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燕麦 β -葡聚糖对妊娠期糖尿病患者血糖调节 及妊娠结局影响的临床研究*

徐飞飞 于永华 林琳 孙欣 黄明莉[△]

(哈尔滨医科大学附属第一医院妇产科 黑龙江 哈尔滨 150000)

摘要 目的:研究燕麦 β -葡聚糖对妊娠期糖尿病患者血糖调节及妊娠结局的影响。**方法:**选取2020年08月至2021年01月在本院产科门诊规律产检并确诊为GDM的孕妇,按照是否服用燕麦 β -葡聚糖随机分为观察组和对照组,两组均采取医学营养治疗,观察组为自愿服用燕麦 β -葡聚糖的患者,观察两组患者在不同时间段的空腹血糖变化以及胰岛素需求量、孕期BMI增加量、分娩方式、新生儿出生体重、母婴不良妊娠结局之间的差异。**结果:**两组患者观察期间平均空腹血糖水平整体呈下降趋势;两组患者在不同时间段空腹血糖水平的差异,治疗4周时 $P>0.05$,治疗8周后 $P<0.05$;观察组患者孕期BMI增加量($4.56\pm 2.00\text{ Kg/m}^2$)显著低于对照组($5.34\pm 2.21\text{ Kg/m}^2$, $P<0.05$);观察组患者剖宫产率(64.62%)低于对照组(70.77%),两组患者的剖宫产率、新生儿出生体重、胰岛素需求量无明显差异, $P>0.05$;两组患者的母婴不良围产期结局无明显差异($P>0.05$)。**结论:**燕麦 β -葡聚糖可以降低妊娠期糖尿病患者的空腹血糖水平,控制孕期体重增长的同时不影响胎儿正常的生长发育,对母婴不良妊娠结局无改善作用,不会产生除已知结局之外的其他不良结局。

关键词:燕麦 β -葡聚糖;妊娠期糖尿病;医学营养治疗;妊娠结局

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Clinical Study which the Effect of Oat β -Glucan on Blood Glucose Regulation and Pregnancy Outcomes in Patients with Gestational Diabetes Mellitus*

XU Fei-fei, YU Yong-hua, LIN Lin, SUN Xin, HUANG Ming-li[△]

(Department of Obstetrics and Gynecology, The First Affiliated Hospital of Harbin Medical University,

Harbin, Heilongjiang, 150000, China)

ABSTRACT Objective: To study the effect of oat β -glucan (OBG) on blood glucose regulation and pregnancy outcome in patients with gestational diabetes mellitus (GDM). **Methods:** The pregnant women with GDM diagnosed by regular obstetrics in the obstetrics clinic of our hospital from August 2020 to January 2021 were randomly divided into observation group and control group according to whether they took OBG. Both groups were treated with medical nutrition, and the observation group was took OBG voluntarily. The changes of fasting blood glucose at different time periods, and the differences in insulin requirement, increase in BMI during pregnancy, delivery method, newborn birth weight, and adverse pregnancy outcomes between the two groups were observed. **Results:** The average fasting blood glucose levels of the two groups of patients showed an overall downward trend during the observation period. The difference in fasting blood glucose levels at different time periods between the two groups was $P>0.05$ after 4 weeks of treatment, and $P<0.05$ after 8 weeks of treatment. The increase of BMI during pregnancy in the observation group ($4.56\pm 2.00\text{ Kg/m}^2$) was significantly lower than that of the control group ($5.34\pm 2.21\text{ Kg/m}^2$, $P<0.05$); the cesarean section rate in the observation group (64.62%) was lower than that in the control group (70.77%), the difference between the two groups in cesarean section rate, newborn birth weight and insulin requirement was $P>0.05$; there was no significant difference in the adverse perinatal outcome between the two groups ($P>0.05$). **Conclusion:** OBG can reduce the fasting blood glucose level of patients with GDM, control the weight gain during pregnancy without affecting the normal growth and development of the fetus, has no effect on adverse pregnancy outcomes, and will not produce other adverse outcomes other than the known ones.

Key words: Oat β -glucan; Gestational diabetes mellitus; Medical nutrition therapy; Pregnancy outcome

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作者简介:徐飞飞(1992-),硕士研究生,主要研究方向:妊娠期糖尿病,电话:18845763120, E-mail: 1225320409@qq.com

[△] 通讯作者:黄明莉,女,博士、硕士生导师,教授,主任医师,主要研究方向:干细胞、产科相关疾病, E-mail: doctor_hml@163.com

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前言

妊娠期糖尿病(Gestational diabetes mellitus, GDM)是由葡萄糖不耐受造成的暂时性糖尿病,患者妊娠前无糖代谢异常^[1],可能跟参与胰岛素敏感性的激素失衡和胰腺 β 细胞功能障碍有关^[2]。全球范围内 GDM 的患病率呈逐年上升的趋势^[3],而治疗手段相对局限,主要包括生活方式干预、注射胰岛素和口服降糖药物^[4]。其中,胰岛素是 GDM 的一线治疗药物^[4],每日注射胰岛素的行为增加了孕妇精神压力和皮肤感染的可能性;口服降糖药物由于缺乏长期的新生儿安全数据,尚未获得美国食品和药物监督管理局的批准^[5]。已经证实 GDM 是孕产妇及其后代发展为 2 型糖尿病的独立危险因素^[6]。因此,在孕期实现血糖控制平稳可以为预防和减轻 2 型糖尿病的负担提供机会。

燕麦 β -葡聚糖(Oat β -glucan, OBG)是燕麦的主要活性成分,为一种可溶性膳食纤维,属于低血糖生成指数饮食^[7],主要存在于燕麦胚乳等植物细胞壁中,由纤维三糖、四糖和较长的纤维低聚糖连接而成^[8]。OBG 无基因毒性,不与金属离子络合影响矿物质和维生素在体内的吸收^[9],通过增加胃内容物的粘度、延迟胃排空降低糖尿病患者的餐后血糖^[10]。除此之外,OBG 具有降低血脂、抗氧化、益生菌特性、免疫调节和抗肿瘤等多种功能^[11],但未见到在 GDM 患者的相关报道。因此,本研究探讨 OBG 对 GDM 患者血糖调节及妊娠结局的影响,提供饮食治疗的新思路。

1 资料与方法

1.1 研究对象

选取 2020 年 08 月至 2021 年 01 月在哈尔滨医科大学附属第一医院产科门诊规律产检并确诊为 GDM 的孕妇。纳入标准:(1)首次发现且符合 GDM 的诊断标准^[12];(2)18 岁 $\leq$ 年龄 $\leq$ 40 岁;(3)宫内单胎妊娠;(4)精神和认知正常,知情同意。排除标准:(1)其他代谢性疾病;(2)严重的肝肾功能损伤、心脑血管疾病或者消化系统疾病;(3)OBG 不耐受;(4)正在服用或近期服用过干扰代谢的药物;(5)妊娠期高血压疾病;(6)肥胖(孕前 BMI $\geq$ 30 Kg/m²)或血脂异常(甘油三酯 $>$ 2.83 mmol/L、总胆固醇 $>$ 6.48 mmol/L)^[13];(7)血糖控制效果欠佳需要药物治疗。

1.2 样本量计算

将研究对象随机分成对照组和观察组,两组比例 1:1,按照样本量计算公式得出每组样本量为 54,预计失访率为 15%,每组各需 64 例,共计 128 例。

1.3 研究过程

1.3.1 分组 符合入组标准的患者共计纳入 130 例。观察组(n=65):医学营养治疗+OBG(3.5 g/d);对照组(n=65):医学营养治疗。

1.3.2 实施过程 所有患者入组前对其健康宣教,入组后由营养师制定营养计划;根据孕前 BMI 计算每日所需总能量,其中,碳水化合物、蛋白质以及脂肪所占比例分别为 55%、20%、25%;按照"90 kcal 食物交换法"计算食物交换份数,把各类食物份数按照三餐的能量占比 10%~15%、30%、30%分派于各餐;根据孕妇的习惯和喜好选择并互换食物,制定平衡膳食。根据个人情况拟定运动方案。观察组进食的 OBG,是由珠海津之敦医药科技有限公司生产的"力脂妥"(每包重量 5 g,含 3.5 g OBG),每 100 g 力脂妥提供能量 1548 KJ,含蛋白质 2.5 g、脂肪 0.6 g、碳水化合物 87.3 g、钠 757 mg,产生的热量及脂肪计算在一日总能量内。

1.3.3 观察指标 (1)一般资料:年龄、身高、孕前 BMI、确诊孕周、75 g 口服葡萄糖耐量试验(OGTT)血糖值;(2)血糖及身体测量指标:空腹血糖、胰岛素需求量、BMI 增加量;(3)妊娠终止时相关指标:孕周、分娩方式、新生儿体重;(4)不良围产期结局:产妇方面(早产、胎膜早破、羊水过多、羊水过少、羊水污染、子痫前期、胎盘早剥、妊娠期肝内胆汁淤积症、高脂血症)及新生儿方面(巨大儿、低出生体重儿、胎儿生长受限、胎儿宫内窘迫、新生儿窒息、新生儿低血糖)。

1.3.4 追踪随访 指导孕妇监测血糖,记录摄入的食物及用量、运动方式及时间、空腹体重,每两周对孕妇进行回访,评估其膳食、血糖控制、体重增长及运动情况,如有不适及时调整或改用胰岛素,必要时退出研究。

1.4 统计分析

统计软件为 SPSS 23.0,计量资料符合正态分布的用均数 $\pm$ 标准差($\bar{x}\pm s$)表示,不符合正态分布的以中位数和四分位数间距[P50(P25-P75)]表示,数据比较分别采用 t 检验、秩和检验;计数资料以率表示,数据比较用 χ^2 检验。当 $P<0.05$ 时差异具有统计学意义。

2 结果

2.1 一般资料进行比较

两组患者入组时的年龄、身高、孕前 BMI、确诊孕周、OGTT 血糖值之间无差异, $P>0.05$ 。见表 1。

2.2 空腹血糖及身体测量指标进行比较

两组患者空腹血糖的差异比较,入组及干预 4 周时, $P>0.05$;干预 8 周及分娩后, $P<0.05$ 。两组胰岛素需求量无差异, $P>0.05$ 。两组患者孕期 BMI 增加量有显著差异, $P<0.05$ 。见表 2。

表 1 两组的一般资料比较[($\bar{x}\pm s$), P50(P25-P75)]

Table 1 Comparison of general information between the two groups[($\bar{x}\pm s$), P50(P25-P75)]

Groups	Age (year)	Height (m)	Pre-pregnancy BMI(Kg/m ²)	Diagnosed gestational week (week)	Fasting blood glucose (mmol/L)	1h blood glucose (mmol/L)	2h blood glucose (mmol/L)
Observation group	31.57 $\pm$ 3.14	1.63(1.60-1.67)	22.87 $\pm$ 2.82	25.93 $\pm$ 0.89	5.00 $\pm$ 0.46	10.06 $\pm$ 1.57	8.54 $\pm$ 1.49
Control group	32.69 $\pm$ 4.33	1.63(1.60-1.66)	22.94 $\pm$ 2.73	26.23 $\pm$ 1.26	5.17 $\pm$ 0.59	9.86 $\pm$ 1.40	8.12 $\pm$ 1.52

表 2 两组空腹血糖及测量指标的比较[n(%), ($\bar{x} \pm s$)]Table 2 Comparison of fasting blood glucose and measurement indexes between the two groups[n(%), ($\bar{x} \pm s$)]

Groups	Fasting blood glucose {mmol/L}				Insulin requirement	Increase of BMI (Kg/m ²)
	Intake	After 4 weeks	After 8 weeks	childbirth		
Observation group	5.00±0.46	4.76±0.42	4.40±0.56*	4.18±0.60*	0(0.00)	4.56±2.00*
Control group	5.17±0.59	4.92±0.58	4.80±0.70	4.61±0.71	1(1.54)	5.34±2.21

Note: Compared with the control group, * $P < 0.05$.

两组患者观察期间平均空腹血糖水平整体呈下降趋势。与 见图 1。
对照组相比,观察组下降幅度大、离散程度低,降糖效果理想。

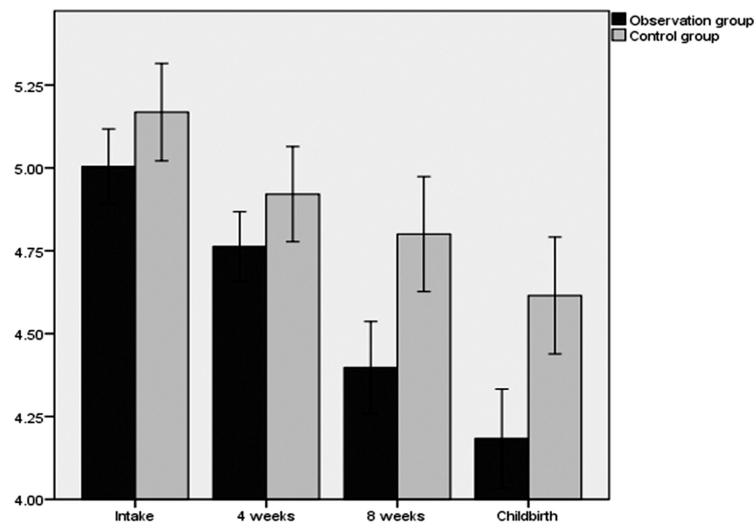


图 1 两组患者不同时间空腹血糖比较

Fig.1 Comparison of fasting blood glucose between two groups of patients at different times

2.3 妊娠终止时相关指标进行比较

对照组剖宫产率分别为 64.62 %、70.77 %，差异无统计学意义

两组患者分娩孕周、新生儿体重无差异, $P > 0.05$; 观察组和 ($P > 0.05$)。见表 3。

表 3 两组妊娠终止时的指标比较[n(%), ($\bar{x} \pm s$)]Table 3 Comparison of indicators at termination of pregnancy between the two groups[n(%), ($\bar{x} \pm s$)]

Groups	Gestational week of delivery (week)	Newborn weight (g)	Natural childbirth	Cesarean section
Observation group	38.71(37.43-39.36)	3300.62±497.04	23(35.38)	42(64.62)
Control group	38.71(37.71-39.50)	3207.54±624.53	19(29.23)	46(70.77)

2.4 不良围产期结局进行比较

体重儿、胎儿生长受限、胎儿宫内窘迫、新生儿窒息、新生儿低血糖方面无差异, $P > 0.05$ 。两组患者整体不良妊娠结局无差异, $P > 0.05$, 见表 4。

与对照组相比,观察组患者在早产、胎膜早破、羊水过多、羊水过少、羊水污染、子痫前期、胎盘早剥、妊娠期肝内胆汁淤积症、高脂血症方面无差异, $P > 0.05$; 新生儿在巨大儿、低出生

表 4 两组不良围产期结局的比较[n(%)]

Table 4 Comparison of adverse perinatal outcomes between the two groups[n(%)]

Groups	Parturients			Newborns		
	None of the above endings	Any kind	Two or more	None of the above endings	Any kind	Two or more
Observation group[n (%)]	34(52.31)	20(30.77)	11(16.92)	57(89.69)	8(12.31)	0(0.00)
Control group[n (%)]	31(47.69)	17(26.15)	17(26.15)	55(84.62)	8(12.31)	2(3.08)

3 讨论

GDM 是由遗传、环境和表观遗传等因素相互作用引起的暂时性疾病,与胰岛素抵抗密切相关,可导致不良围产期结局,甚至产生终生后遗证^[14,15]。有研究显示,GDM 患者孕期血糖平稳的控制正常范围内会减少围产期不良结局及相应并发症的发生^[16]。因此,GDM 患者维持孕期血糖平稳正常是预防不良结局的有效途径。

3.1 降糖效果分析

本研究观察组 65 例患者中无人出现过敏及其他不良反应,证明 OBG 用于 GDM 患者是安全的。一项健康主张指出,每天 3-4 g OBG 有助于降低糖尿病患者的餐后血糖^[17],但其并未指出对 GDM 患者空腹血糖的作用。与对照组相比,本研究观察组在治疗 4 周时空腹血糖水平较前下降,差异无统计学意义($P>0.05$);治疗 8 周后空腹血糖水平具有统计学差异(4.40 ± 0.56 mmol/L vs 4.80 ± 0.70 mmol/L, $P<0.05$),且观察组血糖离散程度低,说明 OBG 作用于机体代谢使血糖缓慢降低,并趋于相对稳定的状态。Xu 等^[18]人的研究指出低血糖指数饮食对 GDM 患者的空腹血糖和胰岛素需求量均无显著影响,这与本研究结果存在一定出入,考虑与饮食结构不同、样本量不充分有关。

3.2 孕期体重控制效果分析

妊娠期体重增加过多会产生诸多并发症,增加过少则无法满足母儿代谢需求,二者均会造成严重的不良后果。因此,适宜的体重增长对于妊娠结局至关重要^[19]。Huang 等^[20]人的动物研究表明,OBG 以剂量依赖性方式作用于下丘脑 PYY3-36-NPY 轴增强餐后饱腹感,间接促进胆囊收缩素的释放以降低食欲,进而降低肥胖小鼠的体重。本研究观察组患者平均体重增加量 (12.19 ± 5.54 Kg) 和孕期 BMI 增加量 (4.56 ± 2.00 Kg/m²) 均低于对照组 (14.14 ± 5.76 Kg, 5.34 ± 2.21 Kg/m²),且 BMI 增加量之间有显著差异($P<0.05$),说明 OBG 能适当控制 GDM 患者孕期体重增长,然而具体的作用机制仍不清楚,有待大量动物试验及临床研究证明。

3.3 对围产期不良结局的影响分析

GDM 诊疗不及时,会对母婴及子代带来短期和长期的不良影响^[21]。有人总结了 GDM 对胎儿及新生儿造成的不良影响,如巨大儿、高胆红素血症、新生儿低血糖和肩难产的风险增加,其子代在儿童和成年早期患肥胖症、2 型糖尿病和自闭症的可能性较高^[22]。本研究两组新生儿在分娩孕周、出生体重方面没有差异($P>0.05$),与 Xu 等^[18]人的研究结果一致,且均无低出生体重儿和新生儿低血糖病例,证明 OBG 在控制产妇产期体重、降低血糖的同时不影响胎儿在宫内的正常生长发育。本研究观察组和对照组在剖宫产率方面没有差异 (64.62% vs 70.77% , $P>0.05$),得出与 Viana^[23]相同的结论,说明医学营养治疗对于 GDM 患者的孕期管理效果良好,OBG 在此基础上是否能够降低剖宫产率有待进一步大样本的观察研究验证。有学者发现 GDM 患者进行低血糖指数饮食后早产发生率相对较高^[24],本研究两组患者早产率无统计学差异($P>0.05$),可能和样本量不足够大有关。此外,与对照组相比,观察组相应的不良围产期结局之间无统计学差异($P>0.05$),表明 OBG 不能够改善母婴不良妊娠结局,亦不会产生除上述已知结局之外的其他不良结局。

综上所述,我们发现 OBG 可以降低 GDM 患者的空腹血糖水平,适当控制孕期体重增长而不影响胎儿正常的宫内生长发育,对母婴不良妊娠结局无改善作用,不会产生除已知结局之外的其他不良结局。因此,OBG 用于 GDM 患者以降低空腹血糖、控制孕期体重增长过多是安全可行的,为 GDM 患者的饮食治疗提供了新的思路。然而在大多数研究中,此类研究受随访时间短以及样本量不足的限制,需要大规模、大样本的随机对照试验确定其治疗 GDM 及预防远期并发症发生的有效性,进而有助于在临床上推广应用。

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