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非小细胞肺癌同期放化疗改良的放疗剂量递增研究

A modified radiation dose escalation study of concurrent chemoradiotherapy for patients with nonsmall cell lung cancer

中文关键词: 非小细胞肺癌 同期放化疗 剂量递增 长春瑞滨 卡铂

英文关键词: Non-small cell lung cancer Concurrent chemoradiotherapy Dose escalation Vinorelbine Carboplatin

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中文摘要：

背景与目的：尽管美国放射治疗肿瘤组已经报道了非小细胞肺癌(non-small cell lung cancer，NSCLC)同期放化疗的放疗最大耐受剂量(maximum-tolerated dose，MTD)为74 Gy，但是由于东西方人群的体质差异和我们关于食管癌同期放化疗的剂量递增试验的结果，美国的74 Gy是否能够安全应用到东方人群中尚不清楚。本研究进行此改良的剂量递增试验以确定NSCLC同期放化疗放疗剂量的MTD。**方法：**19例初治NSCLC患者接受三维适形放射治疗(three-dimensional conformal radiation therapy，3D-CRT)，每天1次，每次2.0 Gy，每周5次。应用改良的Fibonacci法，从低剂量逐渐上升到高剂量，起始放疗剂量为62 Gy，递增剂量为4 Gy，每剂量组至少3例，如无剂量限制毒性(dose-limiting toxicity，DLT)出现则进入下一剂量组，直至出现DLT，DLT的低一剂量水平即为MTD。参考RTOG剂量递增结果最高MTD设为70 Gy。化疗于放疗第1天开始，采用长春瑞滨联合卡铂方案(vinorelbine and carboplatin，NC)。**结果：**放疗病灶的近期有效率(CR+PR)为77.8%，其中CR占27.8%，PR占50.0%，SD占11.1%，PD占11.1%。全组出现1例DLT，为Ⅲ级放射性肺炎，再以相同剂量入组9例，未出现DLT。主要不良反应为放射性肺炎、放射性食管炎、粒细胞减少、食欲减退、恶心和乏力，程度均较轻易于临床处理。**结论：**3D-CRT联合同期长春瑞滨和卡铂方案化疗可将胸部放疗剂量递增到70 Gy，其不良反应可以耐受，根据试验设计确定70 Gy即为此改良剂量递增试验的MTD。

英文摘要：

Background and purpose: Although Radiation Therapy Oncology Group (RTOG) in USA reported a maximum-tolerated dose (MTD) of 74 Gy in non-small cell lung cancer (NSCLC), but due to differences in physique between Oriental and Western patients and results in our chemoradiotherapy escalation trial for esophageal carcinoma, it was unclear whether the 74 Gy of America could be safely applied to Oriental patients. We conducted this modified dose escalation trial to define MTD for Chinese patients with NSCLC who received three-dimensional conformal radiation therapy (3D-CRT) with concurrent chemotherapy. **Methods:** Previously untreated patients with NSCLC received 3D-CRT, 5 daily fractions of 2.0 Gy per week. Radiation dose escalation was performed by modified Fibonacci sequence. The starting doses was 62 Gy and the esclation dose was 4 Gy. Every cohort contained at least 3 patients. If no dose-limiting toxicity (DLT) was observed, the next dose level was opened for enrollment. The courses were repeated until DLT appeared. MTD was declared as one dose level below the level at which DLT appeared. A maximal MTD was set to be 70 Gy according to the results of RTOG. **Results:** Nineteen patients were recruited including one was withdrawn. Only 1 DLT of grade 3 radiation-induced pneumonia was observed at the level of 70 Gy cohort. No DLT was observed any more after 9 patients were treated in that dose level. The major side effects were radiation-induced pneumonia, radiation-induced esophagitis, neutropenia, anorexia, nausea and fatigue. All the side effects were manageable clinically. **Conclusion:** Integration of high-dose 3D-CRT with concurrent vinorelbine and carboplatin is feasible in Chinese population, and dose escalation of thoracic radiotherapy to 70 Gy is possible with acceptable toxicity. We define that 70 Gy is MTD according to the modified dose escalation trial design. A phase Ⅱ trial based on this results is ongoing to further evaluate its safety and efficacy.

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