

Original Article

Adjuvant Chemotherapy in Colorectal Cancer: A Prospective Phase II Trial with Oxliplatin plus 5-Fluorouracil and Leucovorin

Tzung-Hsin Chou, King-Jen Chang, Jin-Tung Liang*, John Huang, Po-Huang Lee

Division of Colorectal Surgery, Department of Surgery, National Taiwan University Hospital, Taipei, Taiwan

Abstract.

Purpose: This study aimed to investigate the effects of combining oxaliplatin with 5-Fluorouracil and Leucovorin (FL) as an adjuvant therapy for the treatment of stage II and III colorectal cancer after radical surgery.

Methods: From 2004 to 2005, 20 patients with stage II and III colorectal cancers who had undergone radical surgery were enrolled in this prospective study. The operative method and post-operative disease-free survival, overall survival, and complications were recorded and discussed.

Results: There were 12 males and 8 females, with a mean age of 56.05 ± 9.74 years. Three cases had T3 tumors while the other 17 had T4 tumors. Nine cases were stage II and the rest were stage III of the disease. Seven cases (35%) underwent right hemi-colectomy, two (10%) left hemi-colectomy, and 11 (55%) low anterior resection. The overall survival rate was 95% and the disease-free survival rate was 85%. Only grade one (one patient) and grade two (two patients) neuropathy were noted in the study. No major surgical- or treatment-related complications were noted.

Conclusions: Patients who received Oxaliplatin plus 5-Fluorouracil and Leucovorin (FL) treatment showed promising results for the adjuvant treatment for stage II and stage III colorectal disease. The results became even more significant one year after.

Keywords : Colon Cancer, chemotherapy, oxaliplatin

原著論文

大腸癌之輔助性化學治療:一項運用 Oxliplatin 加上 5-Fluorouracil 及 Leucovorin 前瞻性之第二階段臨床試驗

周宗欣 張金堅 梁金銅* 黃約翰 李伯皇

國立台灣大學附設醫院外科部 大腸直腸外科

中文摘要

目的: 本實驗之目的在於研究大腸癌根治性手術後接受 oxliplati 加上 5-Fluorouracil 及 Leucovorin (FL) 輔助治療的結果。

方法: 由 2004 至 2005 年, 共有 20 位因罹患第二期或第三期大腸直腸癌之病患於接受根治性手術後, 納入此前瞻性研究中。手術方式, 術後無疾病存活率, 整體存活率以及併發症等皆被記錄並加以比較。

結果: 共有 12 位男性及 8 位女性病患，平均年齡為 56.05 ± 9.74 歲。3 位腫瘤大小為 T3，其他 17 位為 T4。9 位為第二期病患，其餘的為第三期病患。7 位病患(35%)接受右側大腸根治性切除，2 位(10%)接受左側切除，11 位(55%)接受下前位切除。整體存活率為 95%。無病存活率為 85%。本實驗中併發症僅有偵測到 1 位病患有一度神經病變，及 2 位病患有一度神經病變。並無手術相關或是治療相關的主要併發症發生。

結論: 罹患第二及第三期大腸癌之病患，於手術後接受 Oxaliplatin，5-Fluorouracil 及 Leucovorin (FL) 治療初步顯示出令人滿意的結果。此結果於手術後一年後應更有其顯著性。

關鍵字: 大腸癌、化療、oxaliplatin

INTRODUCTION

Approximately 15-20% of newly diagnosed patients with colorectal cancer have metastasis on initial presentation. In the past, 5-Fluorouracil (5-FU) plus leucovorin (LV) was the only effective chemotherapeutic regimen for metastatic colorectal cancer and achieved a median survival of less than 12 months[1]. To further improve this, incorporation of a new therapeutic agent, oxliplatin or irinotecan, to 5-FU plus LV (FL) has been advocated[2]. Several studies have shown that the combination of oxaliplatin plus FL seem to have better results than that of irinotecan plus FL in the treatment of metastatic disease[2-4]. Oxliplatin and irinotecan have likewise been advocated to combine with FL in recent years as adjuvant treatment for stage II and III.

Oxliplatin is a third-generation platinum derivative, which when combined with FL, is among the most effective chemotherapies for metastatic colorectal cancer[3,5-7]. Since there have been few species-based studies describing the use of oxliplatin plus LV for the treatment of stage II and III colorectal cancer, the purpose of this study was to investigate the result of combining oxaliplatin with FL as an adjuvant therapy

for stage II and III colorectal cancer after radical surgery in Orientals.

MATERIALS AND METHODS

From July 2004 to June 2005, 20 patients diagnosed as stage II and III colorectal cancer without evidence of distant metastasis were enrolled in the study. Pre-operative study for staging included pre- and post-operative serum CEA level, colonic barium double-contrast study, and abdominal computerized tomography. The specimens were all sent for pathologic examination for accurate staging after radical surgery. All of the patients diagnosed as stage II and III and confirmed by pathology examination received adjuvant chemotherapy with oxliplatin plus FL at least seven weeks after radical surgery.

All of the patients had regular follow-up at the out-patient clinic every 3 months, with serum CEA level testing. Colonoscopy was arranged at 6 months and 1 year after operation, while positron emission tomography (PET) and computed tomography scans were arranged at 12 months post-operatively and once cancer recurrence was suspected.

In the study, each cycle of chemotherapy was composed of a 2-hour infusion of 200 mg leucovorin per square meter of body surface area, followed by a bolus of 400 mg fluorouracil per square meter, and then a 22-hour infusion of 600 mg fluorouracil per square meter. These were given on 2 consecutive days every 14 days for 12 cycles. Two-hour infusion of 85

*Corresponding author: Jin-Tung Liang M.D.

*通訊作者：梁金銅醫師

Tel: +886-2-23123456 ext.3456

Fax: +886-2-23934358

E-mail: b1401021kimo@yahoo.com.tw