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肾康注射液联合前列地尔注射液对慢性肾炎患者肾功能及脂糖代谢的影响*

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摘要 目的：探讨肾康注射液联合前列地尔注射液对慢性肾炎（CN）患者肾功能及脂糖代谢的影响。**方法**：选取2015年1月至2017年10月海南省中医院收治的CN患者108例为研究对象，按照随机数字表法分为对照组（n=54）和研究组（n=54）。对照组给予前列地尔注射液治疗，研究组在前列地尔注射液的基础上联合肾康注射液治疗，两组均连续治疗12d。比较两组治疗前后肾功能指标、脂糖代谢指标、临床疗效及不良反应发生情况。**结果**：与治疗前比较，两组治疗后24h尿蛋白定量（24h-UPro）、尿白蛋白排泄率（UAER）、血尿素氮（BUN）、血肌酐（SCr）水平均降低，且研究组低于对照组（*P<0.05*）。与治疗前比较，两组治疗后甘油三酯（TG）、总胆固醇（TC）、低密度脂蛋白胆固醇（LDL-C）、空腹血糖（FBG）水平均降低，高密度脂蛋白胆固醇（HDL-C）水平升高，且研究组TG、TC、LDL-C、FBG水平较对照组降低，HDL-C水平较对照组升高（*P<0.05*）。研究组总有效率为92.59%，高于对照组的77.78%，组间比较差异有统计学意义（*P<0.05*）。研究组不良反应发生率为5.56%，与对照组的7.41%比较差异无统计学意义（*P>0.05*）。**结论**：肾康注射液联合前列地尔注射液治疗CN具有较好的疗效，能有效改善患者肾功能和脂糖代谢，且不会增加不良反应的发生，值得临床推广应用。

关键词：慢性肾炎；肾康注射液；前列地尔注射液；疗效；肾功能；脂糖代谢

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Effect of Shen Kang Injection Combined with Alprostadil Injection on Renal Function and Lipid and Glucose Metabolism in Patients with Chronic Nephritis*

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ABSTRACT Objective: To investigate the effect of Shen Kang injection combined with Alprostadil injection on renal function and lipid and glucose metabolism in patients with chronic nephritis (CN). **Methods:** A total of 108 patients with CN, who were treated in Traditional Chinese Medicine Hospital of Hainan Province from January 2015 to October 2017, were selected and were randomly divided into control group (n=54) and study group (n=54). The control group was treated with Alprostadil injection, and the study group was treated with Shen Kang injection on the basis of Alprostadil injection. The two groups were treated continuously for 12 days. The indexes of renal function, the indexes of lipid and glucose metabolism, clinical efficacy and adverse reaction before and after treatment were compared between the two groups. **Results:** Compared with before treatment, the levels of 24h urine protein quantitative (24h-UPro), urinary albumin excretion rate (UAER), blood urea nitrogen (BUN), serum creatinine (SCr) were decreased in the two groups after treatment, and the study group was lower than the control group (*P<0.05*). Compared with before treatment, the levels of Triglyceride (TG), total cholesterol (TC), low density lipoprotein cholesterol (LDL-C), and fasting blood glucose (FBG) in the two groups after treatment were all decreased, and the level of High density lipoprotein cholesterol (HDL-C) was increased, the levels of TG, TC, LDL-C and FBG in the study group were lower than those in the control group, and the level of HDL-C was higher than that in the control group (*P<0.05*). The total effective rate of the study group was 92.59%, which was higher than that of 77.78% in the control group, and there was a significant difference between the two groups (*P<0.05*). The incidence of adverse reactions in the study group was 5.56%,and there was no significant difference compared with the 7.41% of the control group (*P>0.05*). **Conclusion:** Shen Kang injection combined with Alprostadil injection has a good effect in the treatment of CN. It can effectively improve renal function and lipid and glucose metabolism, and it does not increase the incidence of adverse reactions, which is worthy of clinical application.

Key words: Chronic nephritis; Shen Kang injection; Alprostadil injection; Curative effect; Renal function; Lipid and glucose metabolism

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前言

慢性肾炎(chronic nephritis,CN)是一种病情进展缓慢、发病原因各异的肾小球疾病,其临床表现有高血压、血尿、蛋白尿以及浮肿等,同时常伴有不同程度的肾功能受损,严重时将进展为慢性肾衰竭[1-3]。目前临床上对 CN 的治疗尚无特效药,一般以改善或缓解临床症状、防止或延缓肾功能衰竭以及防治并发症为主要目的[4,5]。有研究报道[6,7],常规的西医疗法对 CN 患者的病情进展具有一定的延缓作用,但效果并不令人满意。目前,CN 的常用治疗药物为抗血小板聚集药物、降压药物、利尿剂、免疫抑制剂等,这些药物对 CN 的治疗有一定疗效,但通常不良反应率和复发率都偏高[8-10]。前列地尔是一种天然前列腺素,具有较高的生物活性,其可抑制免疫复合物的形成以及血小板的聚集,同时还可增强肾小球滤过率以及抑制肾小管的纤维化,进而改善肾功能[11]。肾康注射液是一种中药复合注射液,其可通过改善肾小管的重吸收而起到促进肾功能恢复的作用[12]。为了探讨肾康注射液和前列地尔注射液对 CN 患者的疗效,本研究以两者联合使用对患者肾功能及脂糖代谢的影响进行分析,旨在为 CN 的用药选择提供参考,现进行如下阐述。

1 资料与方法

1.1 一般资料

选取 2015 年 1 月至 2017 年 10 月海南省中医院收治的 CN 患者 108 例为研究对象,纳入标准:(1)符合《内科学》中关于 CN 的诊断标准[13];(2)伴有面部浮肿、高血压、高血脂;(3)自愿参与本研究,并签署同意书。排除标准:(1)重度肾损伤者;(2)对本研究药物过敏者;(3)妊娠或哺乳期妇女;(4)合并严重肿瘤疾病者;(5)精神失常者。将纳入对象按照随机数字表法分为研究组(n=54)和对照组(n=54)。研究组男 34 例,女 20 例;年龄 20-73 岁,平均(53.78± 10.56);病程:1-13 年,平均(5.23± 1.45)。对照组男 32 例,女 22 例;年龄 23-71 岁,平均(54.34± 10.98);病程:1-12 年,平均(5.78± 1.77)。两组一般资料经统计分析差异无统计学意义(*P>0.05*),均衡可比。本研究符合海南省中医院伦理委员会的相关规定。

1.2 方法

两组患者入院后均给予 CN 的基础治疗,包括低盐、低蛋白以控制饮食、消肿、利尿、控制血糖、血压等。实施基础治疗后,对照组给予前列地尔注射液(北京泰德制药有限公司,国药准字:H10980024) 治疗,10 μg/ 次,0.9%氯化钠液 10 mL 稀释后静脉推注,1 次 /d,连续治疗 12d。研究组在对照组的基础上加用肾康注射液(西安世纪盛康药业有限公司,国药准字:Z20040110)治疗,静脉滴注,60 mL/ 次,5%葡萄糖液稀释后静脉滴注(合并糖尿病者改为 0.9%氯化钠液稀释),1 次 / 天,连续治疗 12d。

1.3 观察指标

1.3.1 肾功能及脂糖代谢指标检测 肾功能指标包括 24h 尿蛋白定量(24h urine protein quantitative,24h-UPro)、尿白蛋白排泄率(UAER)、血尿素氮(blood urea nitrogen,BUN)、血肌酐(serum creafinine,SCr)。脂糖代谢指标包括甘油三酯(triglyceride,TG)、总胆固醇(total cholesterol,TC)、低密度脂蛋白胆固醇(low density lipoprotein cholesterol,LDL-C)、高密度脂蛋白胆固醇(high density lipoprotein cholesterol,HDL-C)、空腹血糖(fasting blood glucose,FBG)。分别于治疗前和治疗 12d 后采取所有患者晨起空腹静脉血 3 mL,经 4000 r/min 离心 10 min,离心半径 8 cm,分离上清液,采用全自动生化分析仪(美国贝克曼库尔特公司,型号:AU5800)测定 BUN、SCr 以及各脂糖代谢指标水平,采用反射免疫法(试剂盒购自武汉博士德公司)测定 UAER 水平,具体操作按照试剂盒说明书进行。收集患者 24h 尿液总量,全部混合并摇匀,送化验室检测 24h-UPro 水平。

1.3.2 疗效评价[14] 显效:治疗 12d 后,患者临床症状完全消失或有明显改善,肾功能和脂糖代谢指标水平明显改善;有效:治疗 12d 后,患者临床症状基本改善,且肾功能和脂糖代谢指标水平有所改善;无效:治疗 12d 后,患者临床症状无改善甚至加重,肾功能和脂糖代谢指标水平无改善。总有效率为显效率和有效率之和。

1.3.3 不良反应 观察并记录两组患者治疗期间的不良反应发生情况。

1.4 统计学方法

采用 SPSS 22.0 统计软件进行统计分析,肾功能和脂糖代谢水平等计量资料以($\bar{x}\pm s$)形式描述,给予 t 检验,临床疗效、不良反应发生率等计数资料以(%)形式描述,给予 x^2 检验,将 α=0.05 作为检验标准。

2 结果

2.1 两组肾功能比较

治疗前,两组 24h-UPro、UAER、BUN、SCr 水平比较差异无统计学意义(*P>0.05*);与治疗前比较,两组治疗后 24h-UPro、UAER、BUN、SCr 水平均降低,且研究组低于对照组(*P<0.05*)。见表 1。

表 1 两组肾功能指标比较($\bar{x}\pm s$)

Table 1 Comparison of renal function indexes between two groups ($\bar{x}\pm s$)

Groups	n	Time	24h-UPro(g/h)	UAER(mg/min)	BUN(mmol/L)	SCr(μmol/L)
Study group	54	Before treatment	2.53± 0.34	1.21± 0.78	15.54± 3.23	234.89± 23.56
		After treatment	1.83± 0.56*#	0.80± 0.45*#	9.67± 1.21*#	149.34± 16.78*#
Ccontrol group	54	Before treatment	2.54± 0.53	1.23± 0.67	15.33± 3.67	235.56± 22.12
		After treatment	1.87± 0.31*	0.95± 0.14*	11.67± 1.34*	187.90± 17.13*

Note: compared with before treatment, **P<0.05*; compared with the control group, #*P<0.05*.

2.2 两组脂糖代谢比较

治疗前，两组 TG、TC、LDL-C、HDL-C、FBG 水平经统计分析差异无统计学意义（*P>0.05*）；与治疗前比较，两组治疗后 TG、TC、LDL-C、FBG 水平均降低，HDL-C 水平升高，且研究组 TG、TC、LDL-C、FBG 水平较对照组降低，HDL-C 水平较对照组升高（*P<0.05*）。见表 2。

表 2 两组脂糖代谢指标比较（$\bar{x}\pm s$，mmol/L）

Table 2 Comparison of lipid metabolism indexes between two groups（$\bar{x}\pm s$，mmol/L）

Groups	n	Time	TG	TC	LDL-C	HDL-C	FBG
Study group	54	Before treatment	3.93± 0.54	4.12± 0.31	2.89± 0.34	1.18± 0.23	7.89± 1.27
		After treatment	3.14± 0.31*#	3.67± 0.16*#	2.24± 0.18*#	1.70± 0.35*#	5.23± 1.56*#
Ccontrol group	54	Before treatment	3.94± 0.30	4.13± 0.29	2.88± 0.36	1.17± 0.21	7.90± 0.34
		After treatment	3.34± 0.45*	3.95± 0.14*	2.44± 0.23*	1.38± 0.37*	6.45± 0.67*

Note: compared with before treatment, *$P<0.05$; compared with the control group, #$P<0.05$.

2.3 两组临床疗效比较

研究组总有效率为 92.59%，高于对照组的 77.78%（*P<0.05*）。见表 3。

表 3 两组临床疗效比较[n(%)]

Table 3 Comparison of clinical efficacy between two groups [n (%)]

Groups	n	Excellence	Effective	Invalid	Total effective rate
Study group	54	21(38.89)	29(53.70)	4(7.41)	50(92.59)
Ccontrol group	54	16(29.63)	26(48.15)	12(22.22)	42(77.78)
x^2					4.696
P					0.030

2.4 两组不良反应情况比较

研究组发生血管疼痛 2 例，局部红肿 1 例，不良反应反生率为 5.56%(3/54)；对照组发生血管疼痛 3 例，局部红肿 1 例，不良反应反生率为 7.41%(4/54)；两组不良反应均不影响治疗，停药后自行恢复，两组不良反应发生率比较差异无统计学意义（x^2=0.153，*P*=0.696）。

3 讨论

随着人们生活方式和工作压力的增大，CN 在全世界范围内发病率呈逐年上升趋势，而我国的 CN 患者每年也在不断增加，因此 CN 的早期诊断及治疗已成为研究的热点[15-17]。CN 的发病机制较为复杂，通常是因患者发生脂糖代谢异常、肾小管间质变性、高血压、尿蛋白等引起肾小球硬化，最终导致肾功能减退，同时还伴有血管内皮损伤、血小板聚集，从而引发患者形成微血栓[18-20]。在 CN 的治疗中，常存在复发的现象，一般都只能对症治疗，而不能根治[21]。常规的西药疗法一般采用阿托伐他汀、缬沙坦等进行治疗，但疗效并不显著，同时不良反应也较多[22]。现代中医认为，CN 的治疗需从多靶点进行，包括改善气血功能活动、调节人体脏腑以及整体机能，通过多角度改善患者的临床症状，以延缓病情的进展[23]。

本研究结果显示，治疗后，研究组总有效率高于对照组（*P<0.05*）。说明两药的联合使用比仅用前列地尔注射液具有更好的疗效。中医学认为，CN 多表现为淤血内存、湿毒、脾肾阴阳虚衰，治疗应从改善血流、控制血压、血糖着手。肾康注射液是一种中药复方制剂，其组成成分为黄芪、丹参、红花、大黄，这四药合用，能益气活血、通腑利湿、降逆泄浊[24]。前列地尔可扩张血管，稳定血流动力学，从而增加肾小球血流量，改善其肾功能[25]。因此，两药的联合使用可提高治疗 CN 的疗效。本研究还显示，与治疗前比较，两组治疗后 24h-UPro、UAER、BUN、SCr 水平均降低，且研究组低于对照组（*P<0.05*），与治疗前比较，两组 TG、TC、LDL-C、FBG 水平均降低，HDL-C 水平升高，且研究组 TG、TC、LDL-C、FBG 水平较对照组降低，HDL-C 水平较对照组升高（*P<0.05*）。提示肾康注射液联合前列地尔注射液能够明显降低 CN 患者尿蛋白、血糖、血脂水平，能有效的改善患者肾功能和脂糖代谢。脂糖代谢紊乱可能是肾功能衰退的结果，其在 CN 的病情进展中起了重要作用，同时，脂糖代谢紊乱可导致脂糖在肾小球内沉积，堵塞肾小球微血管，以致形成微血栓，进而加速对肾功能的损害[26,27]。肾康注射液中的黄芪可增强肾小球滤过膜通透性以及增加肾血流量，从而改变肾小球内环境，进而增加肾小球滤过率，对肾脏起到保护作用；而大黄则可以纠正脂类水平紊乱、降低 BUN、SCr 水平、抑制肾小管纤维化以及抑制肾小球细膜细胞增殖；丹参则具有消除氧自由基、促进组织修复以及抑制肾细胞凋亡的作用，同时也可以增加血小板中环核苷酸的水平，抑制血小板的聚集；红花则可以活血祛瘀通络，增加脂糖代谢的能力，促进肾小球对免疫复合物的清除，达到保护肾功能的作用[28]。前列地尔注射液中的前列素 E1 是一种血管活性药，其可以通过调节肾小球的动脉血流，从而降低肾小球内压，延缓肾功能损害[29]。另外，本研究结果显示，两组不良反应发生率比较差异无统计学意义（*P>0.05*），说明与单独使用前列地尔注射液比较，加用肾康注射液并不会增加患

者的不良反应。既往研究也表明[30],中医药的使用对部分不良反应有改善作用,并不会增加 CN 患者不良反应的发生,与本研究结果相符。

综上所述,肾康注射液联合前列地尔注射液治疗 CN 可以改善患者肾功能,同时可纠正脂糖代谢紊乱,不良反应少,其治疗疗效优于单纯使用前列地尔注射液,是治疗 CN 的有效药物选择。

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