

左乙拉西坦或奥卡西平单药治疗局灶性癫痫临床研究

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【摘要】 目的 对比左乙拉西坦与奥卡西平单药治疗局灶性癫痫的临床疗效及安全性。方法 选择 2020 年 10 月至 2022 年 10 月福建省立医院诊断与治疗的 476 例局灶性癫痫患者,分为左乙拉西坦组 (275 例) 和奥卡西平组 (201 例),均持续治疗 12 个月,分析两组及不同亚组的总有效率和不良反应发生率。结果 左乙拉西坦组总有效率为 57.82% (159/275),奥卡西平组总有效率为 46.77% (94/201),左乙拉西坦组高于奥卡西平组 ($\chi^2 = 5.696, P = 0.017$)。不同年龄的局灶性癫痫患者左乙拉西坦总有效率差异有统计学意义 ($\chi^2 = 6.785, P = 0.034$),其中,青年患者总有效率高于未成年患者 ($\chi^2 = 3.898, P = 0.048$) 和中老年患者 ($\chi^2 = 4.946, P = 0.026$)。发病后首次影像学正常的局灶性癫痫患者左乙拉西坦总有效率 ($\chi^2 = 5.349, P = 0.021$) 和奥卡西平总有效率 ($\chi^2 = 10.036, P = 0.002$) 均高于影像学异常患者。同一亚组不同药物疗效分析:对于青年局灶性癫痫患者,左乙拉西坦总有效率高于奥卡西平 ($\chi^2 = 6.591, P = 0.010$)。左乙拉西坦组有 13 例 (4.73%) 出现不良反应,奥卡西平组有 19 例 (9.45%) 出现不良反应,奥卡西平组高于左乙拉西坦组 ($\chi^2 = 4.135, P = 0.042$)。结论 与奥卡西平单药治疗相比,左乙拉西坦单药治疗局灶性癫痫的临床疗效较好,且对于青年患者疗效更佳,不良反应发生率较低;发病后首次影像学正常的局灶性癫痫患者两种药物疗效均优于影像学异常患者。

【关键词】 癫痫,部分性; 左乙拉西坦; 奥卡西平; 药物相关性副作用和不良反应

Clinical study of levetiracetam or oxcarbazepine monotherapy in the treatment of focal epilepsy

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【Abstract】 **Objective** To compare the clinical efficacy and safety of levetiracetam and oxcarbazepine in the treatment of focal epilepsy. **Methods** A total of 476 patients with focal epilepsy treated at Fujian Provincial Hospital from October 2020 to October 2022 were selected. Based on their medication, they were divided into the levetiracetam group (n = 275) and the oxcarbazepine group (n = 201). Both groups underwent continuous treatment for 12 months. The overall effective rate and incidence of adverse reactions in both groups and different subgroups were analyzed. **Results** The overall effective rate in the levetiracetam group was 57.82% (159/275), and in the oxcarbazepine group was 46.77% (94/201).

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The overall effective rate in the levetiracetam group was higher than that in the oxcarbazepine group ($\chi^2 = 5.696, P = 0.017$). Efficacy analysis of levetiracetam monotherapy across different age subgroups showed statistically significant differences ($\chi^2 = 6.785, P = 0.034$), with the overall effective rate in younger patients being higher than that in minors ($\chi^2 = 3.898, P = 0.048$) and middle-aged/older patients ($\chi^2 = 4.946, P = 0.026$). Levetiracetam was more effective in patients with initially normal imaging compared to those with abnormal imaging ($\chi^2 = 5.349, P = 0.021$). In the oxcarbazepine monotherapy subgroup analysis, oxcarbazepine was also more effective in patients with initially normal imaging ($\chi^2 = 10.036, P = 0.002$). Efficacy analysis of the same subgroup with different medications indicated that for younger patients with focal epilepsy, levetiracetam was superior to oxcarbazepine ($\chi^2 = 6.591, P = 0.010$). In the levetiracetam group, 13 cases (4.73%) experienced adverse reactions, while the oxcarbazepine group had 19 cases (9.45%). The incidence of adverse reactions in the oxcarbazepine group was higher than that in the levetiracetam group ($\chi^2 = 4.135, P = 0.042$). **Conclusions** Compared to oxcarbazepine monotherapy, levetiracetam monotherapy demonstrated better clinical efficacy in treating focal epilepsy, particularly in younger patients. The incidence of adverse reactions in levetiracetam was lower. Both medications were more effective in patients with initially normal imaging compared to those with abnormal imaging.

【Key words】 Epilepsies, partial; Levetiracetam; Oxcarbazepine; Drug-related side effects and adverse reactions

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癫痫是全球排名第 4 位的神经系统疾病, 病例数 > 7000 万例^[1]。国际抗癫痫联盟(ILAE)将癫痫分为局灶性、全面性、未知起源三大类^[2-3], 其中局灶性癫痫是最常见类型, 局部神经元突发性异常放电导致短暂性神经功能障碍。癫痫患者病死率是正常人群的 2~5 倍, 猝死风险至少是健康人群的 20 倍以上^[4]。抗癫痫发作药物(ASM)治疗的主要目标是在不诱发不良反应的前提下实现完全无发作, 降低发病率和病死率, 并改善生活质量^[5]。新型抗癫痫发作药物中左乙拉西坦和奥卡西平常用于治疗局灶性癫痫^[6-7], 但对特定亚组相关疗效及安全性的临床指导仍不充分, 有待进一步探究。基于此, 本研究对比左乙拉西坦与奥卡西平单药治疗局灶性癫痫的临床疗效及安全性, 并根据患者个体特点进行亚组分析, 以为临床用药提供更具体的指导。

资料与方法

一、临床资料

1. 纳入标准 (1)局灶性癫痫的诊断符合《国际抗癫痫联盟对癫痫发作类型的操作性分类: 国际抗癫痫联盟分类与术语委员会的立场文件》^[2]中对局灶性癫痫的诊断定义及分类标准。(2)规律服用左乙拉西坦或奥卡西平, 且既往 6 个月内未服用其他抗癫痫发作药物。(3)年龄 > 4 岁。(4)所有患者及其家属均知情并同意临床资料用于科研。(5)本研究

经福建省立医院伦理委员会审核批准(审准号: K2021-04-047)。

2. 排除标准 (1)有假性癫痫发作史或表现。(2)无法准确记录发作信息。(3)依从性差, 临床资料不完整或失访。

3. 一般资料 选择 2020 年 10 月至 2022 年 10 月在福建省立医院神经内科门诊或住院治疗的局灶性癫痫患者共 476 例, 男性 273 例, 女性 203 例; 年龄 5~80 岁, 中位年龄 22(14, 31)岁, 未成年(<18 岁) 160 例(33.61%)、青年(18~44 岁) 258 例(54.20%)、中老年(≥ 45 岁) 58 例(12.18%); 病程 0~75 年, 中位病程 3(1, 8)年; 143 例(30.04%)发病后首次影像学异常。根据患者用药情况进行分组, 左乙拉西坦单药治疗者为左乙拉西坦组(275 例), 奥卡西平单药治疗者为奥卡西平组(201 例)。奥卡西平组发病后首次影像学异常占比较高($P = 0.000$), 性别、年龄、病程等一般资料组间差异无统计学意义(均 $P > 0.05$, 表 1)。

二、研究方法

1. 药物治疗方案 左乙拉西坦组患者服用左乙拉西坦(规格: 0.50 g/片, 比利时 UCB 公司), 起始剂量为 0.50 g/次、2 次/d, 根据患者治疗情况及耐受情况, 每 2 周增加或减少药物剂量(一般增量为 250 或 500 mg/次, 2 次/d), 最大剂量 ≤ 3 g/d。奥卡西平组患者服用奥卡西平片(规格: 300 mg/片, 意大利

表 1 左乙拉西坦组与奥卡西平组患者一般资料的比较

Table 1. Comparison of general information between the levetiracetam group and the oxcarbazepine group

| 组别 | 例数 | 性别[例(%)] | | 年龄[例(%)] | | | 病程 [$M(P_{25}, P_{75})$, 年] | 影像学异常 [例(%)] |
|--------------|-----|------------|------------|------------|------------|-----------|----------------------------------|-----------------|
| | | 男性 | 女性 | 未成年 | 青年 | 中老年 | | |
| 左乙拉西坦组 | 275 | 162(58.91) | 113(41.09) | 103(37.45) | 140(50.91) | 32(11.64) | 3.00(1.00, 8.00) | 64(23.27) |
| 奥卡西平组 | 201 | 111(55.22) | 90(44.78) | 57(28.36) | 118(58.71) | 26(12.94) | 4.00(1.00, 9.00) | 79(39.30) |
| χ^2 或Z值 | | 0.645 | | 4.322 | | | -1.285 | 14.199 |
| P值 | | 0.422 | | 0.119 | | | 0.199 | 0.000 |

χ^2 test for comparison of sex, age, imaging abnormalities, and Mann-Whitney *U* test for comparison of duration, 性别、年龄、影像学异常的比较采用 χ^2 检验,病程的比较采用Mann-Whitney *U*检验

Novartis 公司),起始剂量为 300 mg/次、2 次/d,根据患者治疗及耐受情况,每周增加或减少药物剂量(每周增量 ≤ 600 mg),最大剂量 ≤ 2400 mg/d。两组均持续治疗 12 个月。

2. 疗效及安全性评价 每 3~6 个月随访一次,连续随访 12 个月。按照性别、年龄及发病后首次影像学表现进行亚组分析,观察各亚组疗效和不良反应。(1)疗效评价:完全控制,治疗后无发作;显著有效,治疗后发作频率明显减少,较治疗前下降 $> 50\%$;可能有效,治疗后发作频率有所减少,较治疗前下降 25%~50%;无效,治疗后发作频率减少 $< 25\%$,甚至发作频率增加。计算总有效率[总有效率(%)=(完全控制例数+显著有效例数)/总例数 $\times 100\%$]。(2)安全性评价:关注的不良反应主要包括中枢神经系统反应,如嗜睡、头晕、头痛、认知功能障碍等;过敏反应,如皮疹、瘙痒、呼吸困难等;血液系统反应,如白细胞计数减少、贫血等;肝功能损害,如肝酶谱升高等;消化系统反应,如恶心、呕吐、腹泻、食欲下降等。上述不良反应依据随访时患者描述的服药后新发症状、实验室检查结果及病史作出诊断。

3. 统计分析方法 采用 SPSS 27.0 统计软件进行数据处理与统计分析。计数资料以相对数构成比(%)或率(%)表示,采用 χ^2 检验。正态性检验采用 Shapiro-Wilk 检验。呈非正态分布的计量资料以中位数和四分位数间距[$M(P_{25}, P_{75})$]表示,采用 Mann-Whitney *U* 检验。以 $P \leq 0.05$ 为差异具有统计学意义。

结 果

两组疗效分析:左乙拉西坦组患者治疗后完全控制 56 例(20.36%)、显著有效 103 例(37.45%)、可

能有效 35 例(12.73%)、无效 81 例(29.45%),总有效率为 57.82%(159/275);奥卡西平组患者治疗后完全控制 42 例(20.90%)、显著有效 52 例(25.87%)、可能有效 39 例(19.40%)、无效 68 例(33.83%),总有效率为 46.77%(94/201);左乙拉西坦组总有效率高于奥卡西平组且差异有统计学意义($\chi^2 = 5.696, P = 0.017$)。

左乙拉西坦单药治疗不同亚组疗效分析:对于男性(56.17%, 91/162)和女性(60.18%, 68/113)局灶性癫痫患者,左乙拉西坦单药治疗的总有效率差异无统计学意义($P = 0.508$);对于不同年龄的局灶性癫痫患者,左乙拉西坦单药治疗未成年患者的总有效率为 52.43%(54/103),青年患者为 65%(91/140),中老年患者为 43.75%(14/32),差异有统计学意义($P = 0.034$),其中青年患者总有效率分别高于未成年患者($\chi^2 = 3.898, P = 0.048$)和中老年患者($\chi^2 = 4.946, P = 0.026$);发病后首次影像学正常的局灶性癫痫患者(61.61%, 130/211)左乙拉西坦单药治疗的总有效率高于影像学异常患者(45.31%, 29/64)且差异有统计学意义($P = 0.021$,表 2)。

奥卡西平单药治疗不同亚组疗效分析:对于男性(46.85%, 52/111)和女性(46.67%, 42/90)局灶性癫痫患者,奥卡西平单药治疗的总有效率差异无统计学意义($P = 0.980$);对于不同年龄的局灶性癫痫患者,奥卡西平单药治疗未成年患者的总有效率为 43.86%(25/57),青年患者为 49.15%(58/118),中老年患者为 42.31%(11/26),差异无统计学意义($P = 0.715$);发病后首次影像学正常的局灶性癫痫患者(55.74%, 68/122)奥卡西平单药治疗的总有效率高于影像学异常患者(32.91%, 26/79)且差异有统计学意义($P = 0.002$,表 3)。

同一亚组不同药物疗效分析:对于男性局灶性

表 2 左乙拉西坦单药治疗不同亚组总有效率的比较 [例(%)]**Table 2.** Comparison of overall effective rate of different subgroups of levetiracetam [case (%)]

| 亚组 | 例数 | 总有效率 | χ^2 值 | P值 |
|-------|-----|------------|------------|-------|
| 性别 | | | 0.438 | 0.508 |
| 男性 | 162 | 91(56.17) | | |
| 女性 | 113 | 68(60.18) | | |
| 年龄 | | | 6.785 | 0.034 |
| 未成年 | 103 | 54(52.43) | | |
| 青年 | 140 | 91(65.00) | | |
| 中老年 | 32 | 14(43.75) | | |
| 影像学表现 | | | 5.349 | 0.021 |
| 正常 | 211 | 130(61.61) | | |
| 异常 | 64 | 29(45.31) | | |

表 3 奥卡西平单药治疗不同亚组总有效率的比较 [例(%)]**Table 3.** Comparison of overall effective rate of different subgroups of oxcarbazepine [case (%)]

| 亚组 | 例数 | 总有效率 | χ^2 值 | P值 |
|-------|-----|-----------|------------|-------|
| 性别 | | | 0.001 | 0.980 |
| 男性 | 111 | 52(46.85) | | |
| 女性 | 90 | 42(46.67) | | |
| 年龄 | | | 0.671 | 0.715 |
| 未成年 | 57 | 25(43.86) | | |
| 青年 | 118 | 58(49.15) | | |
| 中老年 | 26 | 11(42.31) | | |
| 影像学表现 | | | 10.036 | 0.002 |
| 正常 | 122 | 68(55.74) | | |
| 异常 | 79 | 26(32.91) | | |

表 4 同一亚组不同用药总有效率的比较 [例(%)]**Table 4.** Comparison of overall effective rate of different medications in the same subgroup [case (%)]

| 亚组 | 左乙拉西坦 | | 奥卡西平 | | χ^2 值 | P值 |
|-------|-------|------------|------|-----------|------------|-------|
| | 例数 | 总有效率 | 例数 | 总有效率 | | |
| 男性 | 162 | 91(56.17) | 111 | 52(46.85) | 2.297 | 0.130 |
| 女性 | 113 | 68(60.18) | 90 | 42(46.67) | 3.684 | 0.055 |
| 未成年 | 103 | 54(52.43) | 57 | 25(43.86) | 1.078 | 0.299 |
| 青年 | 140 | 91(65.00) | 118 | 58(49.15) | 6.591 | 0.010 |
| 中老年 | 32 | 14(43.75) | 26 | 11(42.31) | 0.012 | 0.912 |
| 影像学正常 | 211 | 130(61.61) | 122 | 68(55.74) | 1.106 | 0.293 |
| 影像学异常 | 64 | 29(45.31) | 79 | 26(32.91) | 2.297 | 0.130 |

癫痫患者,左乙拉西坦与奥卡西平总有效率分别为 56.17%(91/162)和 46.85%(52/111),差异无统计学意义($P=0.130$);对于女性局灶性癫痫患者,左乙拉西坦与奥卡西平总有效率分别为 60.18%(68/113)和 46.67%(42/90),差异无统计学意义($P=0.055$,表 4)。对于青年局灶性癫痫患者,左乙拉西坦的总有效率(65%, 91/140)高于奥卡西平(49.15%, 58/118),差异具有统计学意义($P=0.010$),但对于未成年、中老年局灶性癫痫患者,两种药物疗效差异无统计学意义($P=0.299, 0.912$;表 4)。对于发病后首次影像学正常的局灶性癫痫患者,左乙拉西坦与奥卡西平的总有效率分别为 61.61%(130/211)和 55.74%(68/122),差异无统计学意义($P=0.293$);对于发病后首次影像学异常的局灶性癫痫患者,左乙拉西坦与奥卡西平的总有效率分别为 45.31%(29/64)和 32.91%(26/79),差异亦无统计学意义($P=0.130$,表 4)。

两组安全性分析:左乙拉西坦组 275 例中 13 例(4.73%)出现不良反应,包括食欲下降 3 例、记忆力下降 3 例、嗜睡 2 例、头晕 2 例、头痛 1 例、腹泻 1 例、皮疹 1 例;奥卡西平组 201 例患者中 19 例(9.45%)出现不良反应,包括疲乏 6 例、头晕 4 例、嗜睡 3 例、恶心 3 例、记忆力下降 1 例、皮肤瘙痒 1 例、皮疹 1 例;奥卡西平组不良反应发生率高于左乙拉西坦组且差异有统计学意义($\chi^2=4.135, P=0.042$)。

讨 论

癫痫是一种常见的由多种病因导致的慢性神经系统疾病,反复癫痫发作严重影响患者认知功能和生活质量^[8-9],除癫痫自身外,治疗不恰当也影响癫痫患者预后和生活质量^[10]。局灶性癫痫是最常见的癫痫类型^[11],选择合适、安全且疗效好的药物至关重要。左乙拉西坦及奥卡西平均为广泛应用于临床一线的新型抗癫痫发作药物^[12-13],左乙拉西

坦是一种广谱抗癫痫发作药物,与中枢神经系统突触囊泡蛋白 2A(SV2A)相结合,阻止神经递质释放,对局灶性和全面性癫痫疗效和耐受性良好^[14-15]。奥卡西平可阻断脑组织电压门控性钠离子通道(VGSC),降低神经元兴奋性,对局灶性癫痫有良好疗效^[16]。评估二者对于局灶性癫痫的疗效及不良反应,对于指导临床用药的选择有重大意义。

既往关于左乙拉西坦与奥卡西平对癫痫治疗效果的研究结论不一。有研究认为,左乙拉西坦与奥卡西平对癫痫的疗效相当^[17-19];也有研究认为,对于成年局灶性癫痫患者,奥卡西平单药治疗较左乙拉西坦单药治疗更有效^[20];而一项观察性研究发现,局灶性癫痫患者于左乙拉西坦单药治疗 3 年后无发作率高于奥卡西平^[21];也有研究指出,服用左乙拉西坦的癫痫患者无发作率随着时间的推移而增加,并认为对于局灶性癫痫的长期治疗,左乙拉西坦较奥卡西平更有效^[22-23]。本研究结果显示,左乙拉西坦单药治疗对于局灶性癫痫患者的总有效率高于奥卡西平,表明两种药物在疗效上存在差异,左乙拉西坦疗效更佳。同时,本研究还针对性别、年龄和发病后首次影像学表现的药物疗效进行亚组分析:对于不同性别的局灶性癫痫患者,左乙拉西坦与奥卡西平疗效无明显差异;对于不同年龄的局灶性癫痫患者,奥卡西平疗效并无明显差异,而左乙拉西坦对于青年患者疗效较未成年和中老年患者更佳,且在此类人群中,左乙拉西坦疗效较奥卡西平更佳;左乙拉西坦与奥卡西平对于发病后首次影像学正常的局灶性癫痫患者疗效均优于异常患者。

此外,本研究还发现,左乙拉西坦与奥卡西平的大多数不良反应轻微且短暂,与既往研究结果相一致^[24-25]。既往有研究显示,左乙拉西坦单药治疗的疗效和安全性更佳,奥卡西平因不良反应发生率较高,较左乙拉西坦有更高的治疗失败率^[21,26]。本研究结果显示,奥卡西平组患者不良反应发生率高于左乙拉西坦组,主要表现为疲乏、头晕、嗜睡、恶心、记忆力下降、皮肤瘙痒、皮疹等;左乙拉西坦不良反应发生率较低,主要包括食欲下降、记忆力下降、嗜睡、头晕、头痛、腹泻、皮疹等。

综上所述,对于局灶性癫痫患者,与奥卡西平单药治疗相比,左乙拉西坦单药治疗的临床疗效更佳,且对于青年患者疗效更佳;不良反应发生率较低;发病后首次影像学正常患者两药疗效均优于影

像学异常患者。在临床用药中,应结合患者疾病特点以及耐受性,合理选择药物。本研究尚存创新性不足、样本量较小、纳入患者仅限本院等局限性,尚待开发新的药物疗效评价指标,进行大样本量、多中心临床研究进一步验证。

利益冲突 无

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· 小词典 ·

中英文对照名词词汇(三)

- 生长激素 growth hormone(GH)
- 生殖细胞肿瘤 germ cell tumors(GCT)
- 嗜酸性肉芽肿 eosinophilic granuloma(EG)
- 体感诱发电位 somatosensory-evoked potential(SEP)
- 体重指数 body mass index(BMI)
- 调强放射治疗 intensity modulated radiation therapy(IMRT)
- 突触囊泡蛋白 2A synaptic vesicle protein 2A(SV2A)
- 完全缓解 complete response(CR)
- 微血管减压术 microvascular decompression(MVD)
- 无进展生存期 progression free survival(PFS)
- 纤维肌发育不良 fibromuscular dysplasia(FMD)
- 线粒体脑肌病伴高乳酸血症和卒中样发作
mitochondrial encephalomyopathy with lactic acidemia and
stroke-like episodes(MELAS)
- 小脑后下动脉 posterior inferior cerebellar artery(PICA)
- 小脑前下动脉 anterior inferior cerebellar artery(AICA)
- 小脑上动脉 superior cerebellar artery(SCA)
- 心因性非癫痫性发作
psychogenic non-epileptic seizures(PNES)
- 牙釉质细胞瘤型颅咽管瘤
adamantinomatous craniopharyngioma(ACP)
- 异己手综合征 alien hand syndrome(AHS)
- 影像归档和通信系统
picture archiving and communication system(PACS)
- 远端运动潜伏期 distal motor latency(DML)
- 运动单位动作电位 motor unit action potential(MUAP)
- 运动后易化 post-exercise facilitation(PEF)
- 运动神经传导速度 motor nerve conduction velocity(MNCV)
- 运动诱发电位 motor-evoked potential(MEP)
- Zarit照顾者负担量表 Zarit Burden Interview(ZBI)
- 中国抗癌协会 China Anti-Cancer Association(CACA)
- 注意力缺陷多动障碍
attention deficit hyperactivity disorder(ADHD)
- 椎动脉 vertebral artery(VA)
- 自体骨髓浓缩物 autologous bone marrow concentrate(BMC)
- 总生存期 overall survival(OS)
- 阻塞性睡眠呼吸暂停 obstructive sleep apnea(OA)
- 最大用力收缩 maximal exertional contraction(MEC)