

食管癌术后复发患者调强放疗同步化疗（5-Fu+奈达铂）的Ⅱ期临床研究

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Phase II Study of Intensity-Modulated Radiotherapy Combined with 5-Fluorouracil and Nedaplatin Chemotherapy in Recurrent Esophageal Carcinoma after Curative Operation

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摘要

目的

评价食管癌根治术后复发患者调强放疗同步化疗（5-Fu+奈达铂）的近期疗效和不良反应。方法选取2009年6月—2010年6月44例符

合入组条件的食管癌术后复发患者,均采用调强放疗同步化疗（5-Fu+奈达铂）方案进行治疗。调强放疗:GTV给量60 Gy/30 f, 2.0 Gy/f;CTV给量54 Gy/30 f, 1.8 Gy/f。同步化疗在放疗的第1周和第4周进行,具体为:5-Fu 750 mg/ (m²·d), d1~5, 奈达

铂80 mg/ (m²·d), d1。主要观察终点是1年生存率,次要观察终点是不良反应。结果全组总有效率为86% (38/44)。1年和2年

总生存率分别为72.7%和60%。1年和2年无进展生存率分别为63.6%和36.6%。放化疗期间出现Ⅰ、Ⅱ和Ⅲ度骨髓抑制的患者分别为

16% (7/44)、50% (22/44)和34% (15/44);出现Ⅰ度和Ⅱ度胃肠道反应的患者分别为45% (20/44)、55% (24/44);出现Ⅰ度和

Ⅱ度肝/肾功能生化指标异常的患者分别为77% (34/44)、23% (10/44),未发现Ⅲ度及以上胃肠道及肝/肾功能生化指标异常者

。所有不良反应经对症处理后均好转,全组患者均顺利完成放化疗计划,无疗程中断或延迟者。结论食管癌根治术后复发患者进行调强放疗同步化疗（5-Fu+奈达铂）的近期疗效好,不良反应小,值得进行Ⅲ期临床研究。

关键词: 食管癌 复发 放疗 化疗

Abstract:

Objective

To analyze the feasibility and safety of postoperative recurrent esophageal carcinoma patients treated by intensity-modulated radiotherapy combined with 5-Fluorouracil(5-Fu) and nedaplatin chemotherapy.MethodsForty-four

esophageal carcinoma patients suffered recurrence after their definitive resection in our department from June 2009 to June 2010.Intensity-modulated radiotherapy combined with 5-Fu and nedaplatin chemotherapy was performed

in the patients(gross tumor volume,GTV) of IMRT was prescribed to 60 Gy/30f, 2.0 Gy/f and 5-Fu and nedaplatin

concurrent chemotherapy was used by 5-Fu 750 mg/ (m²·d), d1~5, nedaplatin 80 mg/ (m²·d), d1 at week 1 and

week 4.The primary endpoint was 1-year survival rate and the second endpoint was toxicity related to the

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treatment.ResultsThe overall response rate (CR+PR) was 86% (38/44) .1- and 2-year overall survival rate was 72.7% and 60%,respectively.1- and 2-year progression-free survival rate was 63.6% and 36.6%,respectively.Univariate

analysis outcome showed that only recurrent site was related with prognosis ($\chi^2=22.848, P=0.000$) .All the patients undergone this treatment smoothly.Grade I ,II and III leukocytopenia was observed in 16% (7/44), 50% (22/44), and 34% (15/44) patients, respectively.Grade I,and II digestive tract toxicity was observed in 45% (20/44), 55% (24/44) patients, respectively.Grade I ,and II liver/renal toxicity was observed in 77% (34/44), and 23% (10/44) patients, respectively.Over grade 3 digestive tract and liver/renal toxicity were not found.All the toxicities were gone after corresponding therapy.ConclusionConcurrent chemotherapy with 5-Fu and nedaplatin plus intensity-modulated radiotherapy is an effective and feasible regimen and would be considered as a better option

for postoperative recurrent esophageal carcinoma patients,which could be deserved to be applied to phase III clinical trial.

Key words: Esophageal carcinoma Recurrence Radiotherapy Chemotherapy

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