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马来酸氟伏沙明片联合氨磺必利治疗精神分裂症患者的疗效及安全性分析 *

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摘要 目的:分析马来酸氟伏沙明片联合氨磺必利治疗精神分裂症患者的临床疗效及安全性。**方法:**选择我院 2014 年 2 月~2018 年 2 月收治的 182 例精神分裂症患者,按随机数字表法分为对照组 99 例和研究组 83 例。对照组采用氨磺必利治疗,研究组在对照组基础上联合马来酸氟伏沙明片治疗。比较两组临床疗效,治疗前后血脂代谢、总胆汁酸(TBA)水平,阳性与阴性症状量表(PANSS)评分,生活质量,及不良发生情况。**结果:**治疗后,研究组总有效率为 91.57%,显著高于对照组(P<0.05);两组治疗前后空腹血糖(FPG)、糖化血红蛋白(HbA1c)、甘油三酯(TG)、总胆固醇(TC)、低密度脂蛋白 -C(LDL-C)、高密度脂蛋白 -C(HLD-C)、总胆汁酸(TBA)水平比较均无统计学意义(P>0.05);两组治疗后 PANSS 评分均较治疗前显著下降,生活质量评分较治疗前均明显上升,且研究组 PANSS 评分显著低于对照组,而生活质量评分明显高于对照组,差异均有统计学意义(P<0.05)。治疗过程中,两组均有体重增加、口渴及便秘发生,两组不良反应发生情况比较差异无统计学意义(P>0.05)。**结论:**马来酸氟伏沙明片联合氨磺必利治疗能够提高精神分裂症患者疗效,对机体糖脂代谢及肝功能影响较小,有良好的用药安全性。

关键词:精神分裂症;马来酸氟伏沙明片;氨磺必利;糖脂代谢;总胆汁酸
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Analysis of the Clinical Effect and safety of Fluvoxamine Maleate Tablets Combined with Sulfamethoxalide on the Patients with Schizophrenia*

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ABSTRACT Objective: To analyze the clinical effect and safety of fluvoxamine maleate tablets combined with sulfamethoxalide on the patients with schizophrenia. **Methods:** 182 schizophrenic patients who were treated from February 2014 to February 2018 in our hospital were divided into 99 cases in the control group and 83 cases in the research group according to the random number table method. The control group was treated with sulfamethoxalide, and the research group was treated with fluvoxamine maleate tablets on the basis of control group. Then the clinical efficacy, changes of blood lipid metabolism, level of total bile acid (TBA), positive and negative symptom scale (PANSS) score, quality of life before and after treatment and the incidence of adverse events were compared between two groups. **Results:** After treatment, the total effective rate in the research group was 91.57%, which was significantly higher than that in the control group (P<0.05). The fasting blood glucose (FPG), glycosylated hemoglobin (HbA1c), triglycerides (TG), total cholesterol (TC), low-density lipoprotein C (LDL-c), high-density lipoprotein C (HLD-c), and levels of TBA of both groups showed no statistically significant difference before and after treatment (P>0.05). After treatment, the PANSS scores of both groups were significantly decreased compared with those before treatment, and the quality of life scores were significantly increased compared with those before treatment, The PANSS score in the research group were significantly lower than that in the control group, while the quality of life score was significantly higher than that in the control group(P<0.05). During treatment, the incidence of weight gain, thirst and constipation showed no statistically significant difference between the two groups (P>0.05). **Conclusion:** Fluvoxamine maleate tablets combined with sulfamethoxalide can improve the curative effect of patients with schizophrenia, it had little effect on the glucose and lipid metabolism and liver function with good drug safety.

Key words: Schizophrenia; Fluvoxamine Maleate Tablet; Sulfamethoxalide; Glycolipid Metabolism; Total Bile Acid
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前言

精神分裂症为常见精神病，主要表现为情感、思维等方面障碍，部分患者出现程度不一的社会功能精神活动衰退，病程多迁延、易反复发作，明显影响患者身心健康[1,2]。抗精神病药物是精神分裂症的首选药物，尽管第一代抗精神病药物的效果较好，但其不良反应明显，有一定局限性[3]。氨黄必利为第 2 代抗精神病药物，可阻断相关区域多巴胺能神经元，从而发挥治疗作用，但单一药物治疗难以达到良好效果[4]。

研究表明[5]在抗精神病药物治疗基础上联合小剂量抗抑郁药物能够提高精神分裂症患者疗效。马来酸氟伏沙明片在抑郁症治疗中的疗效已得到临床研究证实，可改善精神分裂症患者焦虑、抑郁及阴性症状[6]。既往已有研究证实马来酸氟伏沙明片、氨磺必利在精神分裂症中的疗效，但多为单一药物治疗，二者联合是否优于单药尚无明确定论[7]。近年来，随着抗精神病药物在临床上的广泛应用，其副反应备受临床关注。Kahn RS 等[8]研究发现奥氮平、利培酮等药物能够增加药物所致的糖脂代谢及肝功能异常的风险。本研究主要探讨了马来酸氟伏沙明片联合氨磺必利对精神分裂症患者的疗效和安全性。

1 资料与方法

1.1 一般资料

本研究纳入 182 例精神分裂症患者，入选标准：符合精神分裂症诊断标准[9](至少含以下 2 项)：① 明显的意志缺乏或者减退；② 愚蠢行为、怪异行为、或者紧张综合征；③ 明显的情感淡漠、或者情感倒错；④ 语词新作、病理性象征思维、思维逻辑倒错；⑤ 妄想心境、妄想知觉或者其它荒谬妄想；⑥ 被洞悉体验护照被动、被控制；⑦ 强制性思维、思维中断、思维被播散、被撤走、被插入；⑧ 明显的思维内容贫乏、言语不连贯、思维破裂、思维松弛；⑨ 反复出现的言语性幻听；阳性与阴性症状量表(PANSS)评分 >60 分；无本研究药物禁忌症。排除标准：继发于情感高涨、智能障碍、意识障碍；心、肝肾等主要脏器明显异常；糖尿病、高血脂症；过敏性体质；酒精及药物依赖史；内分泌代谢明显异常。

按随机数字表法将所有患者分为对照组 99 例和研究组 83 例。对照组中，男 43 例，女 56 例；年龄 20~48 岁，平均(28.09± 8.51)岁；病程 1~4 年，平均(2.59± 0.42)年。研究组中，男 38 例，女 45 例；年龄 18~45 岁，平均(28.63± 7.41)岁；病程 1~4 年，平均(2.73± 0.35)年。两组一般资料比较无统计学差异(P>0.05)，具有可比性。

1.2 治疗方法

对照组采用氨磺必利治疗，氨磺必利(齐鲁制药有限公司，0.2 g/ 片，20130812)初始剂量为 100 mg/d，2 周内根据病情逐渐增加至 300 mg/d，分早晚两次口服，持续治疗 8 周。研究组在对照组基础上联合马来酸氟伏沙明片治疗，口服 50 mg/d 马来酸氟伏沙明片 (丽珠集团丽珠制药厂，50 mg，20130519)，每天 1 次，持续治疗 4 周。于治疗结束时评估疗效，记录治疗期间不良反应的发生情况。

1.3 观察指标

1.3.1 临床疗效 痊愈[9]：治疗后 PANSS 评分降低超过 75%；显效：PANSS 评分降低在 50%~75%；有效：PANSS 评分降低在 25%~50%；无效：PANSS 评分降低 <25%。临床痊愈率 + 显效率 + 有效率为总有效率。

1.3.2 PANSS 评分 PANSS 采用 1~7 级的 8 级评分法，症状条目均按照极严重、重度、偏重、中度、轻度、极轻、无给出 7~1 分的相应分数，总分越高表明病情越重。主要保护阴性症状量表(被动、淡漠、情绪退缩等 7 个症状条目)、阳性症状量表(幻觉、妄想等 7 个症状条目)、一般精神病理量表(自罪感、焦虑、紧张等 16 个症状条目)[9]。

1.3.3 血脂代谢指标 于治疗前及治疗结束时采集患者 4mL 空腹外周静脉血，常规分离患者血清，采用全自动生化分析仪测定空腹血糖(FPG)、糖化血红蛋白(HbA1c)、甘油三酯(TG)、总胆固醇 (TC)、低密度脂蛋白 -C (LDL-C)、高密度脂蛋白 -C (HLD-C)、总胆汁酸(TBA)浓度。

1.3.4 生活质量评分 于治疗前及结束时采用生活质量综合评定问卷(GQOLI-74)[10]评估患者生活质量，保护躯体功能(运动与感觉功能、性功能、进食功能、躯体不适感、睡眠与精力 5 个因子)、心理功能(自尊、认真功能、正性情感、负性情感、精神紧张度 5 个因子)、社会功能(婚姻与家庭、业余娱乐、工作与学习、人际交往能力、社会支持 5 个因子)及物质生活状态(经济状况、生活环境、社区服务、住房 4 个因子)四个项目，分数越高说明生活质量越好。

1.4 统计学分析

数据处理选用 SPSS18.0 软件包，计量资料用($\bar{x}\pm s$)表示，组间比较选用独立样本 t 检验，计数资料用[(例)%]表示，组间比较采用 x^2 检验比较，以 P<0.05 表示差异有统计学意义。

2 结果

2.1 两组临床疗效比较

治疗后，研究组总有效率为 91.57%，显著高于对照组，差异有统计学意义(80.80%，P<0.05)，见表 1。

2.2 两组治疗前后血清糖脂代谢指标变化的比较

治疗前后，两组 FPG、HbA1c、TG、TC、LDL-C、HLD-C 水平比较差异均无统计学意义(P>0.05)，见表 2、3。

2.3 两组治疗前后血清 TBA 水平的比较

治疗前后，两组血清 TBA 水平比较差异均无统计学意义

表 1 两组临床疗效比较[例(%)]

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

Groups	n	Clinical Recovery	Significant Progress	Progress	Ineffective	Total Effective Rate
Control group	99	34(34.34)	23(23.23)	23(23.23)	19(19.19)	80(80.80)
Research group	83	42(50.60)	20(24.10)	14(16.87)	7(8.43)	76(91.57)▲

Note: Compared with the control group, ▲P<0.05.

(P>0.05)，见表 4。

表 2 两组治疗前后 FPG、HbA1c 水平的比较($\bar{x}\pm s$)

Table 2 Comparison of the FPG and HbA1c levels before treatment and after treatment between two groups($\bar{x}\pm s$)

Groups	n	Time	FPG(mmol/L)	HbA1c(%)
Control group	99	Before treatment	5.04± 0.75	5.90± 0.69
		After treatment	4.98± 0.58	6.03± 0.63
Research group	83	Before treatment	5.15± 0.63	5.89± 0.74
		After treatment	4.90± 0.48	5.95± 0.80

表 3 两组治疗前后血脂代谢指标的比较($\bar{x}\pm s$)

Table 3 Comparison of the blood lipid metabolism index before treatment and after treatment between two groups ($\bar{x}\pm s$)

Groups	n	Time	TG(mmol/L)	TC(mmol/L)	LDL-C(mmol/L)	HDL-C(mmol/L)
Control group	99	Before treatment	1.64± 0.28	4.69± 0.75	2.59± 0.49	1.05± 0.15
		After treatment	1.58± 0.26	4.90± 0.71	2.70± 0.41	1.07± 0.11
Research group	83	Before treatment	1.63± 0.23	4.73± 0.86	2.51± 0.34	1.03± 0.16
		After treatment	1.62± 0.24	4.92± 0.60	2.63± 0.45	1.06± 0.13

表 4 两组治疗前后血清 TBA 水平比较($\bar{x}\pm s$)

Table 4 Comparison of the serum level of TBA before treatment and after treatment between two groups ($\bar{x}\pm s$)

Groups	n	Time	TBA(μmol/L)
Control group	99	Before treatment	13.64± 1.40
		After treatment	14.21± 1.83
Research group	83	Before treatment	13.70± 1.97
		After treatment	13.99± 1.56

3 讨论

精神分裂症为严重致残性精神疾病，具有自杀率高、复发率高等特点，正规、及时、有效的抗精神病治疗至关重要[11,12]。精神分裂症的治疗以药物与非药物为主，其中经颅刺激为安全、无侵入性的影响脑部皮质功能活动的物理疗法，但临床关于其对精神分裂症的疗效尚存争议[13,14]。电休克治疗通过适量电流短暂刺激大脑，导致患者意识丧失，脑部广泛性放电及全身抽搐，起到减轻精神症状的作用，但其可能有一定的麻醉、窒息风险，及治疗后短暂记忆改变等不足[15]。多数精神分裂症患者脑部伴程度不一的神经递质改变，并引起相应的精神症状，抗精神病药物能够调节神经递质表达，从而控制症状，加上药物种类较多，可提供系统、个体化的治疗[16]。因此，药物治疗仍是目前精神分裂症的首选，传统经典抗精神病药物通过阻断多巴胺受体纠正阳性症状，但对阴性症状的效果较不理想，加上其存在椎体外系副反应，明显影响疗效[17,18]。

氨磺必利是非经典类抗精神病药物，对多巴胺 D2、D3 受体均有选择性拮抗作用，在发挥治疗作用的同时椎体外系不良反应风险较低[19]。低剂量优先阻断突触前 D3/D2 受体，中断负反馈机制，促进边缘系统及前额叶皮质中的多巴胺，纠正精神分裂症患者阴性症状[20,21]。高剂量可选择性阻断边缘系统中部突触后多巴胺受体，减少多巴胺结合位点，改善阳性症状[22]。氨磺必利和毒蕈碱 M 受体、组胺 H1 受体等其他非多巴胺受体的亲和力较低，因此不容易引起便秘、嗜睡等不良反应[23]。但有研究报道[24]氨磺必利对部分精神分裂症患者的疗效不甚理想，需联合其他药物治疗。

国外研究显示[25]精神分裂症患者后期多伴程度不一的焦虑、抑郁及强迫症状，并提出安全的联合用药不仅有利于以上症状的控制，且可降低单一大剂量抗精神病药物所致的副反应。马来酸氟伏沙明片主要是作用于脑神经细胞的 5-HT 再摄取抑制剂，对非肾上腺素过程的影响较小，对 5-HT、多巴胺能受体、组胺等几乎无亲和力，安全性较高[26]。其经口服后可快速吸收，主要经肝脏代谢，和机体血浆蛋白结合率高。本研究结果显示，马来酸氟伏沙明片联合氨磺必利组总有效率显著高于氨磺必利组，说明二者联合治疗更有利于疾病的控制，可能与其能够起到相互作用，从而发挥不同的药物机制有关。

尽管马来酸氟伏沙明片联合氨磺必利在精神分裂症上有明显优势，但此类疾病是长期治疗，药物选择需综合考虑个体耐受性、副反应等方面[27]。既往研究显示[28]非经典抗精神病药物更容易引起血脂、血糖紊乱，增加糖尿病、心血管系统疾病危险性，可能与其能够通过拮抗 5-HT 受体影响胰岛素分泌有关。Chen CH 等[29]研究认为抗精神病药物能够促进胰岛素释放及分泌，增加血脂浓度。本研究结果显示马来酸氟伏沙明片及氨磺必利治疗前后血糖、血脂均无明显改变，说明二者对患者糖

脂代谢的影响较小，但此结论需要在以后的研究中进一步分析。血清 TBA 水平能够直观反映肝胆系统状态，肝脏细胞受损时可引起 TNA 代谢障碍，增加 TBA 水平，测定其水平对患者肝脏病情及预后评估有重要价值[30]。肝脏为机体重要的代谢脏器，是蛋白质、糖类合成代谢的主要场所，药物治疗可能增加肝脏负担，影响 TBA 水平[31]。本研究结果显示马来酸氟伏沙明片及氨磺必利治疗均未明显增加肝脏负担，不影响 TBA 水平。PANSS 评分能够直观反映精神分裂症患者病情程度，本研究结果显示马来酸氟伏沙明片及氨磺必利治疗后 PANSS 评分下降更明显，进一步证实其疗效。生活质量是评估精神分裂症患者转归的重要指标，可客观评估患者生理、心理、社会功能等状态。治疗后，马来酸氟伏沙明片联合氨磺必利组生活质量评分相对较高，提示二者联合更能有效改善患者生活质量，且联合治疗组未明显增加药物不良反应，安全性较高。

综上所述，马来酸氟伏沙明片联合氨磺必利治疗能够提高精神分裂症患者疗效，对机体糖脂代谢及肝功能影响较小，有良好的用药安全性。

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