

珍芪补血口服液联合多糖铁复合物对妊娠期缺铁性贫血的临床研究

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摘要: **目的** 探究珍芪补血口服液联合多糖铁复合物对妊娠期缺铁性贫血的治疗效果。**方法** 回顾性选取2019年3月—2020年6月凉山彝族自治州第二人民医院收治的112例妊娠期缺铁性贫血孕妇为研究对象,按照用药方案的不同将患者分为试验组和对照组,每组各56例。两组孕妇均遵医嘱口服维生素C及叶酸片。对照组在此基础上给予多糖铁复合物胶囊口服,0.3 mg/次,1次/d。试验组在对照组的基础上给予珍芪补血口服液,10 mL/次,2次/d。两组均治疗8周。对比两组孕妇临床疗效,比较两组患者治疗前后贫血相关指标,包括血红蛋白(Hb)、血清铁蛋白(SF)、红细胞平均体积(MCV)变化,比较两组患者治疗前后血清转铁蛋白受体(sTfR)、铁幼素(HJV)、膜铁转运蛋白1(FPN1)水平及免疫功能相关指标[辅助性T淋巴细胞(CD4⁺T)、成熟T细胞(CD3⁺T)、CD4⁺/抑制性T淋巴细胞(CD8⁺T)],观察治疗后两组不良妊娠结局发生情况。**结果** 治疗前,两组各项指标比较差异均无统计学意义($P>0.05$)。治疗后,试验组总有效率为98.21%,明显高于对照组的87.50%($P<0.05$)。治疗后两组患者Hb、SF、MCV、HJV、CD4⁺T、CD3⁺T、CD4⁺/CD8⁺水平较治疗前均明显升高($P<0.05$),且试验组明显高于对照组($P<0.05$)。治疗后两组患者血清sTfR、FPN1水平较治疗前均明显降低($P<0.05$),且试验组明显低于对照组($P<0.05$)。两组产妇产后出血及胎儿窘迫、早产、低出生体重儿等不良妊娠结局发生率差异无统计学意义($P>0.05$)。**结论** 珍芪补血口服液联合多糖铁复合物治疗妊娠期缺铁性贫血疗效显著,可有效调节孕妇免疫功能,改善贫血症状,提高红细胞生产速度,且不会增加不良妊娠结局。

关键词: 珍芪补血口服液; 多糖铁复合物; 缺铁性贫血; 免疫功能; 不良妊娠结局

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Clinical study of Zhenqi Buxue Oral Liquid combined with polysaccharide iron complex on iron deficiency anemia during pregnancy

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Abstract: Objective To explore the therapeutic effect of Zhenqi Buxue Oral Liquid combined with polysaccharide iron complex on iron deficiency anemia during pregnancy. **Methods** Total 112 pregnant women with iron deficiency anemia during pregnancy treated in the Second People's Hospital of Liangshan Yi Autonomous Prefecture from March 2019 to June 2020 were retrospectively selected as the research object. According to the different medication schemes, the patients were divided into experimental group and control group, with 56 cases in each group. Both groups of pregnant women took vitamin C and folic acid tablets orally according to the doctor's advice. On this basis, patients in the control group were given polysaccharide iron complex capsule orally, 0.3 mg/time, once a day. On the basis of the control group, patients in the experimental group were given Zhenqi Buxue Oral Liquid, 10 mL/time, twice a day. Both groups were treated for eight weeks. The clinical efficacy of the two groups of pregnant women was compared, and the anemia related indexes of the two groups before and after treatment, including the changes of hemoglobin (Hb), serum ferritin (SF) and mean red blood cell volume (MCV). The levels of serum transferrin receptor (sTfR), ferritin (HJV), ferroportin-1 (FPN1) and immune function indexes [auxiliary T lymphocytes (CD4⁺T), mature T cells (CD3⁺T), CD4⁺/inhibitory T lymphocytes (CD8⁺T)] were compared between the two groups before and after treatment. The adverse pregnancy outcomes of the two groups after treatment were observed. **Results** Before treatment, there was no significant difference in various indexes between two groups ($P>0.05$). After treatment, the total effective rate of the experimental group was 98.21%, which was significantly higher than

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87.50% of the control group ($P < 0.05$). After treatment, the levels of Hb, SF, MCV, HJV, CD4⁺T, CD3⁺T and CD4⁺/CD8⁺ in the two groups were significantly higher than those before treatment ($P < 0.05$), and the levels in the experimental group were significantly higher than the control group ($P < 0.05$). After treatment, the levels of serum sTfR and FPN1 in the two groups were significantly lower than those before treatment ($P < 0.05$), and the levels in the experimental group were significantly lower than those in the control group ($P < 0.05$). There was no significant difference in the incidence of postpartum hemorrhage, fetal distress, preterm birth and low birth weight infants between the two groups ($P > 0.05$). **Conclusion** Zhenqi Buxue Oral Liquid combined with polysaccharide iron complex is effective in the treatment of iron deficiency anemia during pregnancy. It can effectively regulate the immune function of pregnant women, improve the symptoms of anemia, increase the rate of red blood cell production, and will not increase the adverse pregnancy outcome.

Key words: Zhenqi Buxue Oral Liquid; polysaccharide iron complex; iron deficiency anemia; immune function; adverse pregnancy outcome

妊娠贫血为女性在妊娠期常见的一种并发症^[1],发生贫血的孕妇被认定为高危妊娠,妊娠期贫血患者约95%是由缺乏铁元素造成的,故妊娠期贫血类型主要以缺铁性贫血为主^[2]。缺铁性贫血主要是由于机体内对铁的需求和供应失衡,进而阻碍红细胞生成导致^[3]。缺铁性贫血能够降低孕妇对分娩、手术的耐受力,降低免疫功能,增加低出生体质量儿、早产的发生率^[4],还能增加产后并发症的发生甚至提高孕妇死亡率。因此,积极治疗妊娠期缺铁性贫血对母儿健康的保障有重要意义。多糖铁复合物为临床补铁常用药物,对胃黏膜无刺激^[5],安全有效。珍芪补血口服液能够益气、补血、健脾^[6]。故本研究为提高疗效,采用珍芪口服液联合多糖铁复合物治疗妊娠期缺铁性贫血,并分析其对孕妇免疫功能、血清铁蛋白(serum ferritin, SF)、血清转铁蛋白受体(serum transferrin receptor, sTfR)的影响。

1 资料与方法

1.1 临床资料

本研究为回顾性研究。选取2019年3月—2020年6月凉山彝族自治州第二人民医院收治的112例妊娠期缺铁性贫血孕妇为研究对象,年龄22~36岁,平均(26.31±4.27)岁;孕周12~18周,平均(14.52±2.18)周;轻度贫血52例,中度贫血35例,重度贫血25例。

1.2 纳入标准

(1)所有患者均符合《妇产科学》^[7]妊娠期缺铁性贫血相关诊断标准;(2)既往身体健康的单胎妊娠孕妇;(3)知情本研究内容并签署同意书的孕妇。

1.3 排除标准

(1)合并地中海贫血、肾病性贫血、恶性贫血孕妇;(2)合并肝肾功能不全孕妇;(3)合并恶性肿瘤、糖尿病的孕妇。

1.4 治疗方法

两组孕妇均遵医嘱口服维生素C及叶酸片。对

照组在此基础上给予多糖铁复合物胶囊(上海医药集团青岛国风药业股份有限公司,国药准字H20030033,规格:0.15 g,批号20190128、20190710)口服,0.3 mg/次,1次/d。试验组在对照组的基础上给予珍芪补血口服液(浙江康德药业集团股份有限公司,国药准字B20020764,规格:10 mL/支,批号:20190212、20200123)口服,10 mL/次,2次/d。两组均治疗8周后评估各项指标。

1.5 观察指标

1.5.1 临床疗效 结合临床实际与《血液病诊断及疗效标准》评定疗效^[8]:①痊愈:孕妇血红蛋白(Hb)水平大于100 g/L,主要临床症状消失;②有效:孕妇Hb上升水平大于20 g/L,临床症状改善;③无效:孕妇相关临床症状无改善甚至加重。

总有效率=(痊愈+有效)例数/总例数

1.5.2 贫血相关指标检测 分别于治疗前后抽取孕妇空腹血,使用血细胞分析仪检测Hb、SF、红细胞平均体积(MCV)水平。

1.5.3 sTfR、铁幼素(hemojuvelin, HJV)、膜铁转运蛋白1(ferroportin-1, FPN1)水平检测 分别于治疗前后使用微粒子增强透射免疫比浊法检测sTfR水平,使用酶联免疫吸附法检测HJV、FPN1水平。

1.5.4 免疫功能检测 分别于治疗前后抽取孕妇空腹血分离血清,使用碱性磷酸酶标记链霉卵白素法检测辅助性T淋巴细胞(CD4⁺T)、成熟T细胞(CD3⁺T)、抑制性T淋巴细胞(CD8⁺T)水平,并计算CD4⁺/CD8⁺值。

1.5.5 不良妊娠结局观察 于分娩后记录并比较两组孕妇产后出血,胎儿窘迫、早产、低出生体质量儿等不良妊娠结局发生情况。

1.6 统计学分析

使用SPSS 22.0软件分析数据,计量资料使用 $\bar{x} \pm s$ 表示,组内及组间比较采用 t 检验;计数资料采用例或百分比表示,组间比较采用 χ^2 检验,以 $P <$

0.05表示差异有统计学意义。

2 结果

2.1 两组患者基线资料比较

将纳入患者按照用药种类不同分为试验组和对照组,每组各56例。试验组年龄22~35岁,平均年龄(26.12±4.26)岁;孕周12~18周,平均孕周(14.38±2.15)周;轻度贫血25例,中度贫血18例,重度贫血13例。对照组年龄23~36岁,平均年龄(26.58±4.28)岁;孕周13~17周,平均孕周(14.76±2.21)周;轻度贫血27例,中度贫血17例,重度贫血12例。两组孕妇孕周、年龄、疾病严重程度等基线资料比较差异无统计学意义($P>0.05$),具有可比性。

2.2 临床疗效

经过8周药物治疗后,试验组总有效率为98.21%,明显高于对照组的87.50%($P<0.05$),见表1。

表1 两组临床疗效比较

Table 1 Comparison of clinical efficacy between two groups

组别	n/例	痊愈/例	有效/例	无效/例	总有效率/%
对照	56	16	33	7	87.50
试验	56	21	34	1	98.21*

与对照组比较: * $P<0.05$

* $P<0.05$ vs control group

2.3 治疗前后贫血指标变化

治疗前两组患者Hb、SF、MCV水平比较差异不显著($P>0.05$);治疗后两组Hb、SF、MCV水平均较治疗前明显升高($P<0.05$),且试验组明显高于对照组($P<0.05$)。见表2。

2.4 血清sTfR、HJV、FPN1水平比较

治疗前两组患者血清sTfR、HJV、FPN1水平比较,差异无统计学意义($P>0.05$);治疗后,两组血清HJV水平较治疗前均明显升高($P<0.05$),且试验组明显高于对照组($P<0.05$);治疗后两组血清sTfR、FPN1水平较治疗前均明显降低($P<0.05$),且试验组明显低于对照组($P<0.05$)。见表3。

2.5 免疫功能相关指标比较

治疗前两组患者CD4⁺T、CD3⁺T、CD4⁺/CD8⁺水平比较差异不显著($P>0.05$);治疗后两组CD4⁺T、CD3⁺T、CD4⁺/CD8⁺水平较治疗前均明显升高($P<0.05$),且试验组明显高于对照组($P<0.05$)。见表4。

2.6 不良妊娠结局比较

治疗后,两组产妇产后出血及胎儿窘迫、早产、低出生体质量儿等不良妊娠结局比较,差异无统计学意义($P>0.05$)。见表5。

3 讨论

妊娠期妇女血容量大量增加,胎儿生长发育对铁的需求均提高,但是摄入量不足,继而引发孕妇

表2 两组贫血相关指标比较($\bar{x}\pm s$)

Table 2 Comparison of related indexes of anemia between two groups ($\bar{x}\pm s$)

组别	n/例	Hb/(g·L ⁻¹)		SF/(μg·L ⁻¹)		MCV/fL	
		治疗前	治疗后	治疗前	治疗后	治疗前	治疗后
对照	56	84.62±4.05	91.58±5.46*	4.12±0.93	7.86±1.54*	73.58±3.62	79.65±4.11*
试验	56	85.64±4.12	101.78±7.23 [#]	4.23±1.01	11.34±2.15 [#]	74.56±3.68	86.34±4.46 [#]

与同组治疗前比较: * $P<0.05$; 与对照组治疗后比较: [#] $P<0.05$

* $P<0.05$ vs same group before treatment; [#] $P<0.05$ vs control group after treatment

表3 两组血清sTfR、HJV、FPN1水平比较($\bar{x}\pm s$)

Table 3 Comparison of serum sTfR, HJV and FPN1 levels between two groups ($\bar{x}\pm s$)

组别	n/例	sTfR/(mg·L ⁻¹)		HJV/(g·mL ⁻¹)		FPN1/(g·mL ⁻¹)	
		治疗前	治疗后	治疗前	治疗后	治疗前	治疗后
对照	56	3.78±0.95	3.45±0.71*	0.53±0.13	0.67±0.18*	3.39±0.65	2.45±0.46*
试验	56	3.82±1.01	3.20±0.52 [#]	0.51±0.12	0.87±0.25 [#]	3.43±0.67	2.01±0.39 [#]

与同组治疗前比较: * $P<0.05$; 与对照组治疗后比较: [#] $P<0.05$

* $P<0.05$ vs same group before treatment; [#] $P<0.05$ vs control group after treatment

表4 两组免疫功能相关指标比较($\bar{x}\pm s$)

Table 4 Comparison of immune function related indexes between two groups ($\bar{x}\pm s$)

组别	n/例	CD4 ⁺ T/%		CD3 ⁺ T/%		CD4 ⁺ /CD8 ⁺	
		治疗前	治疗后	治疗前	治疗后	治疗前	治疗后
对照	56	34.13±1.45	35.06±2.01*	56.94±2.11	59.06±2.67*	1.18±0.24	1.29±0.28*
试验	56	34.56±1.52	36.11±2.54 [#]	57.23±2.13	61.01±3.78 [#]	1.16±0.23	1.41±0.49 [#]

与同组治疗前比较: * $P<0.05$; 与对照组治疗后比较: [#] $P<0.05$

* $P<0.05$ vs same group before treatment; [#] $P<0.05$ vs control group after treatment

表5 两组不良妊娠结局发生情况比较

Table 5 Comparison of adverse pregnancy outcomes between two groups

组别	n/例	胎儿窘迫/例	产后出血/例	早产/例	低出生体重儿/例	不良妊娠结局发生率/%
对照	56	1	2	3	4	17.86
试验	56	1	1	2	2	10.71

缺铁性贫血的发生^[9]。孕妇胃肠功能、早孕反应、铁剂补充不足、饮食受限等均可引发缺铁性贫血^[10]。贫血可降低孕妇血液携带的氧气和氧疗能力,严重影响胎儿生长发育,还能促进孕妇促肾上腺激素释放激素,使B细胞和T细胞增殖能力降低,促进子宫收缩功能,增加孕妇感染率,还可抑制胎儿体质量生长^[11]。目前治疗妊娠期缺铁性贫血主要以补充铁剂、去除病因为主^[12]。叶酸为血细胞及黏膜生长的必要物质,能够增加体内的叶酸及铁元素,改善血液循环,还可降低神经管畸形的发生及改善妊娠结局^[13]。多糖铁复合物是较为理想的口服铁剂,为低分子多糖和铁的复合物^[14-15],水溶性较为稳定,不含游离的铁离子,能够以分子形式完整地吸收。珍芪补血口服液具有益气补血的功能,能够治疗因气血不足引起的头晕眼花、少气懒言等症状^[16],主要组成为黄芪、珍珠、羊胎盘、生姜、红参、枸杞子、白芷、薏苡仁等。黄芪具有增强免疫功能、利尿、保肝作用;珍珠可养阴熄风、镇心安神,能够增强造血功能,保护肝脏,提升抗病能力;羊胎盘可安神养血、补元气。诸药合用健脾、益气、生血,可有效改善孕妇胃肠吸收能力,提升造血功能,改善贫血症状,疗效显著。本研究结果显示,珍芪补血口服液联合多糖铁复合物治疗妊娠期缺铁性贫血后,试验组总有效率98.21%明显高于对照组87.50%,提示珍芪补血口服液联合多糖铁复合物疗效显著,改善缺铁性贫血孕妇临床症状。

血清sTfR、SF为临床检测缺铁性贫血的常用生化指标^[17],能够反映孕妇早期缺铁情况,常作为缺铁的主要鉴别标准,当血清铁水平升高时血清SF也会升高;血清铁元素缺乏时血清sTfR明显升高,以提高幼红细胞对铁元素的摄入;血清Hb、MCV、HJV均为反映机体贫血状况的常用指标^[18],贫血发生时其水平均降低;FPN1为铁输出分子,铁调素受铁水平的调控,能够维持铁稳定,而FPN1可与铁调素直接作用,其表达受铁调素的影响,进而控制肠道对铁的吸收及循环利用过程,故FPN1升高时提示贫血的发生^[18]。本研究结果显示,治疗后,两组患者Hb、SF、MCV、HJV水平较治疗前均明显升高,

且试验组明显高于对照组;两组血清sTfR、FPN1水平较治疗前均明显降低,且试验组明显低于对照组。提示,珍芪补血口服液联合多糖铁复合物可有效改善孕妇贫血程度。推测可能是补充较为丰富的铁剂后,加速血红蛋白的合成,随着血清中铁水平的提高促进SF的表达,血清sTfR表达减少,在一系列生理病理反应下,孕妇缺铁性贫血程度得到改善。

缺铁性贫血亦可影响孕妇免疫功能,有研究认为,铁为免疫代谢过程中的必需元素,也能参与免疫应答反应^[19];缺乏铁元素时机体被感染的几率增加。CD3⁺、CD4⁺为临床评估免疫功能的常用指标,参与免疫调节,CD4⁺/CD8⁺能够反映免疫功能,免疫功能下降时CD4⁺T、CD3⁺T、CD4⁺/CD8⁺降低^[20]。本研究结果显示,治疗后,两组CD4⁺T、CD3⁺T、CD4⁺/CD8⁺水平较治疗前均明显升高,且试验组明显高于对照组。提示,珍芪补血口服液联合多糖铁复合物可有效提高孕妇免疫功能,可能是因为补充铁剂后,促进T细胞成熟及向辅助性T淋巴细胞分化,有利于维持CD4⁺/CD8⁺平衡。本研究还发现,治疗后,两组产妇产后出血、胎儿窘迫、早产、低出生体重儿等不良妊娠结局比较差异无统计学意义。提示,珍芪补血口服液联合多糖铁复合物并不会增加不良妊娠结局的发生,安全性较高。

综上所述,珍芪补血口服液联合多糖铁复合物治疗妊娠期缺铁性贫血疗效显著,可有效调节孕妇免疫力,改善贫血程度,提高红细胞生产速度,且不会增加不良妊娠结局。

利益冲突 所有作者均声明不存在利益冲突

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