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坎地沙坦酯治疗老年患者原发性高血压的疗效及安全性分析

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摘要 目的:探讨坎地沙坦酯治疗老年高血压患者的疗效和安全性。**方法:**选取我院 110 例老年原发性高血压患者,随机分为观察组(坎地沙坦酯治疗)和对照组(依那普利治疗),对比分析两组患者药物治疗前、后的动态血压监测及相关指标。**结果:**经两个月治疗后,两组患者坐位收缩压(SBP)及舒张压(DBP)谷值均较基线明显降低,观察组下降幅度明显大于对照组,差异有统计学意义($P<0.05$);观察组的总有效率为 90.91%,明显高于对照组的 76.36%,差异有统计学意义($P<0.05$)。**结论:**坎地沙坦酯治疗老年患者原发性高血压疗效显著,可明显降低收缩压和舒张压,是治疗老年性高血压理想的制剂。

关键词:坎地沙坦酯;依那普利;原发性高血压

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Analysis of Efficacy and Safety of Candesartan Cilexetil in the Treatment of Elderly Hypertensive

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ABSTRACT Objective: To explore the efficacy and safety of candesartan cilexetil in the treatment of elderly hypertensive. **Method:** 110 cases of elderly patients with essential hypertension in our hospital were selected and randomly divided into the observation group (treated with candesartan) and the control group (treated with enalapril), ambulatory blood pressure were monitored and related indicators in the two groups of patients were comparatively analyzed before and after treatment. **Results:** After two months of treatment, the sitting systolic blood pressure (SBP) and diastolic blood pressure (DBP) of the two groups were significantly lower, but decreased significantly in the observation group than in control group, the difference had statistical significance ($P<0.05$); The total effective rate of observation group was 90.91%, significantly higher than that of the control group (76.36%), and the difference had statistical significance($P<0.05$). **Conclusion:** Candesartan cilexetil has significantly curative effect in the treatment of elderly patients with essential hypertension, it can significantly reduce the systolic and diastolic blood pressure, which is an ideal preparation in the treatment of elderly patients with essential hypertension.

Key words: Candesartan cilexetil; Enalapril; Essential hypertension

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前言

坎地沙坦酯作为一种高选择性血管紧张素Ⅱ(AngⅡ)的受体拮抗剂,能够抑制肾素-血管紧张素-醛固酮(RAAS)系统^[1-3]。有研究表明^[4-6],坎地沙坦酯是一种新型血管紧张素Ⅱ(AngⅡ)受体拮抗剂,能够特异性、高效地阻断血管紧张素Ⅱ-I型受体,但不影响血管紧张素转换酶(Angiotensin-converting enzyme,ACE)活性,能明显改善高血压病患者的左室重构;其半衰期长,作用时间持久^[7-9]。为了探讨应用坎地沙坦酯治疗老年高血压患者的临床疗效及安全性,本研究对我院老年原发性高血压患者应用坎地沙坦酯治疗,对比分析治疗前、后动态血压监测及相关指标的变化,现报道如下:

1 资料和方法

1.1 一般资料

选取 2009 年 10 月至 2013 年 10 月我院住院及门诊收治的老年原发性高血压患者 110 例,所有患者均符合 2005 年 WHO/ISH 原发性高血压诊断标准^[10,11],其中男 47 例,女 63 例,年龄 55-77 岁,平均 (62.5 ± 6.4) 岁;病程 5-36 年,平均 (8.5 ± 1.2) 年;Ⅰ级 30 例,Ⅱ级 53 例,Ⅲ级 27 例。随机分为观察组和对照组各 55 例,两组患者一般资料差异无统计学意义($P>0.05$),具有可比性,见表 1。

1.2 方法

入组前先行体检、心电图、实验室检查。所有患者在纳入研究前停用其他降压药物,改为服用安慰剂,一次/d,疗程为 2 周。2 周末收缩压(SBP)及舒张压(DBP)符合原发性高血压诊断。观察组予以坎地沙坦酯(奥必欣,昆明源瑞制药有限公司生产)8 mg,每日口服一次;对照组予以依那普利(勤可息,石家庄制药集团欧意药业有限公司生产)10 mg,每日口服一次,连续 8 周。治疗期间每间隔回访周期为一次/7 d,测量服药前血压、心率,记录不良反应发生情况,异常体格检查、心电图及实验室

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表 1 两组患者一般资料比较

Table 1 Comparison of general data in two groups

组别 Indexes	男 / 女 Male/Female	平均年龄(岁) Average age(years)	平均病程(年) The average course of disease(years)	I 级 Grade I	II 级 Grade II	III 级 Grade III
观察组 Observation group	23/32	61.5± 6.2	8.3± 1.2	16	25	14
对照组 Control group	24/31	62.4± 6.1	8.2± 1.1	14	28	13

检查结果。8 周治疗结束后复查。

1.3 评价指标

① 观察组和对照组于治疗 8 周后检测坐位 DBP 谷值,以及治疗 8 周后坐位 SBP 谷值;② 比较两组的疗效:参考 WHO1980 年疾病疗效评定标准^[12,13]。显效:舒张压虽未达到正常范围,但降低 20 mmHg 以上;有效:舒张压下降不到 10 mmHg,但已达到正常范围;无效:未达到以上标准。

1.4 统计学分析

本次研究所得数据采用 Excel 建立数据库,由录入人员双人录入且进行数据校对,用 SPSS 17.0 统计软件进行统计分析,计量资料组间比较采用方差分析,组内比较用配对 t 检验,计数资料用 χ^2 检验, $P<0.05$ 为差异有统计学显著意义。

2 结果

2.1 治疗前后收缩压(SBP)及舒张压(DBP)基线比较

治疗前,患者心电图、生化检查结果相似,差异无统计学意义 ($P>0.05$);观察组和对组治疗 8 周后末坐位 DBP 谷值、SBP 谷值均比基线明显下降,其中观察组 DBP 下降 15.6 ± 6.4 mm Hg,SBP 下降 15.4 ± 8.3 mm Hg,对照组 DBP 下降 8.5 ± 3.5 mm Hg,SBP 下降 7.4 ± 5.4 mm Hg,两组 DBP 谷值和 SBP 谷值下降幅度比较有显著性差异 ($P<0.05$),坎地沙坦酯降压效果优于依那普利,见表 2。

2.2 疗效分析

观察组治疗 8 周后降压显效率为 63.64%,有效率为 27.27%,无效率为 9.10%,总有效率为 90.91%;对照组显效率为 54.55%,有效率为 21.81%,无效率为 23.64%,总有效率为 76.36%,两组间比较有显著性差异 ($\chi^2=4.523, P<0.05$),见表 3。

表 2 治疗前后 DBP 和 SBP 的比较

Table 2 Comparison of DBP and SBP before and after treatment

指标 Indexes	例数 Cases	DBP(mm Hg)			SBP (mm Hg)		
		治疗前 Before treatment	治疗后 After treatment	Δt	治疗前 Before treatment	治疗后 After treatment	Δt
观察组 Observation group	55	90.38± 3.3	72.4± 4.1	15.6± 6.4(*)	134.2± 10.1	115.7± 4.2	15.4± 8.3(*)
对照组 Control group	55	88.3± 4.1	78.3± 5.8	8.5± 3.5(*)	138.7± 11.3	124.5± 8.7	7.4± 5.4(*)

Note: * $P<0.05$.

表 3 两组治疗效果比较

Table 3 Comparison of treatment effects in two groups

指标 Indexes	例数 Cases	显效 Excellence	有效 valid	无效 Invalid	总有效率(%) Total effective rate(%)
观察组 Observation group	55	35(63.64%)	15(27.27%)	5(9.10%)	90.91*
对照组 Control group	55	30(54.55%)	12(21.81%)	13(23.64%)	76.36

Note: * $P<0.05$.

2.3 安全性分析

110 例患者中头晕、头痛者 3 例,其中观察组 1 例,对照组 2 例;皮肤瘙痒 4 例,观察组 1 例,对照组 3 例,均发作轻微且逐渐缓解。无因不良事件而终止试验者。治疗 8 周末两组患者实验室检查结果和心电图变化无显著差异。

3 讨论

坎地沙坦酯为二苯四咪唑类血管紧张素 II 一型受体(AT1)拮抗药,是一种新型的血管紧张素 II 受体拮抗剂,在体内经肠道吸收,完全水解为去酯坎地沙坦的活性代谢物,后者通过竞

争血管紧张素Ⅱ的特异性受体,产生抗血管效应,引起依赖性的外周血管阻力下降,降低血压^[14-16]。研究表明与其他降压药物不同,坎地沙坦酯有如下特点:降压效果好,优于氯沙坦等;用药比较方便且降压作用和降压效应持续时间较长,比其他的沙坦类药物要长;餐前餐后服用均可且对代谢无影响;不良反应较少。临床试验证明坎地沙坦酯除能明显降低血压外更降低高血压合并左心室肥厚和糖尿病患者的心脑血管事件的发生率^[7]。

本试验对我院老年原发性高血压患者应用坎地沙坦酯治疗,旨在探讨坎地沙坦酯治疗老年高血压患者的疗效和安全性。研究表面表明坎地沙坦酯 8 mg 1 次 /d 口服与依那普利 10 mg 1 次 /d 口服均显著降压, 观察组 DBP 下降 15.6 ± 6.4 mm Hg, SBP 下降 15.4 ± 8.3 mm Hg, 对照组 DBP 下降 8.5 ± 3.5 mm Hg, SBP 下降 7.4 ± 5.4 mm Hg, 两组 DBP 谷值和 SBP 谷值下降幅度比较有显著性差异 ($P < 0.05$), 观察组总有效率为 90.91%, 对照组总有效率为 76.36%, 两组间比较有显著性差异 ($P < 0.05$)。并且观察组和对照组均未见明显不良反应, 观察组不良反应的发生程度和例数均较对照组低。同时研究发现, 进一步发现坎地沙坦酯联合其他药物, 如血管紧张素转化酶(ACE)、钙离子拮抗剂、利尿剂等能产生更加强大的降压效果, 考虑可能是作用于不同的靶点, 产生联合效果, 但其主要的联合机制并不明确^[19,20]。

综上所述, 坎地沙坦酯单独用药能明显的降低老年患者 DBP 和 SBP, 其作用时间长, 效果显著。并且没有明显不良反应的发生, 是目前治疗高血压的理想药物, 值得临床广泛推广。

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