

• 论著 •

复方丹参注射液联合硫酸镁对早发型重度子痫前期患者肝肾功能及血管内皮功能的影响

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【摘要】目的 观察复方丹参注射液联合硫酸镁对早发型重度子痫前期患者肝肾功能及血管内皮功能的影响。**方法** 选取2014年4月至2017年1月华中科技大学同济医学院附属武汉儿童医院收治的早发型重度子痫前期患者,依据治疗方法分为两组。对照组(54例)患者在常规治疗基础上给予硫酸镁,观察组(48例)在对照组的基础上给予复方丹参注射液16 mL + 250 mL葡萄糖注射液静脉滴注(静滴),两组均治疗7 d。观察两组患者治疗前后肝肾功能及血管内皮功能的变化。**结果** 治疗后两组患者收缩压(SBP)、舒张压(DBP)及24 h尿蛋白(PRO)水平均较治疗前显著降低,24 h尿量(24 h UV)较治疗前显著增加;且观察组治疗后SBP [mmHg(1 mmHg=0.133 kPa): 116.23±3.51比128.66±7.32], DBP(mmHg: 74.87±4.15比86.44±5.71)以及PRO(g/24 h: 1.17±0.04比2.10±0.02)均显著低于对照组,24 h UV则显著多于对照组(mL: 2 359.37±52.96比1 630.67±98.49),差异均有统计学意义(均P<0.05)。治疗后两组患者丙氨酸转氨酶(ALT)、天冬氨酸转氨酶(AST)、血尿素氮(BUN)及血肌酐(SCr)水平及内皮素-1(ET-1)及ET-1/一氧化氮(NO)比值均显著降低,NO较治疗前显著升高,且以观察组治疗后上述指标的变化较对照组更显著[ALT(U/L): 20.38±1.78比26.28±2.11, AST(U/L): 25.49±2.28比32.62±1.53, BUN(mmol/L): 3.28±0.07比4.23±0.11, SCr(μmol/L): 222.78±10.82比276.44±8.49, ET-1(ng/L): 95.91±4.44比117.35±5.51, NO(μmol/L): 71.95±2.12比60.6±1.41, ET-1/NO: 1.36±0.05比2.17±0.05, 均P<0.05]。**结论** 复方丹参注射液联合硫酸镁能有效改善重度子痫前期患者肝肾功能,增强血管内皮功能,疗效显著。

【关键词】 复方丹参注射液; 硫酸镁; 早发型重度子痫前期; 肝肾功能; 血管内皮功能

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【Abstract】Objective To investigate the effects of compound Danshen injection combined with magnesium sulfate on liver and renal functions and endothelial function in patients with early onset type of severe preeclampsia. **Methods** One hundred and two patients with early onset type severe preeclampsia admitted into Wuhan Children's Hospital Affiliated to Tongji Medical College, Huazhong University of Science and Technology from April 2014 to January 2017 were enrolled. According to the treatment methods, they were divided into two groups. The patients in the control group (54 cases) were given magnesium sulfate on the basis of conventional treatment, the observation group (48 cases) was given intravenous Danshen injection 16 mL + 250 mL glucose injection intravenous drip on the basis of the treatment in control group, and the therapeutic course in both groups was 7 days. The changes of liver and kidney functions and vascular endothelial function before and after treatment were observed in the two groups. **Results** After treatment, the levels of systolic blood pressure (SBP), diastolic blood pressure (DBP) and 24-hour urine protein (PRO) were significantly lower than those before treatment, while the 24-hour urine volumes (24 h UV) were markedly increased compared with those before treatment in the two groups; after treatment, SBP [mmHg (1 mmHg = 0.133 kPa): 116.23±3.51 vs. 128.66±7.32], DBP (mmHg: 74.87±4.15 vs. 86.44±5.71) and PRO (g/24 h: 1.17±0.04 vs. 2.10±0.02) in the observation group were significantly lower than those in the control group, while the 24 h UV was obviously higher than that in the control group (mL: 2 359.37±52.96 vs. 1 630.67±98.49), all the differences being statistically significant (all P < 0.05). After treatment, the levels of alanine aminotransferase (ALT), aspartate aminotransferase (AST), blood urea nitrogen (BUN) and serum creatinine (SCr), the endothelin-1 (ET-1) and ET-1/nitric oxide (NO) ratio in the two groups were all significantly lower, NO was markedly higher, and the changes of the above indicators were more significant in the observation group [ALT (U/L): 20.38±1.78 vs.

vs. 26.28 ± 2.11 , AST (U/L): 25.49 ± 2.28 vs. 32.62 ± 1.53 , BUN (mmol/L): 3.28 ± 0.07 vs. 4.23 ± 0.11 , SCr ($\mu\text{mol}/\text{L}$): 222.78 ± 10.82 vs. 276.44 ± 8.49 , ET-1 (ng/L): 95.91 ± 4.44 vs. 117.35 ± 5.51 , NO ($\mu\text{mol}/\text{L}$): 71.95 ± 2.12 vs. 60.6 ± 1.41 , ET-1/NO ratio: 1.36 ± 0.05 vs. 2.17 ± 0.05 , all $P < 0.05$]. **Conclusion** The efficacy of compound Danshen injection combined with magnesium sulfate for treatment of patients with early onset type severe preeclampsia is remarkable, as it can effectively improve liver and kidney functions and enhance vascular endothelial function in such patients.

【Key words】 Compound Danshen injection; Magnesium sulfate; Early onset type severe preeclampsia; Liver and renal function; Vascular endothelial function

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重度子痫前期是妊娠期特有的疾病,也是造成产妇死亡的重要因素之一,早发型重度子痫前期是指在孕34周以内发生的子痫,患者常出现血液高凝状态,血压升高、蛋白尿增多及下肢水肿等症状,若治疗不及时还会导致多种并发症的发生,严重影响了孕妇及胎儿的健康。目前临幊上关于重度子痫前期的治疗主要包括解痉、降压、镇静、利尿等,硫酸镁是目前治疗此病的常用药物,能有效预防产妇惊厥,保护胎儿,但该药在降低患者并发症方面不具备优势,且长期使用会出现镁离子(Mg^{2+})中毒现象^[1]。复方丹参注射液是一种纯中药复方制剂,能有效降低患者血压及血脂,且具有镇静及安眠的作用,已逐渐应用于临床^[2-3]。但有关复方丹参注射液治疗早发型重度子痫前期的研究资料不足。本研究旨在探讨复方丹参注射液联合硫酸镁对早发型重度子痫前期患者肝肾功能及血管内皮功能的影响,现报告如下。

1 资料与方法

1.1 研究对象的选择:选择2014年4月至2017年1月在本院治疗的早发型重度子痫前期患者102例。

1.1.1 纳入标准:①符合重度子痫前期的诊断标准:收缩压(SBP)≥160 mmHg(1 mmHg=0.133 kPa)或舒张压(DBP)≥110 mmHg;24 h持续尿蛋白或24 h尿蛋白(PRO)≥2 g;血肌酐(SCr)≥106 mmol/L;血小板计数(PLT)< $100 \times 10^9/\text{L}$;②无子痫前期病史。

1.1.2 排除标准:①严重肝肾功能不全;②恶性肿瘤;③对治疗中使用的药物有过敏现象;④有高血压及血液系统疾病。

1.1.3 伦理学:本研究符合医学伦理学标准,并经本院医学伦理委员会批准,所有检测和治疗方法取得患者或家属知情同意。

1.2 研究分组:按治疗方法不同将患者分为对照组(54例)和观察组(48例)。两组患者年龄、孕期和生产史等一般资料比较差异均无统计学意义(均 $P>0.05$;表1),具有可比性。

表1 两组患者一般资料比较($\bar{x} \pm s$)

组别	例数 (例)	年龄(岁)		孕期(周)		初产妇 (例)	经产妇 (例)
		范围	$\bar{x} \pm s$	范围	$\bar{x} \pm s$		
对照组	54	24~35	28.12 ± 2.13	28~33	31.22 ± 1.42	38	16
观察组	48	23~36	28.41 ± 3.12	27~34	31.67 ± 1.87	35	13

1.3 治疗方法:两组患者均给予补充白蛋白、高蛋白低脂低盐饮食、心痛定降压及地西洋镇静等常规治疗。两组均治疗7 d。

1.3.1 对照组:在常规治疗基础上给予硫酸镁(开封制药有限公司生产),首次取硫酸镁5 g加入到100 mL 5%葡萄糖注射液中静脉滴注(静滴),30 min内滴完;再取硫酸镁15 g加入到1000 mL 5%葡萄糖注射液中,10 h滴完,每日1次。

1.3.2 观察组:在对照组的基础上给予复方丹参注射液(四川升和药业股份有限公司生产),规格为每支2 mL,取8支加入到250 mL 5%葡萄糖注射液中静滴,每日1次。

1.4 检测指标及方法:于治疗前和治疗7 d后测量两组患者SBP及DBP;收集患者尿液,测定24 h尿量(24 h UV),采用双缩脲法测定两组患者治疗前后PRO水平;取两组患者静脉血,用全自动生化分析仪检测天冬氨酸转氨酶(AST)、丙氨酸转氨酶(ALT)、血尿素氮(BUN)及血肌酐(SCr)水平;采用酶联免疫吸附试验(ELISA)检测患者血清内皮素-1(ET-1)及一氧化氮(NO)水平。

1.5 统计学方法:使用SPSS 19.0统计软件进行分析,符合正态分布的计量资料以均数±标准差($\bar{x} \pm s$)表示,采用t检验;计数资料以例表示,采用 χ^2 检验。 $P<0.05$ 为差异有统计学意义。

2 结果

2.1 两组患者治疗前后临床指标的变化比较(表2):两组治疗前SBP、DBP、PRO及24 h UV比较差异均无统计学意义(均 $P>0.05$);治疗后两组SBP、DBP及PRO均较治疗前显著降低,24 h UV较治疗前显著增加,且以观察组上述指标的变化较对照组更显著(均 $P<0.05$)。

表2 两组患者治疗前后临床指标的变化比较($\bar{x} \pm s$)

组别	时间	例数(例)	SBP(mmHg)	DBP(mmHg)
对照组	治疗前	54	167.49±8.09	105.59±4.16
	治疗后	54	128.66±7.32 ^a	86.44±5.71 ^a
观察组	治疗前	48	168.58±8.49	106.76±4.07
	治疗后	48	116.23±3.51 ^{ab}	74.87±4.15 ^{ab}

组别	时间	例数(例)	PRO(g/24 h)	24 h UV(mL)
对照组	治疗前	54	4.17±0.09	1 081.23±17.44
	治疗后	54	2.10±0.02 ^a	1 630.67±98.49 ^a
观察组	治疗前	48	4.18±0.09	1 080.33±13.05
	治疗后	48	1.17±0.04 ^{ab}	2 359.37±52.96 ^{ab}

注:与治疗前比较,^aP<0.05;与对照组比较,^bP<0.05

2.2 两组患者治疗前后肝肾功能指标的变化比较(表3):两组治疗前ALT、AST、BUN及SCr比较差异均无统计学意义(均P>0.05);治疗后两组上述指标均较治疗前显著降低,且以观察组的降低程度较对照组更显著(均P<0.05)。

表3 两组患者治疗前后肝肾功能指标的变化比较($\bar{x} \pm s$)

组别	时间	例数(例)	ALT(U/L)	AST(U/L)
对照组	治疗前	54	34.34±3.07	45.90±2.19
	治疗后	54	26.28±2.11 ^a	32.62±1.53 ^a
观察组	治疗前	48	34.52±2.95	46.04±2.25
	治疗后	48	20.38±1.78 ^{ab}	25.49±2.28 ^{ab}

组别	时间	例数(例)	BUN(mmol/L)	SCr(μmol/L)
对照组	治疗前	54	6.24±0.09	322.36±3.04
	治疗后	54	4.23±0.11 ^a	276.44±8.49 ^a
观察组	治疗前	48	6.27±0.09	321.12±2.91
	治疗后	48	3.28±0.07 ^{ab}	222.78±10.82 ^{ab}

注:与治疗前比较,^aP<0.05;与对照组比较,^bP<0.05

2.3 两组患者治疗前后血管内皮功能的变化比较(表4):两组治疗前ET-1、NO及ET-1/NO比值比较差异均无统计学意义(均P>0.05);治疗后两组ET-1及ET-1/NO水平均较治疗前显著降低,NO水平较治疗前显著升高,且以观察组治疗后的变化较对照组更显著(均P<0.05)。

表4 两组患者治疗前后血管内皮功能的变化比较($\bar{x} \pm s$)

组别	时间	例数(例)	ET-1(ng/L)	NO(μmol/L)	ET-1/NO比值
对照组	治疗前	54	136.29±3.70	54.58±2.40	2.60±0.11
	治疗后	54	117.35±5.51 ^a	60.60±1.41 ^a	2.17±0.05 ^a
观察组	治疗前	48	132.96±2.08	55.23±2.81	2.66±0.09
	治疗后	48	95.91±4.44 ^{ab}	71.95±2.12 ^{ab}	1.36±0.05 ^{ab}

注:与治疗前比较,^aP<0.05;与对照组比较,^bP<0.05

3 讨论

早发型重度子痫前期是产科的常见并发症之一,也是威胁产妇及胎儿健康的重要因素,具有发病时间早、病情进展迅速、距离足月时间长及并发症较多等特点,且新生儿多为早产,存活率较低。早发

型重度子痫前期的发病机制包括基因及胎盘异常、胎盘中毒性物质增多、内皮细胞功能受损等^[4],患者常出现高血压、蛋白尿增多、肝肾功能受损、血小板水平增加及严重水肿等症状,严重者甚至会影响孕妇及胎儿的生命安全。临幊上早发型重度子痫前期的治疗方法主要是使用药物控制患者症状,硫酸镁是目前使用较多的药物,能有效抑制中枢神经,松弛骨骼肌,进而达到解痉、镇静及降压的效果;也能有效抑制N-甲基-D-天冬氨酸受体,降低细胞内钙离子(Ca²⁺)浓度,直接阻滞Ca²⁺通道,使Ca²⁺浓度进一步降低,因此硫酸镁治疗重度子痫前期有一定的优势,但长期使用患者会出现镁离子中毒的风险^[5-6]。中医学认为,重度子痫前期的发病机制主要是由于患者本身脏气虚弱,再加上孕期阴血养胎,导致精血不足,从而出现阴不敛阳,属于本虚标实证,故应以补气养阴、健脾利湿、活血化瘀为治疗原则。复方丹参注射液是一种纯中药制剂,主要由丹参及降香两种中药配制而成,丹参中含有丹参酮,能活血化瘀,养血调经,安神止痛;降香性温,入肝经,能起到理气镇痛,行瘀止血的作用。结果显示,复方丹参注射液能有效抑制血小板聚集和合成,改善机体凝血功能异常,扩张微循环,改善细胞代谢障碍;恢复肾小球基底膜通透性,从而降低尿蛋白^[7-9]。

本研究观察复方丹参注射液联合硫酸镁对早发型重度子痫前期患者肝肾功能及血管内皮功能的影响,结果表明,治疗后两组患者SBP、DBP及PRO水平均显著降低,24 h UV显著增加,且以观察组的变化较对照组更显著。说明复方丹参注射液联合硫酸镁能有效改善重度子痫前期患者的临床症状,促进患者康复。丹参注射液中的丹参酮能有效降低胆固醇合成,改善脂质代谢紊乱,从而有助于患者血压及肾功能的恢复,使机体恢复正常^[2]。结果显示,子痫前期患者常存在不同程度肝肾功能异常,这可能是由于心血管系统长期高负荷状态所致,ALT及AST是评价机体肝功能的重要指标,其水平的高低直接反映机体肝损伤的程度,而子痫前期患者的血管痉挛现象导致肝脏出现缺血损伤,使血中ALT及AST水平显著升高^[10-11];BUN及SCr是评价肾功能的重要指标,重度子痫前期患者肾小球扩张及肾小管痉挛现象明显,从而导致肾脏滤过功能下降,造成BUN及SCr水平的升高^[12-13]。本研究显示,治疗后两组患者ALT、AST、BUN及SCr水平均较治疗前显著降低,且以观察组治疗后上述指标的降低

程度较对照组更显著。说明复方丹参注射液联合硫酸镁能有效降低重度子痫前期患者肝肾损伤,增强患者肝肾功能。

血管内皮功能紊乱亦是重度子痫前期患者较常存在的现象,NO是机体内皮细胞合成的血管舒张因子,能有效增强鸟苷酸环化酶的活性,促进其表达,从而使血管舒张;ET-1是一种强效的血管收缩因子,其水平高低与患者血压呈显著正相关,且能有效拮抗NO的舒血管作用^[14-16]。本研究显示,治疗后两组患者ET-1及ET-1/NO水平均较治疗前显著降低,NO则较治疗前显著升高,且观察组上述指标的变化程度较对照组更显著。说明复方丹参注射液联合硫酸镁能有效改善重度子痫前期患者血管活性物质水平,从而改善血管内皮功能,这可能与复方丹参注射液中的有效成分能抑制血小板聚集和合成,改善机体凝血功能异常和细胞代谢障碍,扩张微循环有关,但具体机制尚需进一步研究。

综上所述,复方丹参注射液联合硫酸镁能有效改善重度子痫前期患者的临床症状、肝肾功能和血管内皮功能,短期疗效显著,但对母婴妊娠结局是否有益仍需深入研究。

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