



硫辛酸在缺血性心衰患者中的应用效果：一项随机、双盲、安慰剂对照研究

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· 会议摘要 ·

硫辛酸在缺血性心衰患者中的应用效果： 一项随机、双盲、安慰剂对照研究



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[摘要] **目的** 探讨硫辛酸药物补充治疗策略在缺血性心衰患者中的安全性和有效性。**方法** 本研究采用随机、双盲、安慰剂对照的研究设计(ClinicalTrials.gov 注册号 NCT03491969)。2019年1月至2023年1月在中国4家医疗中心入组300例缺血性心衰患者,以1:1的比例随机分配至硫辛酸补充治疗组和安慰剂对照组(给药剂量为600 mg/d)。主要终点是全因死亡或因心衰再住院的复合终点。次要终点是非致死性心肌梗死、非致死性脑卒中,以及随机化后24个月相较于基线的左心室射血分数和6分钟步行距离的变化值。**结果** 共277例患者纳入主要分析(硫辛酸组138例、安慰剂组139例)。硫辛酸组和安慰剂组分别有32例(23.2%)和40例(28.8%)患者发生主要终点事件。与安慰剂组相比,硫辛酸组缺血性心衰患者发生全因死亡或因心衰再住院复合事件的风险有降低趋势($HR=0.753$, 95%CI 0.473~1.198, $P=0.231$; 图1A~1C),绝对风险降低值为5.6%,相对风险降低值为19.4%。使用硫辛酸预防1例不良事件的需治疗人数(number needed to treat, NNT)为18例。次要终点的分析中,硫辛酸组和安慰剂组分别有35例(25.4%)和47例(33.8%)患者发生主要不良心血管事件(major adverse cardiovascular events, MACE)的复合终点,包括心衰再住院、全因死亡事件、非致死性心肌梗死、非致死性脑卒中($HR=0.685$, 95%CI 0.442~1.062, $P=0.091$; 图1D)。相比于安慰剂组,硫辛酸组患者的左心室射血分数显著改善($\beta=3.20$, 95%CI 1.14~5.23, $P=0.002$),6分钟步行距离明显延长($\beta=31.7$, 95%CI 8.3~54.7, $P=0.008$)。在安全性分析中,硫辛酸药物的使用并没有增加不良事件的发生风险。**结论** 硫辛酸药物补充治疗策略在改善缺血性心衰患者的预后中有潜在应用价值,能够显著改善缺血性心衰患者的左心室射血分数和6分钟步行距离。

[关键词] 硫辛酸;缺血性心衰;左心室射血分数;6分钟步行距离;预后

[中图分类号] R 541.6 **[文献标志码]** B

Efficacy of alpha-lipoic acid in patients with ischemic heart failure: a randomized, double-blind, placebo-controlled study

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[Abstract] Objective To explore the safety and effects of alpha-lipoic acid (ALA) in patients with ischemic heart failure (IHF). **Methods** A randomized, double-blind, placebo-controlled trial was designed (ClinicalTrials.gov registration number NCT03491969). From January 2019 to January 2023, 300 patients with IHF were enrolled in four medical centers in China, and were randomly assigned at a 1 : 1 ratio to receive ALA (600 mg daily) or placebo on top of standard care for 24 months. The primary outcome was the composite outcome of hospitalization for heart failure (HF) or all-cause mortality events. The second outcome included non-fatal myocardial infarction (MI), non-fatal stroke, changes of left ventricular ejection fraction (LVEF) and 6-minute walking distance (6MWD) from baseline to 24 months after randomization. **Results** Finally, 138 patients of the ALA group and 139 patients of the placebo group attained the primary outcome. Hospitalization for HF or all-cause mortality events occurred in 32 patients (23.2%) of the ALA group and in 40 patients (28.8%) of the placebo group ($HR=0.753$, 95%CI 0.473-1.198, $P=0.231$; Figure 1A-1C). The absolute risk reduction (ARR) was 5.6%, the relative risk reduction (RRR) associated with ALA therapy was approximately 19.4% compared to placebo, corresponding to a number needed to treat (NNT) of 18 patients to prevent one event. In the secondary outcome analysis, the composite outcome of the major adverse cardiovascular events (MACE) including the hospitalization for HF, all-cause mortality events, non-fatal MI or non-fatal stroke occurred in 35 patients (25.4%) in the ALA group and 47 patients (33.8%) in the placebo group ($HR=0.685$, 95%CI 0.442-1.062, $P=0.091$; Figure 1D). Moreover, greater improvement in LVEF ($\beta=3.20$, 95%CI 1.14-5.23, $P=0.002$) and 6MWD ($\beta=31.7$, 95%CI 8.3-54.7, $P=0.008$) from baseline to 24 months after randomization were observed in the ALA group as compared to the placebo group. There were no differences in adverse events between the study groups. **Conclusions** These results show potential long-term beneficial effects of adding ALA to IHF patients. ALA could significantly improve LVEF and 6MWD compared to the placebo group in IHF patients.

[Key Words] alpha-lipoic acid; ischemic heart failure; left ventricular ejection fraction; 6-minutewalking distance; prognosis

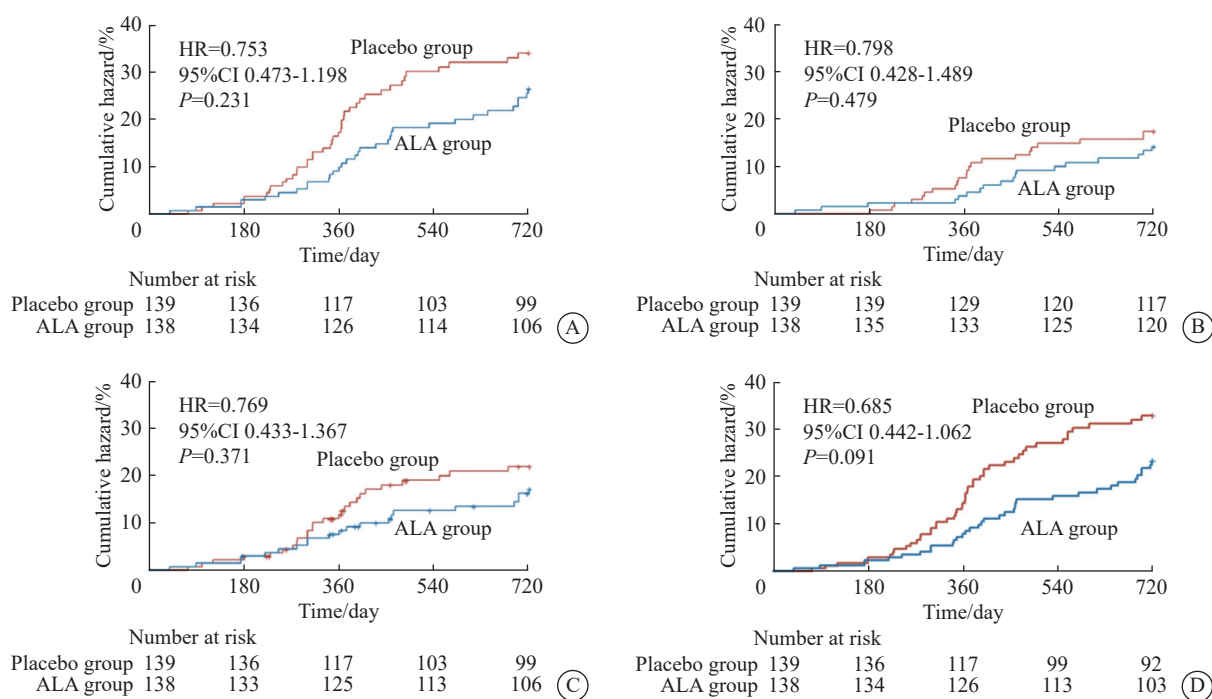


图1 硫辛酸组和安慰剂组患者的 Kaplan-Meier 生存曲线

Figure 1 Kaplan-Meier curves of patients in the alpha-lipoic acid group and the placebo group

A: Primary outcome (a composite of death from any causes and hospitalization for heart failure); B: All-cause mortality events; C: Hospitalization for heart failure; D: Major adverse cardiovascular events including the hospitalization for heart failure, all-cause mortality events, non-fatal myocardial infarction or non-fatal stroke.

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