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临床研究与应用

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含聚乙二醇脂质体多柔比星的CHOP样方案治疗初治老年晚期弥漫大B 细胞淋巴瘤的II期临床研究*

桂琳, 石远凯, 杨建良, 刘鹏, 秦燕

作者单位: 中国医学科学院, 北京协和医学院肿瘤医院肿瘤研究所内科, 抗肿瘤分子靶向药物临床研究北京市重点实验室(北京市100021)

Pegylated liposomal doxorubicin in CHOP regimen for untreated elderly patients with advanced diffuse large B-cell lymphoma: results from a prospective phase II study

Lin GUI, Yuankai SHI, Jianliang YANG, Peng LIU, Yan QIN

Department of Medical Oncology, Cancer Institute/Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College; Beijing Key Laboratory of Clinical Study on Anticancer Molecular Targeted Drugs, Beijing 100021, China

摘要

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摘要

目的: 评价含聚乙二醇脂质体多柔比星(PLD)的CHOP样方案治疗初治老年晚期弥漫大B淋巴瘤(DLBCL)的疗效和安全性。方法: 2011年11月至2014年3月共入组30例患者, 中位年龄70(63~80)岁, 24例(80.0%)国际预后指数 ≥ 3 分; 21例联合应用利妥昔单抗。进行前瞻性II期临床研究, 以含PLD的CHOP样方案治疗初治老年晚期DLBCL。PLD剂量为30mg/m², 环磷酰胺、长春新碱和强的松采用标准CHOP方案中的剂量。CD20阳性的患者可联合利妥昔单抗, 计划完成6个周期。结果: 客观缓解率为86.7%, 其中完全缓解率为66.7%。中位随访20.1(0.7~38.5)个月, 18个月总生存率及无进展生存率分别为82.4%及70.1%。主要不良反应为中性粒细胞减少。24例(80.0%)发生3~4级中性粒细胞减少。研究中患者左室射血分数及血清肌钙蛋白T无显著变化。4例(13.3%)在PLD输注后新发无症状性心电图异常。结论: 含PLD的CHOP样方案是治疗初治老年晚期DLB-CL患者毒性可接受的备选方案, 缓解率较高, 心脏安全性较好。

关键词: 聚乙二醇脂质体多柔比星, 弥漫大B 细胞淋巴瘤, 老年, 心脏毒性

Abstract:

Objective: To evaluate the efficacy and safety of pegylated liposomal doxorubicin (PLD) in CHOP regimen for untreated elderly patients with advanced diffuse large B-cell lymphoma (DLBCL). Methods: In a prospective phase II study, we analyzed the feasibility of PLD-modified CHOP regimen in elderly patients with advanced stages of DLBCL. PLD was administered at 30mg/m² in combination with cyclophosphamide, vincristine, and prednisone at standard doses every 21d for six cycles. CD20positive patients were given option for rituximab treatment. Results: From November 2011 to March 2014, 30 patients with a median age of 70 years (range: 63 to 80) were enrolled in this study. Up to 24 cases (80.0%) obtained an International Prognostic Index of ≥ 3 . The overall re-sponse rate was 86.7%, and the complete remission rate was 66.7%. With a median follow-up of 20.1 months, the 18-month overall and progression-free survival rates were 82.4% and 70.1%, respectively. The main toxicity was neutropenia, reaching grades 3 to 4 in the 24 cases (80.0%). No significant changes existed in patients' left ventricular ejection fraction and serum troponin-T during the study. Four patients (13.3%) showed asymptomatic abnormal changes in electrocardiogram after PLD infusion. Conclusion: CHOP regimen with PLD is an effective alternative for the treatment of DLBCL in elderly patients, exhibiting an acceptable toxicity.

Key words: pegylated liposomal doxorubicin diffuse large B-cell lymphoma elderly cardiac toxicity

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通讯作者: 石远凯 E-mail: syuankai@cicams.ac.cn

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地址：天津市河西区体院北环湖西路肿瘤医院内 300060

电话/传真：(022)23527053 E-mail: cjco@cjco.cn cjcotj@sina.com 津ICP备09011441号-3