Original Article

Postoperative Follow-up Strategies for the Detection of Recurrence in Patients with Early-stage Colorectal Cancer

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Key Words
Early-stage;
Colorectal cancer;
Surveillance;
Recurrence

Background and Objectives. As there are differing opinions regarding the surveillance of patients with early-stage colorectal cancer, we aimed to determine whether the early detection of recurrence provides similar benefits to patients with early-stage (stage I) and late-stage (stage II and III) colorectal cancer.

Methods. Patients who underwent curative resection between January 1995 and December 2011 for stage I-III primary colorectal adenocarcinoma were enrolled. Variable values and recurrence patterns in patients with early- and late-stage disease were compared.

Results. Between 1995 and 2011, 10,224 patients underwent curative surgery for colon or rectal cancer of pathological stages I, II, or III. Recurrence occurred in 2,568 patients (25.11%). The most common sites of recurrence for early-stage disease were the lungs (36.3%) and liver (32.4%), and for late-stage disease were liver (38.1%) and the lungs (26%). In both early-stage and late-stage disease, recurrence was mostly detected by identifying abnormalities in carcinoembryonic antigen levels; abnormal image was the second most commonly used technique to detect recurrence. Of the 130 patients with early-stage disease who experienced recurrence after curative surgery, 40.7% underwent secondary curative surgery for the recurrent disease, with median survival time of 32 months; however, that of patients who did not undergo surgery was 17 months ($p < 0.001$). In late-stage patients who experienced recurrence, 33.6% of them underwent secondary curative-intent surgery. Among these, the median survival time was 32 months, and that of those who did not was 13 months ($p < 0.001$).

Conclusions. Patients with late- and early-stage disease who have recurrent cancer derive similar benefits from secondary curative surgery under similar surveillance strategy. However, it may be important to consider factors such as patient stress caused by surveillance and the cost-effectiveness of surveillance.

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Since 1982, cancer has been the leading cause of death in Taiwan; in 2018, 48,784 people died of cancer, accounting for 28.22% of all deaths. Furthermore, with respect to the incidence of different types

of cancer, colorectal cancer has the highest incidence among men and the third highest incidence among women. Among different cancer types, colorectal cancer is associated with the third highest mortality rate.[1] In Taiwan, approximately 77% of patients with newly diagnosed colorectal cancer undergo surgery. Follow-up strategies designed to detect recurrence in patients after they have undergone surgery are crucial, and pathological analysis of resected specimens is the most efficient method for assessing disease prognoses. Among patients with colorectal cancer, the overall recurrence rate after curative surgery ranges between 24% and 43%. Approximately 95% of the recurrence in patients with colorectal cancer occurs within 5 years after curative surgery, and in a majority of cases, recurrence occurs within 2 years. The most common sites of recurrence are the liver and lungs.[2,3]

It has been found that the duration between initial treatment and recurrence is significantly associated with survival.[4] Therefore, proper postoperative surveillance strategies should be considered to enable the early detection of recurrence in patients who have asymptomatic recurrence; the implementation of such strategies may lead to an increase in the proportion of patients who are eligible to receive curative therapy.[5] Detection of recurrence may lead to effective treatment; furthermore, compared to patients who do not undergo any surveillance, patients who undergo surveillance may have better clinical outcomes. However, with respect to surveillance strategies, varying recommendations have been made. Moreover, although there is a consensus regarding surveillance strategies for patients with resected colorectal cancer, this consensus is only with respect to stage II or III disease.

The current guidelines of the National Comprehensive Cancer Network (NCCN) provide different suggestions for different pathological stages of cancer. For patients with stage I disease, the use of colonoscopy has been suggested for follow-up evaluations; for patients with stage II or III disease, regular monitoring of carcinoembryonic antigen (CEA) levels and the performance of chest, abdomen, and/or pelvic computed tomography (CT) have been suggested. Additionally, it is not recommended that CEA-level evaluations and CT be performed routinely > 5 years after a

patient has undergone curative surgery.[6] The guidelines of the American Society of Clinical Oncology (ASCO) are similar to those of the NCCN; in the ASCO guidelines, follow-up surveillance of patients with stage I colon cancer, except through the use of colonoscopy, has not been recommended.[7] Conversely, in the European Society for Medical Oncology's guidelines regarding surveillance after surgery for localized colon cancer, there are no differences in the recommendations made for disease of stages I, II, and III.[8]

Therefore, as there are differing opinions regarding surveillance, in this study, we aimed to determine whether the benefits of early detection of recurrence in patients with stage I colorectal cancer are similar to the benefits in patients with stage II and III colorectal cancer. Moreover, we endeavored to investigate whether the performance of curative surgery after recurrence provides survival benefits to patients with colorectal cancer.

Patients and variables

Detailed data regarding the baseline characteristics of patients was retrieved from the Colorectal Section Tumor Registry of Chang-Gung Memorial Hospital. This study was approved by the Institutional Review Board of the hospital. The patient-related variables considered in this study were age and sex, and the tumor-related variables we considered were tumor location (colon and rectum), histological tumor grade (grades according to differentiation [well-, moderately, and poorly differentiated]), and CEA levels before surgery. Patients who underwent curative resection for stage I to III primary colorectal adenocarcinoma between January 1995 and December 2011 were enrolled. We divided the patients into the following two groups according to the pathological stages of cancer defined by the American Joint Committee on Cancer's staging criteria: patients with early-stage (stage I) disease and patients with late-stage (stage II and III) disease.

Follow-up and end points

Different physicians in the same department at

this institute adopted similar follow-up routines and adjuvant-treatment protocols. All patients were evaluated weekly by a multidisciplinary team to determine the actual stage of cancer according to clinical information and pathology reports. However, final decisions regarding the administration of adjuvant chemotherapy were made according to each physician's opinion and each patient's choice. All patients participated in a follow-up program that included outpatient visits every 3 to 6 months for physical examinations and evaluations of CEA levels; additionally, chest radiography, abdominal sonography or abdominal CT, and colonoscopy were performed postoperatively every 1 to 3 years. The primary endpoint in this study was recurrence. Disease recurrence was initially suspected either through elevations of CEA levels and image results or through the use of other diagnostic modalities; the presence of recurrence was confirmed through histological examinations of biopsy specimens, re-operations, or radiological studies. The time to recurrence in each patient was defined as the duration between the date of performance of initial surgery and the date of confirmation of recurrence. We also determined recurrence rates, median time to recurrence, and patterns of recurrence in patients with early- and late-stage disease. The secondary endpoints were long-term outcomes associated with survival.

Statistical analyses

All analyses were conducted using IBM SPSS Statistics (version 24.0; IBM Corp., Armonk, NY, USA). Clinicopathological characteristics involving categorical variables have been presented using frequencies and proportions and were compared using the $\chi 2$ test. Continuous variables were presented using mean and standard deviation values and were analyzed using Student's t-test. For the estimation of long-term overall survival and time-to-event analyses, the time period extending from the date of curative surgery to the last follow-up date was considered, the Kaplan-Meier method was used, and comparisons were made using the log-rank test. All statistical tests were two-tailed, and p values < 0.05 were considered statistically significant.

Results

Between 1995 and 2011, 10,224 patients underwent curative surgery for colorectal cancer of pathological stages I, II, or III. We compared patient characteristics, such as age, sex, and tumor-related variables in patients with early- and late-stage disease. There were no significant differences between the two groups of patients with respect to age, sex, and preoperative CEA levels. Among the patients with early-stage disease, the number in whom the rectum was the primary cancer site was greater than that in whom it was the colon. There are no significant difference in age, sex and pre-operative CEA level abnormality between early-stage and late-stage. Mostly primary origin is rectum in early-stage (p < 0.001). And histologic grade is poor is rare in early-stage (p < 0.001) (Table 1).

During follow-up periods, recurrence occurred in 2,568 patients (recurrence rate: 25.11% [2,568 of 10,224 patients]) who had undergone curative surgery for colorectal cancer; 130 patients (5.4%) had early-stage disease, and 2,438 (29%) had late-stage disease. The recurrence rate among the patients with early-stage disease was 5.4%, and that among those with late-stage disease was 29%. The median duration from surgery to recurrence was 26 months and 16 months in early-stage and late-stage patients. In most patients, recurrence occurred within 5 years of the performance of initial surgeries. In total, recurrence occurred within 5 and 2 years of the performance of initial surgeries in 88% and of 65% of the patients, respectively.

Table 1. Clinicopathological characteristics of recurrent colorectal cancer, according to different stage

	Early-stage	Late-stage	p value
Study population	130	2438	
Age	65 (57-73)	64 (53-72)	0.271
Sex, male (%)	78 (60)	1389 (57)	0.462
Pre-operative CEA > 5 (%)	22 (16.9%)	1185 (48.6)	0.272
Primary origin			< 0.001
Colon	28	1092	
Rectum	102	1346	
Histologic grade			< 0.001
Well	47	222	
Moderate	78	1983	
Poor	5	233	

Among the patients with early-stage disease, recurrence occurred within 2 and 5 years of the performance of initial surgeries in 44.1% and 83.8%, respectively; among the patients with late-stage disease, recurrence occurred within 2 and 5 years of the performance of initial surgeries in 68.5% and 94.1%, respectively (Fig. 1).

The most common sites of recurrence in early-stage patients were the lungs (36.3%) and the liver (32.4%); in 15.7%, recurrence was locoregional (Fig. 2). Among the patients with late-stage disease, the most common sites of recurrence were the liver (38.1%) and the lungs (26%); 15.2% of these patients had locoregional re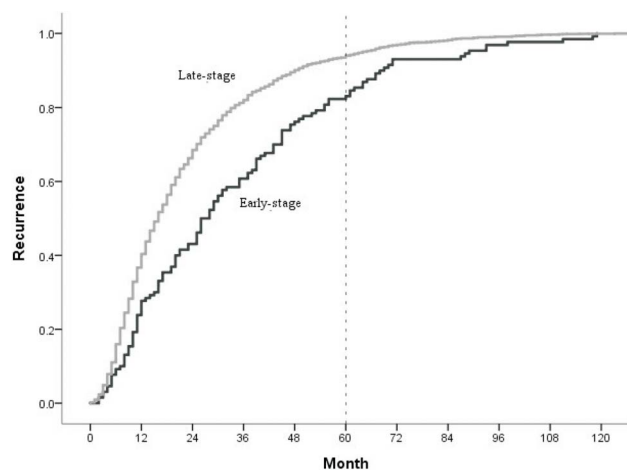currence. With respect to the methods used to detect recurrence, there were no significant differences between the patients with early- and late-stage disease. In most patients with early- and late-stage disease, first recurrences were detected by observing abnormalities in CEA levels (in 65.7% and 65.4% of patients with early-stage and late-stage disease, respectively; $p = 0.941$). The second most commonly used technique was abnormal imaging, including CT scan, chest X ray and sonography, which detecting first recurrences in 30.7% of the patients with early-stage disease and 35.2% with late-stage disease ($p = 0.664$). Evaluation of medical histories and physical examinations were used to detect recurrences in 22.5% of the patients with early-stage disease and 22.7% with late-stage disease. These findings show that in most cases, recurrence was detected when the patients were still asymptomatic (Table 2).

With respect to secondary outcomes, the 130 patients with early-stage disease in whom recurrence occurred after the initial curative surgery, 40.7% underwent secondary curative-intent surgery for recurrence, which means we excluded colostomy or bypass sur-

Fig. 1. Cumulative incidence of recurrence, according to early-stage and late-stage.

Table 2. Detection tool of recurrence, according to early-stage and late-stage

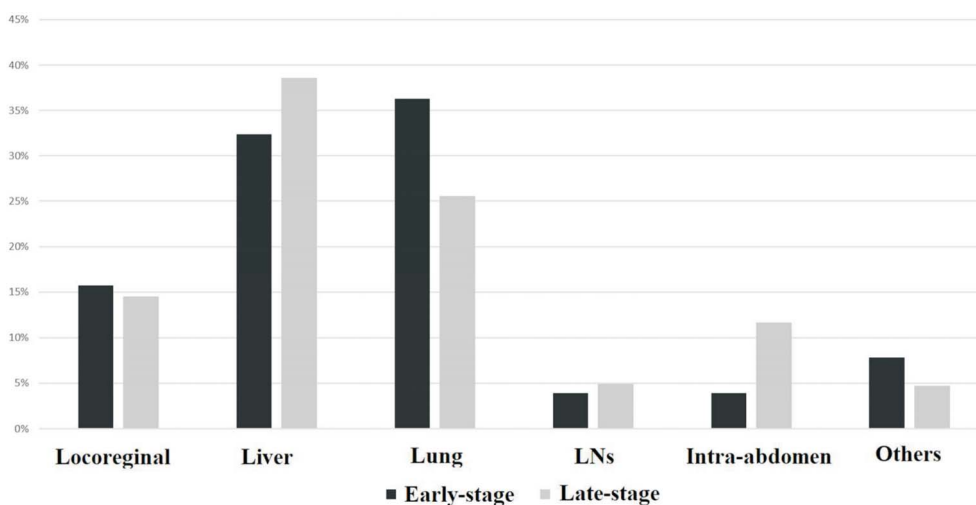| Detection tool	Early-stage (%)	Late-stage (%)	p value
Abnormal CEA	65.7%	65.4%	0.941
Abnormal image	30.7%	35.2%	0.664
Symptoms and PE	22.5%	22.7%	0.272

Fig. 2. Common site of recurrence in colorectal cancer, according to early-stage and late-stage.

gery. Among the patients with early-stage disease, the median survival time of those who underwent secondary surgery was 32 months, and that of those who did not was 17 months ($p < 0.001$). Among the 2,438 patients with late-stage disease and recurrence, 33.6% underwent secondary curative-intent surgery. Among these, the median survival time of the patients who underwent secondary surgery was 32 months, and that of those who did not was 13 months ($p < 0.001$) (Figs. 3, 4)

Discussion

The findings of our study show that approximately 5% of the patients with early-stage disease experienced recurrence. Similar follow-up strategies were used for patients with different disease stages. Due to the implementation of these strategies, approximately 32%-38% of these patients underwent secondary curative surgery. In other studies, the proportion of patients who underwent secondary surgery was found to be between 35% and 47%.[9,10] Additionally, the median survival time of the patients with early-stage disease who underwent secondary curative surgery was 32 months, which was the same as that of the patients with late-stage disease who underwent secondary curative surgery.

Serum CEA is an important tumor marker for colorectal cancer, and it has been reported that the result of CEA tests (involving detections of abnormal CEA levels) is positive for 40%-60% of patients who undergo surgery for colorectal cancer.[11] Serum CEA has a half-life of 3-5 days, and it has been reported that 2 to 4 weeks after a patient undergoes curative surgery, the patient's serum CEA levels decrease and return to a value that is within the normal range.[12-14] Considering a serum for a cutoff of 5 mcg/L, sensitivity and specificity rates were 71 and 88 percent, respectively.[15] In the present study, for patients with either early- or late-stage disease, detection of abnormalities in serum CEA levels was the most commonly used method for detecting recurrence; the second most commonly used technique was image tool. Therefore, imaging techniques and routine monitoring of serum CEA levels are beneficial for the detection of distant recurrence in both types of patients. In previous studies, among patients whose serum CEA levels were normal before they underwent initial surgery, 44% had elevated CEA levels at recurrence.[16,17] In our study, among the patients with early-stage disease whose preoperative serum CEA levels were < 5 ng/mL, 58.4% had elevated CEA levels at recurrence. Among the patients whose preoperative serum CEA levels were > 5 ng/mL, serum CEA levels at recurrence were ≥ 5 ng/mL in 75% and ≥ 10 ng/mL in 56.9%.

In the guidelines of most relevant societies and networks, including the NCCN guidelines, the annual performance of chest radiography is not recommended as a post-treatment surveillance tool. Chest radiogra-
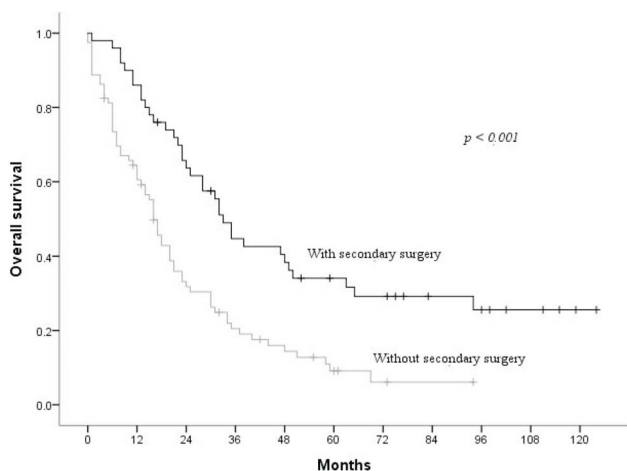

Fig. 3. Survival after secondary curative surgery in early-stage.
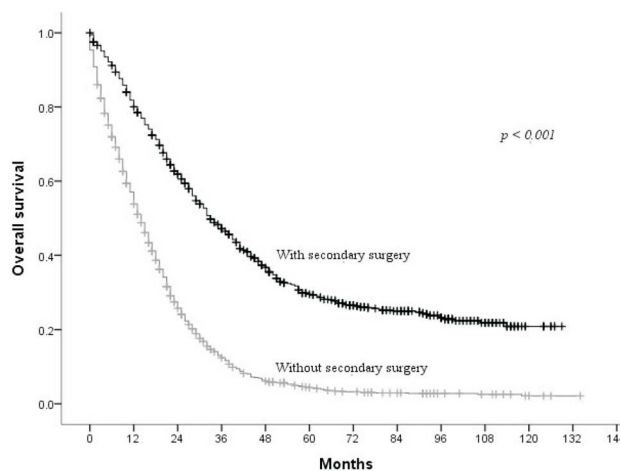

Fig. 4. Survival after secondary curative surgery in late-stage.

phy is a noninvasive and relatively inexpensive tool that can be used for the detection of lung metastases.[18-20] For the patients included in our study, chest radiography had been performed every 1 to 2 years; however, recurrences were mostly detected through the identification of abnormal CEA levels. In our data, due to a large number of patients and long duration of follow-up, we can only know detection of recurrence by abnormal image but cannot specifically know which image tool is.

The purpose of performing surveillance colonoscopy was to detect metachronous colorectal tumors and anastomotic recurrences. It has been reported that metachronous lesions develop in 1.5%-3% of patients with colorectal cancer, and most such lesions develop ≤ 36 months after such patients undergo curative surgery.[18,19] Anastomotic recurrences occur often in patients with rectal cancer, primarily in patients who do not undergo total mesorectal excision and/or pelvic radiation therapy.[21,22]

The most common site of recurrence in our study, lung is the most common site of recurrence and which is slightly greater in early-stage patients compared to late-stage patients whose the most common site of recurrence is liver. The upper and middle thirds of the rectum drain primarily into the superior rectal vein and ultimately, they empty into the liver through the inferior mesenteric vein and portal vein. However, the lower third of the rectum drains into the middle rectal vein, which skips the liver because it drains directly into the inferior vena cava.[23] In the present study, we did not divide colonic or rectal lesions of different stages into different groups. It is important to know which site is the most common site of recurrence.

In most of the major guidelines in which the use of CEA-level monitoring or CT for the surveillance of patients with stage I disease was not suggested, the use of these surveillance methods during follow-up periods was not suggested due to concerns associated with medical expenditure and patient stress from surveillance. Patients with stage II or III colorectal cancer who do not have recurrence are often stressed after undergoing curative resection. Furthermore, false-positive surveillance results may cause more stress in such patients, and it is likely that patients with early-

stage disease have similar stress.[24,25] The cost-effectiveness of surveilling patients with early-stage disease is another concern. It has been previously reported that the proportion of patients with early-stage colon cancer in whom recurrence can be detected through routine monitoring of serum CEA levels and imaging studies is very small.[26] In our study, the recurrence rate in patients with early-stage disease was low (approximately 5%). In the United States, less than $50,000 to $100,000 per quality-adjusted life year for a patient was considered to have an acceptable cost-effectiveness ratio.[27] However, in Taiwan, due to the national health insurance system, which is a part of the social welfare system, performing such surveillance and procedures is relatively cost-effective. Therefore, the cost-effectiveness of surveilling patients with early-stage colorectal cancer must be evaluated in future studies.

A limitation of our study is its retrospective design. Additionally, we did not evaluate patient stress, quality of life, and the cost-effectiveness of surveillance. Most current guidelines suggest only the performance of colonoscopy for follow-up evaluations for patients with stage I disease. In our study, we used serum-CEA-level monitoring and imaging tools for surveillance. Although recurrence occurred in only 5% of the patients with early stage disease, surveillance may still be indicated for the early discovery of recurrence in asymptomatic patients. Recurrence occurred in most patients in the first 5 years following the initial surgeries (in 88% of included patients) and especially in the first 2 years following the initial surgeries (in 65% of included patients). Surveilling patients more than 5 years after they have undergone treatment is not suggested in the current major guidelines. Thus, to determine the benefits of intense and long-term follow-up, further studies may be needed to evaluate whether intense surveillance should be conducted during the first 2 to 3 years following treatment and whether it should be conducted 5 or more years after treatment.[28]

In conclusion, after they have undergone curative surgery, patients with late- and early-stage disease who have recurrent cancer derive similar benefits from secondary curative surgery under similar surveillance

strategy. However, patient stress caused by surveillance and the cost-effectiveness of surveilling patients during follow-up periods may be factors that need to be considered. Furthermore, similar surveillance methods can be used to detect recurrence in patients with both early- and late-stage colorectal cancer, who often experience asymptomatic recurrence.

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<u>原　　著</u>

早期大腸直腸癌術後追蹤之策略

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目的　因為目前對於早期大腸直腸癌術後追蹤仍存在爭議。為了查明大腸直腸癌早期 (病理分類第一期) 的術後追蹤是否與晚期 (病理分類第二、三期) 享有相同的益處。

方法　挑選本院 1995 年至 2011 年轉移性大腸直腸癌術後的患者，分析復發因子。另外也探討患者於復發後接受第二次手術後的存活分析。

結果　於 1995 年至 2011 年，本院共有 10224 名患者接受大腸直腸癌手術，並於術後病理分期為第一至三期。其中共有 2568 名患者發生復發，其中早期大腸癌有 130 位 (5.4%)，晚期則有 2568 位 (25.11%)。而早期最常見發生復發的位置為，肺臟 (36.3%) 以及肝臟 (32.4%)。在發現復發的追蹤工具中，大腸直腸癌早期的患者與晚期並無不同，最常見為血液癌胚胎抗原的異常，第二常見則是影像上的異常。而早期大腸直腸癌患者在發生復發後有 40.7% 進行第二次根治性手術，存活月數中位數為 32 個月，未進行第二次根治性手術的患者存活月數中位數則為 17 個月。

結論　早期大腸直腸癌術後的病人，進行適當的追蹤，可以享有和晚期病人相同益處。但若對早期大腸直腸癌的病人進行追蹤，於追蹤期間病患承受的壓力以及所花費的成本性價比是需要考量的。

關鍵詞　早期大腸直腸癌、術後追蹤、復發。