

doi: 10.13241/j.cnki.pmb.2019.03.029

肾衰宁胶囊联合血液透析对慢性肾功能衰竭患者肾功能及血液流变学的影响*

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摘要 目的:探讨肾衰宁胶囊联合血液透析对慢性肾功能衰竭患者肾功能及血液流变学的影响。**方法:**选取中国医科大学本溪中心医院于2015年1月-2017年9月期间收治的慢性肾功能衰竭患者80例为研究对象。根据随机数字表法将患者分为对照组(n=40)与研究组(n=40),两组患者均给予血液透析治疗,研究组在此基础上联合使用肾衰宁胶囊治疗,疗程均为3个月。观察并比较两组患者治疗3个月后临床疗效及不良反应发生情况,比较两组患者治疗前、治疗3个月后血肌酐(Scr)、尿素氮(BUN)、肾小球滤过率(eGFR)水平及全血高切黏度、全血低切黏度、血浆黏度、红细胞比容。**结果:**研究组患者总有效率为92.50%(37/40),高于对照组的67.50%(27/40),差异有统计学意义($P<0.05$)。两组患者治疗3个月后Scr、BUN水平较治疗前降低,且研究组低于对照组($P<0.05$);而两组患者治疗3个月后eGFR水平较治疗前升高,且研究组高于对照组($P<0.05$)。研究组患者治疗3个月后的全血高切黏度、全血低切黏度、血浆黏度以及红细胞比容均低于对照组($P<0.05$)。对照组不良反应发生率为7.50%,与研究组的10.00%比较差异无统计学意义($P>0.05$)。**结论:**肾衰宁胶囊联合血液透析对慢性肾功能衰竭患者有较好的治疗效果,能够改善患者肾功能状况,同时稳定患者血液流变学,并且安全性较好。

关键词:肾衰宁胶囊;血液透析;慢性肾功能衰竭;肾功能;血液流变学

中图分类号:R692.5; R459.5 **文献标识码:**A **文章编号:**1673-6273(2019)03-523-04

Effect of Shen Shuai Ning Capsule Combine with Hemodialysis on Renal Function and Hemorheology in Patients with Chronic Renal Failure*

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ABSTRACT Objective: To investigate the effect of Shen Shuai Ning capsule combine with hemodialysis on renal function and hemorheology in patients with chronic renal failure. **Methods:** 80 patients with chronic renal failure who were treated in Benxi Central Hospital of China Medical University from January 2015 to September 2017 were selected as the subjects. The patients were divided into control group (n=40) and study group (n=40) according to the number table method, the two groups were given hemodialysis treatment, the study group on the basis of combination of Shen Shuai Ning capsule, the course of treatment was 3 months. The clinical efficacy and adverse reaction of two groups after 3 months of treatment were observed and compared, the serum creatinine (Scr), urea nitrogen (BUN), glomerular filtration rate (eGFR) level and whole blood viscosity, whole blood low shear viscosity, plasma viscosity and hematocrit between the two groups before and after treatment of 3 months were compared. **Results:** The total effective rate of the study group was 92.50% (37/40), which was significantly higher than 67.50% (27/40) of the control group, the difference was statistically significant ($P<0.05$). The levels of Scr and BUN in the two groups after 3 months of treatment was lower than those before treatment, and the study group was lower than that of the control group ($P<0.05$), the level of eGFR in the two groups after 3 months of treatment was higher than that before treatment, and the study group was higher than that of the control group ($P<0.05$). The whole blood viscosity, whole blood low shear viscosity, plasma viscosity and hematocrit in the study group after 3 months of treatment were lower than those of the control group ($P<0.05$). The incidence of adverse reactions in the control group was 7.50%, and there was no significant difference compared with the 10.00% in the study group ($P>0.05$). **Conclusion:** Shen Shuai Ning capsule combine with hemodialysis has a good therapeutic effect on patients with chronic renal failure, it can improve renal function and stabilize blood rheology. And the safety is better.

Key words: Shen Shuai Ning capsule; Hemodialysis; Chronic renal failure; Renal function; Hemorheology

Chinese Library Classification(CLC): R692.5; R459.5 **Document code:** A

Article ID: 1673-6273(2019)03-523-04

* 基金项目:辽宁省科学技术计划项目(2013225327)

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(收稿日期:2018-05-14 接受日期:2018-06-10)

前言

慢性肾功能衰竭是指各种肾脏疾病导致的肾脏功能衰退、肾脏功能丧失引起的一系列代谢紊乱和临床症状的一组临床综合征,为肾内科常见疾病^[1-3]。作为中、晚期慢性肾功能衰竭患者,若不能进行肾脏移植,那么血液透析以及腹膜透析是维持生命的最佳治疗方法,然而有研究资料表明,患者经过长期的透析治疗以后,生活质量及预后并不十分理想^[4,6]。因此,寻找一种安全有效的治疗药物具有积极的临床意义。近年来,中医药辅助治疗慢性肾功能衰竭已成为临床医师们的关注重点,肾衰宁胶囊是一种纯中药制剂,主要有丹参、大黄、太子参、黄连、牛膝、半夏等,具有活血化瘀、通腑泄浊以及健脾祛湿等功效^[7,8]。因此,本研究通过分析肾衰宁胶囊联合血液透析对慢性肾功能衰竭患者肾功能及血液流变学的影响,旨在为临床工作者们完善治疗方式提供数据支持,现报道如下。

1 资料与方法

1.1 一般资料

选取本溪市中心医院于2015年1月-2017年9月期间收治的慢性肾功能衰竭患者80例为研究对象。纳入标准^①:(1)所有患者均符合《中华内科杂志》中有关慢性肾衰竭相关诊断标准;(2)临床资料完整者;(3)对本研究使用药物无禁忌症者;(4)患者及其家属对本研究知情同意并签署知情同意书。排除标准:(1)既往有手术史者;(2)心、肝、肺等脏器功能障碍者;(3)妊娠哺乳期妇女;(4)依从性差,中途退出者。根据随机数字表法将患者分为对照组(n=40)与研究组(n=40),其中对照组男26例,女14例,年龄20-65岁,平均(43.25±5.49)岁;病程1-9年,平均(5.25±1.47)年;原发病种类:高血压肾小动脉硬化12例,慢性肾小球肾炎11例,慢性肾盂肾炎7例,糖尿病肾病5例,多囊肾5例。研究组男23例,女17例,年龄24-66岁,平均(42.89±6.01)岁;病程2-7年,平均(4.95±1.58)年;原发病种类:高血压肾小动脉硬化10例,慢性肾小球肾炎12例,慢性肾盂肾炎8例,糖尿病肾病6例,多囊肾4例。两组患者各项资料比较差异无统计学意义($P>0.05$)。本研究经医院伦理委员会批准同意。

1.2 治疗方法

所有患者入院后均给予常规治疗,包括积极治疗原发病、控制饮食以及体重、控制血压、纠正水电解质平衡等。在此基础上,两组患者行常规血液透析治疗,透析机、聚砜膜透析器产自德国费森尤斯医药用品有限公司,有效膜面积1.5 m²,透析液流量500 mL/min,血流速度180-240 mL/min,低分子肝素抗凝,4h/次,3次/周,治疗3个月。此外研究组辅以肾衰宁胶囊(云南雷允上理想药业有限公司,国药准字:Z53021547,规格:每粒装0.35 g)口服治疗,4粒/次,1次/d,治疗3个月。

1.3 观察指标及检测方法

1.3.1 临床疗效及不良反应 观察并比较两组患者治疗3个月后的临床疗效及不良反应发生情况,疗效判定标准如下^②:临床症状消失,且血肌酐(serum creatinine, Scr)、血尿素氮(blood urea nitrogen, BUN)浓度降低超过30%以上为显效;临床症状基本缓解,且Scr、BUN浓度降低处于5%-30%之间为有效;临床症状未改善,Scr、BUN浓度降低小于5%为无效。

1.3.2 肾功能 观察并比较两组患者治疗前、治疗3个月后的肾功能指标变化,包括:Scr、BUN、肾小球滤过率(glomerular filtration rate, eGFR),于治疗前、治疗3个月后抽取所有患者清晨空腹静脉血3 mL,3000 r/min离心8 min,取上清液待测,其中Scr、BUN采用日立全自动生化分析仪测定,eGFR采用双血浆法进行测定,所有试剂盒均由雅培科技生物工程有限公司提供,严格按照试剂盒说明书操作进行。

1.3.3 血液流变学 观察并比较两组治疗3个月后的血液流变学指标变化,包括:全血高切黏度、全血低切黏度、血浆黏度、红细胞比容。采用普利生LBY-N7500B型全自动血液流变仪进行检测。

1.4 统计学方法

采用SPSS19.0进行统计分析,计数资料以率(%)表示,进行 χ^2 检验,计量资料以均值±标准差($\bar{x}\pm s$)表示,进行t检验,以 $\alpha=0.05$ 为检验水准。

2 结果

2.1 两组患者治疗3个月后临床疗效比较

研究组患者总有效率为92.50%,高于对照组的67.50%,差异有统计学意义($P<0.05$);详见表1。

表1 两组患者临床疗效比较[n(%)]

Table 1 Comparison of the clinical efficacy between the two groups [n(%)]

Groups	n	Effective	Good	Invalid	Total effective rate
Control group	40	10(25.00)	17(42.50)	13(32.50)	27(67.50)
Study group	40	13(32.50)	24(60.00)	3(7.50)	37(92.50)
χ^2	-				7.813
P	-				0.005

2.2 两组患者治疗前、治疗3个月后肾功能比较

两组患者治疗前Scr、BUN以及eGFR水平比较无统计学差异($P>0.05$);两组患者治疗3个月后Scr、BUN水平较治疗前降低,且研究组低于对照组($P<0.05$);而两组患者治疗3个

月后eGFR水平较治疗前升高,且研究组高于对照组($P<0.05$);详见表2。

2.3 两组患者治疗3个月后血液流变学比较

研究组患者治疗3个月后的全血高切黏度、全血低切黏度、

血浆黏度以及红细胞比容均低于对照组($P<0.05$);详见表3。

表2 两组患者肾功能比较($\bar{x}\pm s$)

Table 2 Comparison of renal function between the two groups ($\bar{x}\pm s$)

Groups	n	Scr(mmoL/L)		BUN(mmoL/L)		eGFR(mL/min)	
		Before treatment	After 3 months of treatment	Before treatment	After 3 months of treatment	Before treatment	After 3 months of treatment
Control group	40	420.98± 41.55	385.56± 51.08*	22.31± 2.25	18.23± 3.04*	23.16± 6.23	26.56± 5.65*
Study group	40	418.61± 43.04	303.53± 44.15*	22.07± 2.12	14.69± 3.57*	24.09± 6.74	34.98± 7.17*
t	-	0.251	7.684	0.480	4.755	0.641	5.834
P	-	0.803	0.000	0.633	0.000	0.524	0.000

Note: compared with before treatment,* $P<0.05$.

2.4 两组患者不良反应发生情况比较

对照组患者出现不良反应有3例,其中1例恶心呕吐,2例腹胀,不良反应发生率为7.50%(3/40),研究组患者出现不良

反应有4例,其中1例恶心呕吐,1例腹胀,2例乏力,不良反应发生率为10.00%(4/40),两组患者不良反应发生情况比较差异无统计学意义($\chi^2=0.157, P=0.692$)。

表3 两组患者血液流变学比较($\bar{x}\pm s$)

Table 3 Comparison of Hemorheology between the two groups ($\bar{x}\pm s$)

Groups	n	Whole blood viscosity(mPa/s)	Whole blood low shear viscosity(mPa/s)	lasma viscosity (mPa/s)	Hematocrit(%)
Control group	40	4.39± 1.28	8.68± 1.26	1.45± 0.27	0.45± 0.06
Study group	40	3.48± 1.32	7.79± 0.97	1.28± 0.14	0.32± 0.03
t	-	3.130	3.540	3.535	12.257
P	-	0.002	0.001	0.001	0.000

3 讨论

慢性肾功能衰竭亦可称为尿毒症,其临床症状主要表现为体内水电解质平衡及酸碱平衡遭到破坏、代谢紊乱等,继而影响机体其他脏器系统正常运作,使机体毒素不能自主排出,滞留体内,对患者的生命健康造成了严重的威胁^[11-13]。由于慢性肾功能衰竭的临床症状主要由体内中分子毒素所致,为此,临床多采用透析治疗的方式^[14-16]。血液透析可将患者体内中分子毒素清除和隔离,净化效果较高,现已被临床广泛应用于慢性肾功能衰竭的治疗中,然而血液透析仅能够清除患者体内毒素,对患者肾功能提高效果不明显,且治疗费用昂贵,给患者及其家庭带来一定的经济负担^[17-19]。现代药理学研究表明^[20],肾衰宁胶囊的组成成分中丹参、红花可通肾络、活血淤,改善肾脏血流供应;大黄则可清热解毒、通腑泄浊,促进肠道排出体内毒素;太子参可提高机体免疫力。

本次研究采用肾衰宁胶囊联合血液透析治疗慢性肾功能衰竭患者,结果发现,研究组患者总有效率高于对照组($P<0.05$)。提示肾衰宁胶囊联合血液透析治疗效果优于单一血液透析治疗,可改善患者临床症状,提高患者预后。且两组患者不良反应发生情况比较差异无统计学意义($P>0.05$)。亦表明使用肾衰宁胶囊联合血液透析治疗可获得较好的治疗效果,且不增加副作用,安全有效。本次结果还表明,两组患者治疗3个月后Scr、BUN水平较治疗前减低,且研究组低于对照组($P<0.05$);而两组患者治疗3个月后eGFR水平较治疗前升高,且研究组高于对照组($P<0.05$)。提示肾衰宁胶囊联合血液透析治疗可显

著降低患者Scr、BUN水平,明显改善和恢复肾功能状况。杨勇等人研究报道^[21],肾衰宁胶囊辅助治疗慢性肾功能衰竭,在临床有效率、BUN、Scr和肌酐清除率(creatinine clearance, Ccr)方面等方面效果均较好,与本次研究结果基本一致。分析原因,一方面是由于血液透析治疗延缓了肾功能衰竭进展,提高了患者生存率,另一方面是由于肾衰宁胶囊的药理作用,其成分均具有改善肾血流量、促进毒素排出、抑制肾小球代偿性肥大和高代谢状态等功能,从而达到改善和保护肾功能的目^[22-24]。另外,本研究结果还表明,研究组患者治疗3个月后的全血高切黏度、全血低切黏度、血浆黏度以及红细胞比容均低于对照组($P<0.05$)。血液流变学异常在慢性肾功能衰竭患者发生、发展中起到重要作用,当全血高切黏度、全血低切黏度、血浆黏度等水平升高时,引发血流速度减慢,血流量减小,致使血小板在血管内堆积,血管壁逐渐增厚,最终导致机体其他脏器微循环供血不足,危及患者生命^[25-27]。而红细胞比容反映红细胞和血浆的比例,是影响血黏度的重要因素之一,本次研究中红细胞比容虽降低,但仍处于正常标准范围^[28,29]。因此,肾衰宁胶囊联合血液透析治疗显著改善患者全血高切黏度、全血低切黏度、血浆黏度以及红细胞比容水平,维持患者正常血液微循环^[30]。

综上所述,肾衰宁胶囊联合血液透析治疗慢性肾功能衰竭患者疗效满意,对于患者的肾功能以及血液流变学均具有改善和保护功能,安全无副作用,适于临床推广应用。

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