

• 论著 •

西那卡塞联合活性维生素D治疗维持性血液透析继发性甲状旁腺功能亢进症的疗效观察

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DOI：10.3969/j.issn.1008-9691.2017.06.021

【摘要】目的 观察西那卡塞联合活性维生素D对维持性血液透析(MHD)继发性甲状旁腺功能亢进症(SHPT)患者临床疗效的影响。**方法** 选择2014年4月至2016年4月在解放军武汉总医院血液净化中心行MHD的86例SHPT患者,按随机数字表法将患者分为观察组和对照组,每组43例。对照组口服盐酸西那卡塞,初始剂量为25 mg/d,最大剂量不得超过75 mg/d;观察组在对照组基础上联合阿法骨化醇冲击疗法,两组均连续用药12周。治疗后比较两组临床疗效和血钙、血磷、钙磷乘积、全段甲状旁腺激素(iPTH)水平以及不良反应发生情况的差异。**结果** 观察组治疗后总有效率明显高于对照组[90.70%(39/43)比74.42%(32/43), $P<0.05$];两组治疗后血钙、钙磷乘积均较治疗前升高[血钙(mmol/L):对照组为 2.24 ± 0.25 比 1.99 ± 0.26 ,观察组为 2.60 ± 0.21 比 2.03 ± 0.24 ;钙磷乘积(mmol^2/L^2):对照组为 4.05 ± 0.34 比 3.79 ± 0.35 ,观察组为 4.25 ± 0.37 比 3.86 ± 0.36],血磷(mmol/L :对照组为 1.69 ± 0.14 比 2.09 ± 0.12 ,观察组为 1.15 ± 0.18 比 2.03 ± 0.16)和iPTH(pg/mL :对照组为 297.36 ± 59.73 比 499.54 ± 69.32 ,观察组为 198.53 ± 57.32 比 492.92 ± 67.54)均较治疗前降低(均 $P<0.05$),且以观察组治疗后的变化较对照组更显著[血钙(mmol/L): 2.60 ± 0.21 比 2.24 ± 0.25 ,血磷(mmol/L): 1.15 ± 0.18 比 1.69 ± 0.14 ,钙磷乘积(mmol^2/L^2): 4.25 ± 0.37 比 4.05 ± 0.34 ,iPTH(ng/mL): 198.53 ± 57.32 比 297.36 ± 59.73 ,均 $P<0.05$]。观察组不良反应发生率明显低于对照组[4.65%(2/43)比20.93%(9/43), $P<0.05$]。**结论** 西那卡塞联合活性维生素D治疗SHPT患者疗效显著,可降低iPTH水平,同时减少不良反应发生。

【关键词】 维持性血液透析;继发性甲状旁腺功能亢进;西那卡塞

An observation of curative effect of cinacalcet combined with activated vitamin D for treatment of patients with secondary hyperparathyroidism undergoing maintenance hemodialysis Zhou Lu, Zhao Wenqi, Ye Ting, Ding Kun, Chen Rengui, Liu Na, Su Dongdong

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【Abstract】Objective To observe the clinical curative effect of cinacalcet combined with activated vitamin D for treatment of patients with secondary hyperparathyroidism (SHPT) undergoing maintenance hemodialysis (MHD). **Methods** Eighty-six patients with SHPT undergoing MHD admitted to the Blood Purification Center of Wuhan General Hospital of Chinese People's Liberation Army from April 2014 to April 2016 were enrolled, and they were divided into an observation group and a control group by random number table, 43 cases in each group. The patients in control group were given cinacalcet whose initial dose was 25 mg/d and maximum dose should not exceed 75 mg/d, and the calcium acetate orally; on the basis of control group, the patients in observation group were additionally given activated vitamin D therapy, and both groups were treated for consecutive 12 weeks. After treatment, the clinical therapeutic effect, serum calcium, serum phosphorus, calcium phosphorus product, intact parathyroid hormone (iPTH) levels and the incidence of adverse reactions were compared between the two groups. **Results** The total effective rate in observation group was higher than that of the control group [90.70% (39/43) vs. 74.42% (32/43), $P < 0.05$]. After treatment, the difference of the serum calcium, calcium phosphorus product were higher than those before treatment in both groups [serum calcium (mmol/L): the control group was 2.24 ± 0.25 vs. 1.99 ± 0.26 , observation group was 2.60 ± 0.21 vs. 2.03 ± 0.24 ; calcium phosphorus product (mmol^2/L^2): the control group was 4.05 ± 0.34 vs. 3.79 ± 0.35 , observation group was 4.25 ± 0.37 vs. 3.86 ± 0.36 , all $P < 0.05$], serum phosphorus, iPTH were lower than those before treatment in both groups [phosphorus (mmol/L): the control group was 1.69 ± 0.14 vs. 2.09 ± 0.12 , observation group was 1.15 ± 0.18 vs. 2.03 ± 0.16 ; iPTH (ng/L): the control group was 297.36 ± 59.73 vs. 499.54 ± 69.32 , observation group was 198.53 ± 57.32 vs. 492.92 ± 67.54 , all $P < 0.05$], the degrees of changes in observation group were more significant than those in control group [serum calcium (mmol/L): 2.60 ± 0.21 vs. 2.24 ± 0.25 , serum phosphorus (mmol/L): 1.15 ± 0.18 vs. 1.69 ± 0.14 , calcium phosphorus product (mmol^2/L^2): 4.25 ± 0.37 vs. 4.05 ± 0.34 , iPTH (ng/L): 198.53 ± 57.32 vs. 297.36 ± 59.73 , all $P < 0.05$]; and the incidence of adverse reactions was significantly lower in observation group than that of the control group [4.65% (2/43) vs. 20.93% (9/43), $P < 0.05$]. **Conclusion** Cinacalcet combined with activated vitamin D for treatment of SHPT patients undergoing maintenance hemodialysis shows obvious curative effect, reduces the whole segment of iPTH, and simultaneously has less adverse reactions.

【Key words】 Maintenance hemodialysis; Secondary hyperparathyroidism; Cinacalcet

继发性甲状旁腺功能亢进症(SHPT)是维持性血液透析(MHD)患者临床常见的严重并发症^[1]。因尿毒症可导致钙磷代谢紊乱,活性维生素D缺乏,表现为低血钙,高血磷继而导致甲状旁腺组织增生,肿瘤形成,分泌大量甲状旁腺激素(PTH),形成SHPT^[2-3]。MHD患者短期死亡的原因主要是心脑血管疾病^[4],而长期血液透析(HD)患者发生SHPT会出现骨纤维化和矿化,血管及软组织钙化,增加患者的心血管病死率和全因病死率^[5]。有研究显示,高PTH是影响MHD患者死亡的独立危险因素^[6]。西那卡塞是一种拟钙剂,可以活化甲状旁腺和其他组织中的细胞外钙敏感受器(CaSR),增加CaSR对细胞外钙离子(Ca²⁺)的敏感性,抑制PTH的分泌和1,25-二羟维生素D₃[1,25(OH)₂D₃]的合成,降低血钙、血磷,有效治疗SHPT^[7]。2004年,美国食品药品监督管理局(FDA)批准将西那卡塞作为治疗SHPT的受体激动药,证实其有利于控制慢性肾脏病患者PTH及血钙、磷水平^[8]。此后,研究已证实西那卡塞具有降低PTH及血钙、磷水平的作用^[9]。本研究观察西那卡塞联合活性维生素D对SHPT临床疗效和不良反应的影响,现将结果报告如下。

1 资料与方法

1.1 研究对象的选择:采用前瞻性研究方法,选取2014年4月至2016年4月在广州军区武汉总医院血液净化中心行MHD的86例SHPT患者。

1.1.1 纳入标准:①MHD合并SHPT,年龄>18岁,透析时间>3个月。②经调节饮食、给予降磷药物,骨化三醇冲击治疗6个月,效果欠佳。③对西那卡塞无禁忌证。

1.1.2 排除标准:①合并心、脑、肝、肺等重要器官原发病。②原发性甲状旁腺亢进症。③对本研究用药过敏。

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,取得患者或家属知情同意。

1.2 研究分组:将患者按随机数字表法分为观察组和对照组,每组43例。两组性别、年龄、HD时间及原发病类型比较差异均无统计学意义(均P>0.05;

表1),说明两组资料均衡,有可比性。

1.3 治疗方法:两组均使用碳酸氢钠标准透析液,HD每周3次,每次4 h,血流量为220~250 mL/min,透析液流量为500 mL/min。药物治疗方面:两组均常规给予低磷饮食,每日餐中咀嚼醋酸钙降磷。对照组口服盐酸西那卡塞,初始剂量为25 mg/d,以后根据患者病情及全段甲状旁腺激素(iPTH)水平酌情调整剂量,每2~4周调整1次,最大剂量不得超过75 mg/d,连续用药12周。

观察组在对照组基础上联合阿法骨化醇冲击疗法,iPTH 300~500 ng/L为每次0.5~1.5 μg,iPTH>500~1 000 ng/L为每次1.5~2.5 μg,iPTH>1 000 ng/L每次2.5~5.0 μg;透析结束后,按上述剂量每周服用2次,根据iPTH水平每2~4周调整1次剂量,连续用药12周后进行疗效评定。

1.4 观察指标:①观察两组患者临床疗效。②治疗前及治疗12周后取血,采用全自动血生化仪检测血钙、磷水平,并计算钙磷乘积;采用放射免疫法测定iPTH水平。③观察两组患者治疗期间不良反应如肌肉疼痛、恶心呕吐、继发性低血钙发生情况。

1.5 疗效判定标准:显效为治疗后患者血清iPTH水平降低≥75%;有效为治疗后血清iPTH水平降低25%~74%;无效为治疗后血清iPTH水平降低<25%或升高。总有效率=(显效+有效)/总例数×100%。

1.6 统计学方法:使用SPSS 17.0统计软件分析数据,符合正态分布的计量资料以均数±标准($\bar{x} \pm s$)表示,组间比较采用t检验;计数资料比较采用χ²检验。P<0.05为差异有统计学意义。

2 结果

2.1 两组临床疗效比较(表2):观察组总有效率明显高于对照组(P<0.05)。

表2 两组临床疗效比较

组别	例数 (例)	临床疗效[例(%)]			总有效率 [% (例)]
		显效	有效	无效	
对照组	43	15(34.88)	17(39.54)	11(25.58)	74.42(32)
观察组	43	20(46.51)	19(44.19)	4(9.30)	90.70(39) ^a

注:与对照组比较,^aP<0.05

表1 对照组和观察组患者一般资料比较

组别	例数 (例)	性别(例)		年龄(岁)		HD时间(月)		原发病(例)			
		男性	女性	范围	$\bar{x} \pm s$	范围	$\bar{x} \pm s$	慢性肾小球肾炎	糖尿病肾病	高血压肾病	其他原因
对照组	43	28	15	31~73	55.1±4.6	11~60	38.7±4.8	30	8	4	1
观察组	43	26	17	30~71	54.4±4.7	11~56	37.8±4.3	29	7	5	2

表3 两组治疗前后实验室指标比较($\bar{x} \pm s$)

组别	时间	例数 (例)	血钙 (mmol/L)	血磷 (mmol/L)	钙磷乘积 (mmol ² /L ²)	iPTH (ng/L)
对照组	治疗前	43	1.99±0.26	2.09±0.12	3.79±0.35	499.54±69.32
	治疗后	43	2.24±0.25 ^a	1.69±0.14 ^a	4.05±0.34 ^a	297.36±59.73 ^a
观察组	治疗前	43	2.03±0.24	2.03±0.16	3.86±0.36	492.92±67.54
	治疗后	43	2.60±0.21 ^{ab}	1.15±0.18 ^{ab}	4.25±0.37 ^{ab}	198.53±57.32 ^{ab}

注:与治疗前比较,^aP<0.05;与对照组比较,^bP<0.05

2.2 两组治疗前后血生化指标水平比较(表3):两组治疗前血钙、血磷、钙磷乘积和iPTH 比较差异均无统计学意义(均 P>0.05),治疗后两组血钙、钙磷乘积均较治疗前明显升高,血磷、iPTH 均较治疗前明显下降,且以观察组治疗后上述指标的变化较对照组更显著(均 P<0.05)。

2.3 两组不良反应比较(表4):观察组不良反应发生率明显低于对照组(P<0.05)。

表4 两组不良反应发生情况比较

组别	例数 (例)	不良反应[例(%)]			总发生率 [% (例)]
		恶心呕吐	肌痛	继发性低钙血症	
对照组	43	3(6.98)	2(4.65)	4(9.30)	20.93(9)
观察组	43	1(2.33)	1(2.33)	0(0)	4.65(2) ^a

注:与对照组比较,^aP<0.05

3 讨 论

近年来有研究表明,PTH 增高可使血压升高,左室质量和心血管及全因病死率增加^[10-11]。目前通过药物如活性维生素D、甲状旁腺切除术及肾移植^[12]均可降低PTH 水平,但同时也增加了肠道对食物中钙磷的吸收能力和发生高血钙和高血磷的风险^[13]。而且甲状旁腺主细胞上的CaSR 随甲状旁腺组织增生程度的增高而下调。拟钙剂是一种模拟钙作用于组织的制剂,通过变构激活人类器官组织中的CaSR 从而增加细胞内钙水平并能减少PTH 的分泌^[14]。

西那卡塞是第一种被美国食品药品管理局批准用于治疗甲状旁腺功能亢进症的钙敏感受体激动剂^[7],也是一种拟钙剂,可作用于甲状旁腺主细胞上的CaSR,提高CaSR 对细胞外钙的敏感性,降低PTH 水平,同时可以抑制甲状旁腺组织的增生,相当于外科“甲状旁腺组织切除术”,也可以调节患者体内矿物质代谢,改善肾病患者骨质^[13]。但西那卡塞模拟细胞外液钙的作用,降低了PTH 水平,从而使钙离子水平下降,极易发生低血钙、恶心呕吐、肌痛^[15]。活性维生素D 可作用于维生素D 受体,对甲状旁腺以及肠道受体都具有亲和力,可抑制PTH

原mRNA 的转录过程,有效降低PTH 水平。活性维生素D 也可提高钙离子受体以及维生素D 受体的敏感性,作用于肠道受体,促进小肠对钙的吸收,使血钙水平增加,从而抑制PTH 的分泌^[16]。本研究结果显示,治疗12周后,观察组总有效率、血钙、钙磷乘积均明显高于对照组,血磷、iPTH 水平及不良反应发生率均低于对照组。这与匡彬^[7]的报道相似。

西那卡塞联合活性维生素D 冲击疗法治疗SHPT,可以调节血钙、血磷、钙磷乘积和矿物质以及骨质代谢,同时降低PTH 水平,抑制甲状旁腺组织的增生,不良反应发生率较单用西那卡塞低,值得在临幊上推广使用。

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(收稿日期: 2017-07-12)

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本刊常用不需要标注中文的缩略语

继发性甲状旁腺功能亢进症

(secondary hyperparathyroidism, SHPT)

腹腔间室综合征 (abdominal compartment syndrome, ACS)

急性呼吸窘迫综合征

(acute respiratory distress syndrome, ARDS)

毛细血管渗漏综合征 (capillary leakage syndrome, CLS)

全身炎症反应综合征

(systematic inflammatory response syndrome, SIRS)

阻塞性呼吸睡眠障碍低通气综合征

(obstructive sleep apnea-hypopnea syndrome, OSAHS)

阿尔茨海默病 (Alzheimer's disease, AD)

多器官功能障碍综合征

(multiple organ dysfunction syndrome, MODS)

心肾综合征 ((cardiorenal syndrome CRS)

呼气末正压 (positive end-expiratory pressure, PEEP)

呼吸机相关性肺炎 (ventilator-associated pneumonia, VAP)

社区获得性肺炎 (community-acquired pneumonia, CAP)

经鼻高流量吸氧 (high-flow nasal cannulae, HFNC)

支气管肺泡灌洗液 (bronchoalveolar lavage fluid, BALF)

敏感度 (sensitivity, SEN)

假阳性率 (false positive rate, FPR)

假阴性率 (false negative rate, FNR)

阳性预测值 (positive predictive value, PPV)

总胆红素 (total bilirubin, TBil)

间接胆红素 (indirect bilirubin, IBil)

长谷川痴呆量表 (Hasegawa dementia scale, HDS)

简易精神状态检查 (mini mental state examination, MMSE)

经颅多普勒 (transcranial Doppler, TCD)

磷酸盐缓冲液 (phosphate-buffered saline, PBS)

经食管心脏超声 (transesophageal echocardiography, TEE)

经胸心脏超声 (transthoracic echocardiography, TTE)

经外周静脉置入中心静脉导管

(peripherally inserted central catheter, PICC)

慢性间歇低氧 (chronic-intermittent hypoxia, CIH)

慢性阻塞性肺疾病

(chronic obstructive pulmonary disease, COPD)

酶联免疫吸附试验

(enzyme-linked immunosorbent assay, ELISA)

改善全球肾脏病预后组织

(Kidney Disease : Improving Global Outcomes, KDIGO)

国际腹膜透析学会

(International Society for Peritoneal Dialysis, ISPD)

美国超声心动图协会

(American Society of Echocardiography, ASE)

美国食品药品监督管理局

(American Food and Drug Administration, FDA)

美国心脏协会 (American Heart Association, AHA)

美国心脏病学会 (American College of Cardiology, ACC)

脑干听觉诱发电位

(brainstem auditory evoked potentials, BAEP)

体感诱发电位 (sensory-evoked potential, SEP)

脑血管造影 (cerebral angiography, CA)

空腹血糖 (fasting blood glucose, FBG)

餐后血糖 (postprandial blood glucose, PBG)

血糖水平的标准差

(standard deviations of daily blood glucose, SDBG)

平均血糖波动幅度

(mean amplitude of glycemic excursions, MAGE)

日间血糖平均绝对差

(mean of glycemic daily differences, MODD)

最大血糖波动幅度

(largest amplitude of glycemic excursions, LAGE)