The preliminary results of a Phase II randomized clinical trial of high-dose toremifene chemosensitization in stage III B/IV non-small cell lung cancer  

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**Abstract**  
Objective To investigate whether high-dose toremifene can enhance the efficacy of chemotherapy in non-small cell lung cancer. Methods Untreated stage III B/IV non-small cell lung cancer patients were randomly devided into group A (high-dose toremifene combined with the platinum-based chemotherapy) or group B (the same platinum-based chemotherapy alone). Results A total of 30 eligible patients had been recruited. Hematologic and nonhematologic toxicities were similar with no statistic difference. The median survival for group A was 8 months, 95% CI (6.33–9.37) versus 7.5 months, 95% CI (4.75–10.25) for group B (P = 0.9). One-year survival rate was 31% for group A versus 28% for group B (P = 0.87). The response rate was 25% for group A versus 21% for group B (P = 0.99). Conclusion The results suggest that high-dose toremifene does not enhance the efficacy of platinum-based chemotherapy for III B/IV non-small cell lung cancer but toxicities are well tolerated.

**Key words**  
Toremifene  Non-small cell lung cancer  Drug resistance  Chemotherapy
1. 原因致不能随访的患者

（1）NSCLC患者；（2）NSCLC患者中组织学证实的

的抗肿瘤治疗者；（3）NSCLC患者中治疗期间患者要求退出本

研究队；（4）NSCLC患者伴有急性感染或；（5）NSCLC患者中

活动性充血性心衰；（6）NSCLC患者中晚期或

不可测量的肝转移患者；（7）NSCLC患者中不稳定的脑转移患者

和活动性肺结核或活动性结核性脑膜炎或结核性脑膜炎的

患者。以上情况均列为非依从性病例。

2. 人选前六个月内有迟发性心肌梗

死或患者要求终止研究的。

3. 以上情况均列为非依从性病例。

4. 以上情况均列为非依从性病例。

5. 以上情况均列为非依从性病例。

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21. 以上情况均列为非依从性病例。

22. 以上情况均列为非依从性病例。
组有一例患者住院期间用了一周期含铂方案化疗后回当地化疗!

未加ITT。A、B组各1例均改用其他化疗方案。这两人均属非依从。

两组非依从率分别为。

按照原则这些患者均予随访并纳入结果分析中。

治疗毒性主要毒性为血液毒性，主要表现为中性粒细胞减少发生率。

两组间差异没有统计学意义。

非血液学毒性主要为恶心、呕吐、厌食。两组间毒性差异没有统计学意义。

对照组1例发生中度感染，后来患者死亡。分析与感染相关。

表1 患者的一般资料。

表2 The general characteristics in the patients with NSCLC。

表3 Comparison of toxicities between group A and group B (No. of cases)。

表4 Comparison of the treatment results of two groups。
Verapamil [@] and Cyclosporin A [@] are two drugs commonly used to reverse multidrug resistance in cancer cells. However, at effective concentrations, they can cause significant toxicity.

Toremifene[@] is a drug that has shown promise in reversing multidrug resistance, particularly in breast cancer cells. It acts by inhibiting estrogen signaling and reversing the expression of multidrug resistance proteins.

In one study, toremifene was tested in clinical doses in patients with NSCLC. The results showed a significant increase in drug sensitivity and a reversal of multidrug resistance in vivo.

In summary, toremifene holds promise as a potential drug for reversing multidrug resistance in cancer, but further clinical trials are needed to confirm its efficacy and safety.

References: