

阿托伐他汀钙联合辛伐他汀治疗混合型高脂血症的临床观察

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摘要 目的: 观察阿托伐他汀钙联合辛伐他汀治疗混合型高脂血症的临床疗效和安全性。方法: 78例混合型高脂血症患者随机均分为对照组和观察组。两组患者均给予常规降糖、降血压治疗, 同时停用其他降脂药物。在此基础上, 对照组患者给予阿托伐他汀钙片 20 mg, 每晚睡前口服, qd; 观察组患者在对照组治疗的基础上给予辛伐他汀片 20 mg, 每晚睡前口服, qd。两组患者疗程均为 8 周。观察两组患者的临床疗效, 血脂达标率, 治疗前后的总胆固醇(TC)、甘油三酯(TG)、低密度脂蛋白胆固醇(LDL-C)、高密度脂蛋白胆固醇(HDL-C)及不良反应发生情况。结果: 治疗后观察组患者总有效率、血脂达标率均显著高于对照组, 差异均有统计学意义($P < 0.05$)。治疗后两组患者 TG、TC、LDL-C 均显著低于同组治疗前, 且观察组低于对照组; HDL-C 显著高于同组治疗前, 且观察组高于对照组($P < 0.05$)。两组患者不良反应发生率比较差异无统计学意义($P > 0.05$)。结论: 阿托伐他汀钙联合辛伐他汀治疗混合型高脂血症较单用阿托伐他汀钙疗效更显著, 安全性相当。

关键词 阿托伐他汀钙; 辛伐他汀; 混合型高脂血症; 疗效; 安全性

Clinical Observation of Simvastatin Combined with Atorvastatin Calcium in the Treatment of Mixed Hyperlipidemia

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ABSTRACT OBJECTIVE: To observe the clinical efficacy and safety of atorvastatin calcium combined with simvastatin in the treatment of mixed hyperlipidemia. METHODS: Totally 78 patients with mixed hyperlipidemia were randomly divided into control group and observation group. Two groups of patients were given routine treatment of hypoglycemic and anti-hypertension and stopping other lipid-lowering drugs. Based on it, patients in control group were given Atorvastatin calcium tablets 20 mg; it was taken at bed-time every night, qd. Patients in observation group were given Simvastatin tablets 20 mg based on the treatment of control group; it was orally taken at bed-time every night, qd. The course of both was 8 weeks. The clinical data was observed, including the clinical efficacy, qualified rate of lipid, TC, TG, LDL-C, HDL-C and adverse reactions (ADR) occurrence before and after treatment. RESULTS: The total effective rate and control rate of lipid in observation group were significantly higher than control group, with significant difference($P < 0.05$). After treatment, the TG, TC and LDL-C in 2 groups were significantly lower than before and observation group was lower than control group; HDL-C was significantly higher than before and observation group was higher than control group($P < 0.05$). There was no significant difference in the incidence of adverse reaction ($P > 0.05$). CONCLUSIONS: Atorvastatin calcium combined with simvastatin have more significant efficacy than only atorvastatin calcium in the treatment of mixed hyperlipidemia. They have similar safety.

KEYWORDS Atorvastatin calcium; Simvastatin; Mixed hyperlipidemia; Efficacy; Safety

混合型高脂血症是一种常见的高脂血症临床类型, 严重威胁患者健康, 危险性极高^[1]。对于血脂代谢异常的患者采取及时、有效的干预及治疗措施, 对改善患者的血脂水平、预防心脑血管疾病等具有非常重要的意义^[2]。他汀类药物能有效治疗低密度脂蛋白(LDL)血症和高胆固醇血症, 但治疗混合型高脂血症的临床疗效并不显著。有研究报道, 辛伐他汀联合其他降脂药物治疗混合型高脂血症, 能够起到一定的协同作用, 可降低给药剂量, 提高临床疗效^[3]。阿托伐他汀在降低血脂及改善血管内皮功能方面具有良好的效果, 可与辛伐他汀联合使用^[4]。为此, 在本研究中笔者观察了阿托伐他汀钙

联合辛伐他汀治疗高脂血症的临床疗效及安全性, 以为临床治疗提供参考。

1 资料与方法

1.1 资料来源

选取 2011 年 10 月—2013 年 10 月于浙江绿城心血管病医院心内科诊治的混合型高脂血症患者 78 例, 其中男性 46 例, 女性 32 例; 年龄 43~72 岁, 平均(48.9±8.2)岁; 合并糖尿病 12 例、冠心病 18 例、高血压 26 例。所有患者均符合高脂血症的诊断标准^[5], 肝、肾功能正常。排除标准: (1)甲状腺功能异常; (2)库欣(Cushing)综合征; (3)严重肝、肾功能异常; (4)神经肌肉病; (5)严重心脑血管疾病; (6)不稳定型心绞痛以及肌钙蛋白异常等; (7)对本研究所用药物过敏。采用随机数字表法将

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所有患者均分为对照组和观察组。对照组男性24例,女性15例;平均年龄(50.2±9.6)岁;合并糖尿病7例、冠心病8例、高血压14例。观察组男性22例,女性17例;平均年龄(47.9±7.9)岁;合并糖尿病5例、冠心病10例、高血压12例。两组患者性别、年龄、合并症等基本资料比较,差异均无统计学意义($P>0.05$),具有可比性。本研究方案经浙江绿城心血管病医院医学伦理委员会批准,所有患者均签署了知情同意书。

1.2 治疗方法

两组患者均给予常规降糖、降血压治疗,同时停用其他降脂药物。在此基础上,对照组患者给予阿托伐他汀钙片(辉瑞制药有限公司,规格:20 mg/片)20 mg,每晚睡前口服,qd;观察组患者在对照组治疗的基础上给予辛伐他汀片(杭州默沙东制药有限公司,规格:20 mg/片)20 mg,每晚睡前口服,qd。两组患者疗程均为8周。

1.3 观察指标

观察两组患者的血脂达标率、治疗前后的总胆固醇(TC)、甘油三酯(TG)、低密度脂蛋白胆固醇(LDL-C)、高密度脂蛋白胆固醇(HDL-C)及不良反应发生情况。血脂达标需同时满足下列标准:无动脉粥样硬化疾病;潜在有冠心病危险因素TC<5.2 mmol/L,LDL-C<3.1 mmol/L,TG<1.7 mmol/L;潜在有动脉粥样硬化疾病危险TC<4.7 mmol/L,LDL-C<2.6 mmol/L,TG<1.7 mmol/L。血脂达标率=血脂达标例数/总例数×100%。

1.4 疗效判定标准

显效:治疗后TC下降>20%,TG下降>40%,HDL-C上升>0.25 mmol/L,LDL-C下降>20%;有效:TC、LDL-C下降10%~20%,TG下降20%~40%,HDL-C上升0.10~0.25 mmol/L;无效:未达上述标准。总有效率=(显效例数+有效例数)/总例数×100%。

1.5 统计学方法

采用SPSS 13.0统计软件对所得数据进行分析。计量资料以 $\bar{x}\pm s$ 表示,采用 t 检验;计数资料以率表示,采用 χ^2 检验。 $P<0.05$ 为差异有统计学意义。

2 结果

2.1 两组患者临床疗效比较

治疗后,观察组患者总有效率显著高于对照组,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[例(%)]

Tab 1 Comparison of clinical efficacy between 2 groups [case(%)]

组别	n	显效	有效	无效	总有效率,%
观察组	39	25(64.10)	13(33.34)	1(2.56)	97.44
对照组	39	16(41.02)	14(35.89)	9(23.09)	76.91

2.2 两组患者血脂达标率比较

治疗后,观察组患者血脂达标率显著高于对照组,差异有统计学意义($P<0.05$),详见表2。

2.3 两组患者治疗前后各血脂指标比较

治疗前,两组患者各血脂指标比较,差异均无统计学意义($P>0.05$)。治疗后,两组患者TG、TC、LDL-C均显著低于同组治疗前,且观察组低于对照组;HDL-C显著高于同组治疗前,且观察组高于对照组,差异均有统计学意义($P<0.05$),详见表3。

2.4 不良反应

两组患者不良反应发生率比较差异无统计学意义($P>0.05$),详见表4。

表2 两组患者血脂达标率比较[例(%)]

Tab 2 Comparison of control rate of lipids between 2 groups[case(%)]

组别	n	血脂达标
观察组	39	15(38.46)
对照组	39	5(12.82)

表3 两组患者治疗前后各血脂指标比较($\bar{x}\pm s$,mmol/L)

Tab 3 Comparison of lipid parameters between 2 groups before and after treatment($\bar{x}\pm s$,mmol/L)

组别	n	时间	TC	TG	HDL-C	LDL-C
对照组	39	治疗前	7.21±0.16	3.56±0.26	0.89±0.01	4.68±0.17
		治疗后	5.49±0.10*	3.19±0.06*	0.92±0.03*	3.24±0.10*
观察组	39	治疗前	7.25±0.17	3.69±0.13	0.86±0.02	4.59±0.14
		治疗后	5.01±0.12**	2.63±0.10**	1.03±0.03**	2.81±0.06**

注:与治疗前比较,* $P<0.05$;与对照组比较,** $P<0.05$

Note: vs. before treatment,* $P<0.05$; vs. control group,** $P<0.05$

表4 两组患者不良反应情况比较[例(%)]

Tab 4 Comparison of ADR between 2 groups[case(%)]

组别	n	肝区不适	肌肉疼痛	胃肠不适	总发生率,%
对照组	39	0	0	1(2.56)	2.56
观察组	39	1(2.56)	1(2.56)	1(2.56)	7.68

3 讨论

随着人们生活水平的提高,高脂血症的发病率也随之升高,已成为一种高度危险的疾病^[6]。他汀类药物是羟甲基戊二酸单酰辅酶A还原酶抑制剂,通过竞争性抑制羟甲基戊二酰辅酶A(HMG-CoA)还原酶,阻断细胞内羟甲戊酸代谢途径,使细胞内胆固醇合成减少。该类药物具有降低血脂的作用,能够治疗不能通过饮食控制的高胆固醇血症^[7]。

阿托伐他汀是他汀类血脂调节药物,该药自身并没有活性,通过口服吸收后,其水解产物在体内可竞争性地抑制胆固醇合成过程中的限速酶HMG-CoA还原酶,进而降低胆固醇的合成,同时增加LDL受体的合成(主要为肝细胞),降低血液中胆固醇的水平及LDL-C水平,还可使血清TG水平适度降低、血清高密度脂蛋白水平适度增加。

辛伐他汀能使体内内源性胆固醇的合成受到抑制,使血浆中LDL水平降低^[8]。临床研究发现,他汀类药物能够有效地治疗LDL血症以及高胆固醇血症,但辛伐他汀治疗混合型高脂血症疗效并不显著^[9]。

本研究结果显示,治疗后观察组患者总有效率、血脂达标率均显著高于对照组,差异均有统计学意义。治疗后两组患者TG、TC、LDL-C均显著低于同组治疗前及对照组,HDL-C显著高于同组治疗前及对照组,差异均有统计学意义。两组患者不良反应发生率比较差异无统计学意义。

综上所述,阿托伐他汀联合辛伐他汀治疗高脂血症较单用阿托伐他汀钙疗效更显著,安全性相当。由于本研究纳入的样本量较小,此结论有待大样本、多中心研究进一步证实。

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舒脑欣滴丸辅助治疗缺血性脑卒中康复患者的临床观察

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摘要 目的:观察舒脑欣滴丸辅助治疗缺血性脑卒中康复患者的临床疗效和安全性。方法:将80例缺血性脑卒中康复患者随机均分为对照组和观察组。对照组患者在康复训练的基础上给予血塞通片3片,口服,每日3次;观察组患者在对照组治疗的基础上加用舒脑欣滴丸4丸,口服,每日3次。两组患者疗程均为1个月。观察两组患者的临床疗效,治疗前后的神经功能缺损评分,侧椎动脉(VA)、基底动脉(BA)、大脑中动脉(MCA)和颈内动脉末段(TCA)收缩峰的血流速度,基质金属蛋白酶9(MMP-9)、转化生长因子 β_1 (TGF- β_1)、细胞间黏附分子1(ICAM-1)蛋白表达及不良反应发生情况。结果:治疗后观察组患者总有效率、TGF- β_1 显著高于对照组,MMP-9、ICAM-1显著低于对照组,差异均有统计学意义($P<0.05$)。治疗前两组患者神经功能缺损评分,VA、BA、MCA、TCA收缩峰的血流速度比较,差异均无统计学意义($P>0.05$)。治疗后两组患者神经功能缺损评分均显著低于同组治疗前,且观察组低于对照组;VA、BA、MCA、TCA收缩峰的血流速度均显著高于同组治疗前,且观察组高于对照组,差异均有统计学意义($P<0.05$)。两组患者治疗期间均未见明显不良反应发生。结论:舒脑欣滴丸辅助治疗缺血性脑卒中疗效显著,可促进缺血性脑卒中患者的康复,且安全性较好。

关键词 舒脑欣滴丸;缺血性脑卒中;康复;疗效;安全性

Clinical Observation of Shunaixin Dropping Pills in the Adjuvant Treatment of Patients with Ischemic Stroke

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ABSTRACT OBJECTIVE: To observe the clinical efficacy and safety of Shunaixin dropping pill (SXDP) in the adjuvant treatment of patients with ischemic stroke. METHODS: A total of 80 rehabilitation patients with ischemic stroke were randomly divided into control group and observation group. Patients in the control group were orally given Xuesaitong tablets 3 pills based on the rehabilitation, 3 times a day; patients in observation group were orally given SXDP 4 pills based on the treatment of control group, 3 times a day. The course of both was 1 month. The clinic data was observed, including efficacy, neurological deficits score, the blood flow velocity of bilateral vertebral artery (VA), basilar artery (BA), middle cerebral artery (MCA) and the last paragraph of the internal carotid artery (TCA) systolic peak, matrix metalloproteinase-9 (MMP-9), transforming growth factor- β_1 (TGF- β_1), intercellular adhesion molecule-1 (ICAM-1) protein expression and adverse reaction (ADR) incidence before and after treatment. RESULTS: After treatment, the total effective rate and TGF- β_1 in observation group were significantly higher than control group, MMP-9 and ICAM-1 were significantly lower than control group, with significant differences ($P<0.05$). There was no significant difference among the neurological deficits score, the blood flow velocity of VA, BA, MCA and TCA in 2 groups before treatment ($P>0.05$). After treatment, the neurological deficits score in 2 groups was significantly lower than before and observation group was lower than control group; the blood flow velocity of VA, BA, MCA and TCA in 2 groups were significantly higher than before and observation group was higher than control group, with significant differences ($P<0.05$). There were no obvious adverse reactions in 2 groups during treatment. CONCLUSIONS: SXDP is effective in the treatment of ischemic stroke. It can promote the recovery of patients with ischemic stroke with good safety.

KEYWORDS Shunaixin dropping pills; Ischemic stroke; Rehabilitation; Efficacy; Safety

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