INTRODUCTION

Colorectal cancer is the third most common cancer and one of the most frequent causes of cancer-associated mortality worldwide. Although complete resection is essential for the cure of colorectal cancer, the postoperative complications rate after colorectal cancer surgery has been reported to be 20-40%. Recent studies for gastric and pancreatic cancers have demonstrated that the development of postoperative complications decreased the patient’s survival or increased the risk of disease recurrence.

The aim of the present study was to determine whether the overall survival (OS) and recurrence-free survival (RFS) would be affected by the development of any postoperative complications in the patients who underwent curative resection for colorectal cancer.

PROTOCOL DIGEST OF THE STUDY

Purpose

The aim of the present study was to determine whether the overall survival (OS) and recurrence-free survival (RFS) would be affected by the development of any postoperative complications in the patients who underwent curative resection for colorectal cancer.

Resource

Individual patients’ data of each clinical trial was provided from the Japanese Foundation for Multidisciplinary Treatment of Cancer (JFMC).

Patients

Patient’s data and outcomes of 5530 patients enrolled onto three phase 3 trials of Japanese Foundation for Multidisciplinary Treatment of Cancer (JFMC) studies (7/15/33) were pooled. The details of each individual study had already been reported in peer review journal.

Japanese Foundation for Multidisciplinary Treatment of Cancer 7 and 15: These two randomized trials were both large-scale studies with over 1000 patients, and focused on long-term utilization of oral 5-fluorouracil (FU) as adjuvant chemotherapy for colon or rectal cancer, and compared the overall survival outcomes with the surgery-alone arm or with one of treatment arm.

Japanese Foundation for Multidisciplinary Treatment of Cancer 33: This phase III trial randomly assigned eligible patients from 2005 to 2007 at 233 centers to receive tegafur (UFT, 300 mg/m²/day as tegafur)/leucovorin (LV, 75 mg/day) for 28 of 35 days for 6 months in the control group or for 5 consecutive days per week for 18 months.

Definition of postoperative complications

All information on major surgical complications was...
extracted from the case-report forms for the trial. The patients were classified into those with postoperative complications (C group) and those without postoperative complications (NC group).

Evaluations and statistical analyses

The significance of correlations between postoperative complications and clinicopathological parameters was determined using Fisher’s exact test or the $\chi^2$ test. The OS and RFS curves were calculated using the Kaplan-Meier method, and were compared by the log-rank test. A Cox proportional hazards model was used to perform the univariate and multivariate survival analyses. A value of $P <0.05$ was defined as being statistically significant. The SPSS software package (v11.0 J Win, SPSS, Chicago, IL) was used for all statistical analyses. This study was approved by the Institutional Review Board of the Japanese Foundation for Multidisciplinary Treatment of Cancer.

Data analysis

Individual Patients’ clinic pathological data of a total of 5530 patients from the three trials were already collected and their analyses have been completed. Detailed results of overview of this integrated data will be published elsewhere after scrutinized examination and model based analysis of all the retrieved results.

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Conflict of interest statement

None declared.

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