Hazard rate of tumor recurrence over time: a pooled-analysis of three clinical trials with fluoropyrimidine-based adjuvant chemotherapy for colorectal cancer achieved by the Japanese Foundation for Multidisciplinary Treatment of Cancer (JFMC)

Hiromichi Maeda¹⁾, Koji Oba²⁾, Chikuma Hamada³⁾, Sotaro Sadahiro⁴⁾, Toru Aoyama⁵⁾, Michitaka Honda⁶⁾, Shuhei Mayanagi⁷⁾, Kosuke Kashiwabara²⁾, Junichi Sakamoto^{8,9)}, Shigetoyo Saji⁹⁾, Takaki Yoshikawa¹⁰⁾

1) Cancer Treatment Center, Kochi Medical School Hospital, Kochi University

2) Department of Biostatistics, Graduate School of Medicine, The University of Tokyo

3) Faculty of Engineering, Tokyo University of Science

4) Department of Surgery, Tokai University

5) Department of Surgery, Yokohama City University

6) Department of Disaster Medicine, Fukushima Medical University

7) Division of Esophageal Surgery, Shizuoka Cancer Center Hospital

8) Tokai Central Hospital

9) Japanese Foundation for Multidisciplinary Treatment of Cancer

10) Department of Gastrointestinal Surgery, Kanagawa Cancer Center

Abstract

Estimation of the risk for tumor recurrence after curative resection of colorectal cancer is essential for establishment of a treatment plan and surveillance schedule. Several studies have identified the risk factors for the tumor recurrence occurring within a specific period of time, but the knowledge concerning the transition of the hazard rate over time and the effect of clinical variables on it is scarce.

Herein, we would like to introduce the concept of the present study with summarized methods, and to report the fixation of the data and completion of the analysis.

Key Words: Hazard rate, late, DFS, surveillance, early, UFT

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Introduction

Colorectal cancer appears to affect over 140,000 people and cause over 50,000 deaths in Japan in 2016¹⁾. Significant proportions of the patients with curatively resected Duke's B and C colorectal cancer have tumor recurrence and tumor related-death within 5 years²⁾. One of the strategies to concur this problem is early detection of treatable recurrent thorough intensive postoperative surveillance.

Although surveillance after curative resection of colorectal cancer has to be scheduled according to the risk estimation at each time point, little is known as to the transition of the hazard rate of tumor recurrence with time. Besides, the effect of the clinical variables on

the hazard rate over time remains obscure, especially in Japanese population. In the present study, therefore, we first focused on this clinical question, and then explored the predictive factors of early and late recurrences.

Patients and Methods

Ethics

The institutional review board of Japanese Foundation for Multidisciplinary Treatment of Cancer (JFMC) approved the study protocol. This study was conducted in accordance with the Declaration of Helsinki.

Clinical trials and patients

Data of the patients from three clinical trials, JFMC-project Number 07-8601, 15-890, and 33-0502 were pooled^{2, 3)}. These phase III trials were performed to evaluate the clinical benefits of fluoropyrimidine-based adjuvant chemotherapy.

Corresponding Author: Hiromichi Maeda, MD, PhD. Cancer Treatment Center, Kochi Medical School Hospital, Kochi University, Kohasu, Ogo-cho, Nankoku, Kochi, 783-8505, Japan. Tel: +81-88-880-2370, Fax: +81-88-880-2371, E-mail: hmaeda@kochi-u.ac.jp

Data preparation and Statistical analysis

Disease free survival was set as one of the main outcomes, and defined as the time from randomization to the either of tumor recurrence or death of any causes. Hazard rate over five-year duration was plotted, and the changing recurrent risks were visually assessed. The influence of clinical and pathological factors were also analyzed after stratification of the patients according to the variables of interest. To find out the predictive factors for the early and late recurrence, logistic regression analysis was performed.

Results

Data of 5530 patients eligible for the present study were collected and fixed. Plotting of the hazard rates and relevant statistical analysis were completed. The manuscripts with the details of the findings and the interpretation are in preparation.

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