetes; Blood glucose; Maternal pregnancy outcomes

妊娠期糖尿病(Gestational diabetes mellitus, GDM)是指在妊娠期间发生或者首次发现的糖尿病或者糖耐量异常<sup>[1]</sup>。随着我国居民生活方式的改变,其发病率逐年升高,有调查显示,我国GDM发病率为4.3%<sup>[1]</sup>。GDM患者的血糖控制不良可对母婴的健康造成严重危害,因此需要有效的控制血糖,使其达到或接近正常。麦芪降糖丸具有养阴益气,除烦生津之功效,胰岛素是治疗GDM的首选药物,两药联合可产生协同效果。为此,在本研究中笔者探讨了麦芪降糖丸联合胰岛素对GDM患者相关指标的影响,以为临床治疗提供参考。

## 1 资料与方法

<sup>△</sup> 基金项目:河北省科学技术研究与发展计划项目(No.12277764)

\* 主治医师,讲师。研究方向:妇产科常见病。E-mail: zhuhs73022@sina.com

<sup>#</sup> 通信作者:副主任医师,教授,硕士。研究方向:妇产科常见病、肿瘤病理。电话:0316-2039191

### 1.1 研究对象

选择2011年9月—2015年12月廊坊卫生职业学院附属医院收治的GDM患者135例,均符合《妇产科学》(八版)中相关诊断标准<sup>[2]</sup>:(1)2次或2次以上空腹血糖(FPG)≥5.8 mmol/L;(2)口服葡萄糖耐量试验(OGTT):采用75g葡萄糖耐量试验——正常值上限:FPG 5.6 mmol/L,1h血糖10.3 mmol/L,2h血糖8.6 mmol/L,3h血糖6.7 mmol/L,其中有两项或两项以上达到或超过正常值上限,可诊断为GDM。将所有患者按随机数字表法分为对照组(69例)和观察组(66例)。对照组年龄23~42岁,平均年龄(28.23±3.12)岁;初诊时孕周(28.45±4.15)周,孕次(2.01±0.15)次。观察组年龄21~43岁,平均年龄(28.63±4.27)岁;初诊时孕周(27.89±4.56)周,孕次(2.15±0.23)次。两组患者年龄、初诊时孕周、产次等基本资料比较,差异均无统计学意义( $P>0.05$ ),具有可比性。本研究方案经医院医学伦理委员会审核通过,所有患者均签署了知情同意书。

## 1.2 纳入与排除标准

纳入标准:(1)符合诊断标准;(2)年龄20~44岁。排除标准:妊娠前已确诊为GDM。

## 1.3 治疗方法

对照组患者给予饮食控制,运动疗法,生物合成人胰岛素注射液(丹麦诺和诺德公司,规格:3 ml/支,批准文号:国药准字J20050019),精蛋白生物合成人胰岛素注射液(丹麦诺和诺德公司,规格:3 ml/支,批准文号:国药准字J20050020),按4:2:3:1的比例以4~6单位分别于三餐前及睡前注射,并根据血糖监测结果决定是否调整胰岛素剂量(每次增减2~4单位)。观察组患者在对照组治疗的基础上给予麦芪降糖丸(重庆希尔安药业有限公司,规格:10丸/1 g,批准文号:国药准字Z20025664)6 g,口服,每日4次。两组疗程均为15 d。

## 1.4 观察指标

观察两组患者分娩时的FPG、2 h血糖、糖化血红蛋白(HbA<sub>1c</sub>)、体质量指数(BMI),两组患者妊娠结局(子痫前期、早产、产褥感染、产后出血、新生儿窒息、低体质量儿、夜间低血糖)及不良反应发生情况。

## 1.5 统计学方法

采用SPSS 17.0统计软件对数据进行分析。计量资料以 $\bar{x} \pm s$ 表示,采用 $t$ 检验;计数资料以%表示,采用 $\chi^2$ 检验。 $P < 0.05$ 为差异有统计学意义。

## 2 结果

### 2.1 两组患者FPG、2 h血糖、HbA<sub>1c</sub>、BMI比较

观察组患者FPG、2 h血糖、HbA<sub>1c</sub>、BMI均显著低于对照组,差异均有统计学意义( $P < 0.05$ ),详见表1。

表1 两组患者FPG、2 h血糖、HbA<sub>1c</sub>、BMI比较( $\bar{x} \pm s$ )

Tab 1 Comparison of FPG, 2 h PG, HbA<sub>1c</sub> and BMI between 2 groups ( $\bar{x} \pm s$ )

组别	n	FPG, mmol/L	2 h血糖, mmol/L	HbA <sub>1c</sub> , %	BMI, kg/m <sup>2</sup>
对照组	69	5.93 ± 1.17	8.26 ± 1.18	8.26 ± 1.18	20.23 ± 1.58
观察组	66	5.26 ± 1.21*	6.91 ± 0.97*	6.92 ± 1.71*	18.15 ± 1.26*

注:与对照组比较, \* $P < 0.05$

Note: vs. control group, \* $P < 0.05$

### 2.2 两组患者妊娠结局情况比较

观察组患者子痫前期、早产、低体质量儿、新生儿窒息、夜间低血糖发生例数均显著低于对照组,差异均有统计学意义( $P < 0.05$ ),但两组患者产褥感染、产后出血发生例数比较,差异均无统计学意义( $P > 0.05$ ),详见表2。

表2 两组患者妊娠结局比较[例(%)]

Tab 2 Comparison of maternal pregnancy outcomes between 2 groups [case (%)]

组别	n	子痫前期	早产	产褥感染	产后出血	低体质量儿	新生儿窒息	夜间低血糖
对照组	69	30(28.98)	7(10.14)	2(2.89)	3(4.35)	9(13.04)	7(10.14)	6(8.69)
观察组	66	5(7.57)*	3(4.54)*	1(1.51)	2(3.03)	2(3.03)*	3(4.54)*	1(1.51)*

注:与对照组比较, \* $P < 0.05$

Note: vs. control group, \* $P < 0.05$

### 2.3 不良反应

两组患者治疗期间均未见明显不良反应发生。

## 3 讨论

GDM属于高危妊娠范畴,近年来发病率逐年增加,病情一旦控制不佳,可使子痫前期、流产、羊水过多、早产、酮症酸中毒、巨大儿、胎儿宫内窘迫、感染、剖宫产率、新生儿窒息、新生儿低血糖等多种并发症的发生率增高<sup>[3]</sup>。GDM患者发展为

2型糖尿病的风险较普通人群高7倍以上<sup>[4]</sup>,若GDM患者的血糖能够严格控制,并达到或接近正常水平,可使母婴并发症明显减少。

近年来发现,孕期母体内胰岛素抵抗(IR)是导致GDM的主要原因。增加GDM患者的胰岛素敏感性是治疗GDM的有效方法<sup>[5]</sup>。口服降糖药及胰岛素增敏药能起到降低血糖及增加胰岛素敏感性的作用,但可能会导致胎儿畸形<sup>[6]</sup>,因此临床不建议使用。目前,当饮食控制和运动疗法的疗效欠佳时,胰岛素是治疗GDM的首选方法,但其应用时间和最佳剂量尚未统一<sup>[9]</sup>。

有研究证实,中药可治疗IR、增加胰岛素的敏感性,刺激胰岛B细胞释放胰岛素,提高血清胰岛素水平,增加胰岛素受体数目或提高亲和力,抑制胰高血糖素等胰岛素拮抗激素的分泌,清除自由基,促进糖的利用<sup>[6-7]</sup>。GDM属中医“妊娠消渴”的范畴,《女科百问》曾有记载,“妇人之消多因损血,血虚则热,热则能消饮,所以多消,故与男子之消有异也”<sup>[6]</sup>。妊娠后阴血下聚以养胎,燥热之邪益盛,故易为消渴病,中医认为该病的机制在于“阴虚”贯穿消渴病发展的各个阶段。GDM属糖代谢异常的早期阶段,根据妊娠消渴病的机制,该病治疗应以滋阴为主。麦芪降糖丸由麦冬、黄芪、地黄、天花粉、党参、女贞子、五味子、白茅根、牡丹皮等药材组成,方中黄芪和党参补中益气,麦冬、地黄、天花粉、女贞子、五味子合用生津止渴及滋阴,白茅根、牡丹皮活血化瘀、凉血清热。诸药联合,益气养阴,生津清热,适用于糖尿病之气阴两虚证<sup>[9]</sup>。

本研究结果显示,观察组患者FPG、2 h血糖、HbA<sub>1c</sub>、BMI均显著低于对照组,差异均有统计学意义。这表明,孕30周后麦芪降糖丸联合胰岛素可有效的控制血糖,与相关文献的研究结果一致<sup>[9]</sup>。尤其是中西药结合治疗GDM后HbA<sub>1c</sub>的明显降低,当HbA<sub>1c</sub> < 8%时子痫前期、巨大儿等并发症明显降低。本研究结果还显示,观察组妊娠期妇女子痫前期、早产、低体质量儿、新生儿窒息、夜间低血糖发生例数均显著低于对照组,差异均有统计学意义,但两组患者产褥感染、产后出血发生例数比较,差异均无统计学意义。这表明,孕30周后麦芪降糖丸联合胰岛素可有效的改善GDM患者的妊娠结局,与相关研究结果一致<sup>[10]</sup>。

综上所述,麦芪降糖丸联合胰岛素可有效降低GDM患者的血糖,且安全性较好。由于本研究纳入的样本量较小,故此结论有待大样本、多中心研究进一步证实。

## 参考文献

- [1] Yang H, Wei Y, Gao X, et al. Risk factors for gestational diabetes mellitus in Chinese women: a prospective study of 16, 286 pregnant women in China[J]. *Diabet Med*, 2009, 26(11):1 099.
- [2] 谢幸, 苟文理. 妇产科学[M]. 7版. 北京: 人民卫生出版社, 2013: 75-79.
- [3] Ethridge IK Jr, Catalano PM, Waters TP. Perinatal outcomes associated with the diagnosis of gestational diabetes made by the international association of the diabetes and pregnancy study groups criteria[J]. *Obstet Gynecol*, 2014, 124(3): 571.
- [4] Bellamy L, Casas JP, Hingorani AD, et al. Type 2 diabetes mellitus after gestational diabetes: a systematic review and meta-analysis[J]. *Lancet*, 2009, 373(9 677): 1 773.
- [5] 刘艳娟. 妊娠合并糖尿病孕妇妊娠期妇女不同时期加用胰

# 阿法骨化醇与雷奈酸锶治疗老年绝经期骨质疏松症的疗效与安全性比较<sup>△</sup>

张淑红\*,王 侠,原 野\*(唐山市第二医院,河北唐山 063000)

中图分类号 R453.9 文献标志码 A 文章编号 1001-0408(2016)15-2037-03

DOI 10.6039/j.issn.1001-0408.2016.15.07

**摘要** 目的:比较阿法骨化醇与雷奈酸锶治疗老年绝经期骨质疏松症的疗效和安全性。方法:158例老年绝经期骨质疏松症患者随机分为对照组(79例)和观察组(79例)。所有患者给予碳酸钙D<sub>3</sub>片1片,口服,每日1次。在此基础上,对照组患者给予阿法骨化醇软胶囊2粒,口服,每日1次;观察组患者给予雷奈酸锶干混悬剂1袋,睡前口服,每日1次。两组疗程均为12个月。观察两组患者治疗前及治疗6、12个月后的腰2~4椎体(L2~4)和股骨颈的骨密度(BMD)、骨钙素、总I型胶原氨基端延长肽(TPINP)、视觉模拟法(VAS)评分及不良反应发生情况。结果:治疗前,两组患者L2~4和股骨颈的BMD、骨钙素、TPINP、VAS评分比较,差异均无统计学意义( $P>0.05$ )。对照组患者治疗12个月和观察组患者治疗6、12个月后L2~4的BMD、股骨颈的BMD均显著高于同组治疗前,随治疗时间的延长逐渐升高,且观察组高于对照组;对照组患者治疗12个月和观察组患者治疗6、12个月后TPINP、VAS评分均显著低于同组治疗前,随治疗时间的延长逐渐降低,且观察组低于对照组,差异均有统计学意义( $P<0.05$ );两组患者骨钙素水平均显著高于同组治疗前,随治疗时间的延长逐渐升高,差异均有统计学意义( $P<0.05$ ),但两组间比较差异无统计学意义( $P>0.05$ )。两组患者治疗期间均未见明显不良反应发生。结论:在常规治疗的基础上,雷奈酸锶治疗老年绝经期骨质疏松症的疗效显著优于阿法骨化醇,且安全性相当。

**关键词** 雷奈酸锶;阿法骨化醇;老年绝经期骨质疏松症;疗效;安全性

## Comparison of the Efficacy and Safety of Alfacalcidol and Strontium Ranelate in the Treatment of Senile Menopausal Osteoporosis

ZHANG Shuhong, WANG Xia, YUAN Ye (The Second Hospital of Tangshan City, Hebei Tangshan 063000, China)

**ABSTRACT** OBJECTIVE: To compare the efficacy and safety of alfacalcidol and strontium ranelate in the treatment of senile menopausal osteoporosis. METHODS: 158 elderly menopausal patients with osteoporosis were randomly divided into control group (79 cases) and observation group (79 cases). All patients were orally given 1 Calcium carbonate D<sub>3</sub> tablet, once a day. Based on it, control group was given 2 Alfacalcidol soft capsules, once a day. Observation group was additionally given 1 bag of Strontium ranelate dry suspension, orally before bedtime, once a day. The treatment course for both groups was 12 months. L2-4 and BMD of femoral neck, osteocalcin, TPINP and VAS and ADR before and after 6 and 12 months in 2 groups were observed. RESULTS: Before treatment, there were significant differences in the BMD of L2-4 and femoral neck, osteocalcin, TPINP and VAS scores between 2 groups ( $P>0.05$ ). BMD of L2-4 and femoral neck in control group after 12 months and in observation group after 6 and 12 months were significantly higher than before, and it gradually increased be time in observation, observation group was higher than control group; TPINP and VAS scores in control group after 12 months and in observation group after 6 and 12 months were significantly lower than before, and it gradually decreased be time, observation group was lower than control group, the differences were statistically significant ( $P<0.05$ ); osteocalcin levels in 2 groups were significantly higher than before, and it gradually increased be time, the difference was statistically significant ( $P<0.05$ ), but there was no significant difference between 2 groups ( $P>0.05$ ). There were no ADR during treatment. CONCLUSIONS: Based on the conventional treatment, the efficacy of alfacalcidol and strontium ranelate is superior to alfacalcidol alone in the treatment of senile menopausal osteoporosis, with similar safety.

**KEYWORDS** Strontium ranelate; Alfacalcidol; Senile menopausal osteoporosis; Efficacy; Safety

胰岛素治疗对妊娠结局的影响[J]. 中国妇幼保健, 2015, 30 (34): 5 990.

[6] 许文娟, 曾伟南, 强春芳. 妊娠期糖尿病中药治疗的临床研究[J]. 实用医学杂志, 2011, 6(14): 11.

[7] Fukuhara A, Matsuda M, Nishizawa M, et al. Visfati: a

△基金项目:唐山市科技计划项目(No.13130247b);唐山市科学技术研究与发展计划课题(No.121302052a)

\* 主管护师。研究方向:脊柱疾病的护理。电话:0315-2058020。E-mail:5878202@qq.com

# 通信作者:主任医师,硕士。研究方向:脊椎、椎间盘退变疾病。电话:0315-2058020。E-mail:yyvxin@163.com

protein secreted by visceral fat that mimics the effects of insulin[J]. *Science*, 2005, 307(5 708): 426.

[8] 吕珊珊, 唐桂英, 周年华, 等. 麦芪降糖丸对2型糖尿病模型大鼠影响的实验研究[J]. 世界中西医结合杂志, 2014, 9(9): 934.

[9] 毕显清. 中西医结合治疗妊娠期糖尿病临床疗效观察[J]. 河北医学, 2015, 21(9): 1 572.

[10] 张莉, 王力朋, 张国锋. 中西医结合治疗妊娠期糖尿病疗效观察[J]. 实用医药杂志, 2015, 31(1): 47.

(收稿日期:2016-03-16 修回日期:2016-03-24)

(编辑:陈宏)