Original Article

The Clinical Significance of Uracil-Tegafur (UFUR) was Compared Between Low-risk and High-risk Stage IIA Colorectal Cancer Patients: A Retrospective Study from a Single Center

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Key Words
Uracil-tegafur (UFUR);
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Adjuvant chemotherapy (AC);
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Overall survival (OS)

Purpose. Adjuvant chemotherapy (AC) with fluorouracil-based regimen has been used for patients with stage III colorectal cancer (CRC) for many years, although the limited number of studies for patients with stage IIA CRC and the role of AC in stage II colorectal cancer make this treatment still controversial. The aim of this study is to determine better treatment strategies for low-risk and high-risk patients with stage IIA disease.
Methods. From April 2017 to January 2022, 157 CRC patients with stage IIA who underwent surgery were initially enrolled, with disease-free survival (DFS) and overall survival (OS) between low-risk and high-risk patients with stage IIA who received treatment with AC being respectively compared.
Results. No significant differences in these parameters including sex, age, primary lesion site, histology, microsatellite instable (MSI) status, AC regimen between two groups (all $p > 0.05$) were found, although the group of high-risk patients with stage IIA exhibited significantly inferior overall survival rates than the low-risk group ($p = 0.049$) but not so in disease-free survival rates ($p = 0.112$).
Conclusions. For patient with high-risk stage IIA colorectal cancer, AC is suggested due to a previous study already showing survival benefits. Our results suggest AC with UFUR is an acceptable treatment option for high-risk stage IIA patients without inferior DFS than low-risk stage IIA patients, but those patients with high-risk still have inferior outcomes in the long-term OS rates in our study.

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High incidences of colorectal cancer (CRC) make it the second most common cancer in Taiwan,[1] and the third most common globally with a rapidly increasing trend over recent decades. In Taiwan, 17,643 additional patients were newly diagnosed with CRC in 2022 according to the data from Taiwan Ministry of Health and Welfare.[1]

Stage II CRC patients were defined as the absence of lymph node metastases or distant metastases. Previous studies found better survival in patients with stage IIIA CRC compared to patients with stage IIB/C CRC, although both were treated with AC.[2-6] Another

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study found no statistical significance of survival outcome between stage IIA and IIIA CRC patients with adequate lymph nodes being harvested,[7] while yet another found no statistical significance of survival outcome between stage IIA and IIIA CRC patients with adequate lymph nodes being harvested.[7] Radical surgical resection followed by adjuvant chemotherapy (AC) with combination of fluoropyrimidine and oxaliplatin has been the standard treatment in patients with stage III CRC for years, with known significant reduction in the risk of recurrence and death;[8-11] however, the role of AC in patients with stage II CRC is still controversial and the main treatment for stage II disease is surgical resection.

The criteria of high-risk features for patients with stage II disease are (1) fewer than 12 harvested lymph nodes; (2) T4 tumor stage; (3) bowel obstruction or tumor perforation at the tumor site; (4) poor histologic grade; (5) lymphovascular invasion (LVI); and (6) perineural invasion (PNI). Patients who meet one or more high-risk features are defined as high-risk patients with stage IIA disease. The recurrence rate in high-risk stage II disease is similar to stage III disease, and for these patients, AC with fluoropyrimidine-base regimen is recommended.[13] T4 stage was found to be the most important feature of stage II disease. Some studies have shown that AC was associated with an advantage in overall survival rates (OS) and disease-free survival rates (DFS) in high-risk stage II patients with T4 disease (stage IIB/C), but plays a limited role in patients with low-risk and non-T4 disease (stage IIA).[15,16] One study analyzing high-risk features of stage IIA CRC to determine which affect OS the most, revealed that T4 tumors were associated with the highest risk for reduced OS compared to stage II patients without any high-risk features.[17] Another study of pT4 patients with stage II CRC revealed association with higher OS compared to other high-risk features,[18] while a further study showed stage IIA CRC received AC with significantly higher 5-year OS compared to surgery only, especially in high-risk stage IIA CRC patients.[19]

The latest American Society of Clinical Oncology (ASCO) guidelines recommend against routine use of AC for patients with stage II disease.[12] Patients with pT4 tumors are at higher risk of recurrence and should be offered AC, whereas patients with other high-risk factors could be offered AC. Capecitabine or uracil-tegafur (UFUR) is an alternative oral drug combination for patients with low-risk stage II disease with less side effects and inconvenience.[14,23] The aim of this study is to compare the clinical significance between patients with low-risk stage IIA and high-risk stage IIA who all received AC with UFUR treatment.

Material and Methods

Patients and study design

Patients were retrospectively selected from the database at Kaohsiung Medical University Chung-Ho Memorial Hospital from April 2017 to January 2022. Initially, 157 patients who were pathologic stage IIA CRC after surgery and had received UFUR treatment were enrolled, while patients that had received neoadjuvant chemotherapy initially with follow-up time being less than 6 months were excluded. The study protocol was approved by the Institutional Review Board of Kaohsiung Medical University Hospital (KMUHIRB-E(I)-20230267).

Clinicopathological features

All patients were diagnosed by colonoscopy and underwent abdominal and pelvic computed tomography (CT) scans for preoperative cancer staging. Disease staging was defined by the American Joint Committee on Cancer (AJCC) 8th edition. Parameters included sex, age, Eastern Cooperative Oncology Group (ECOG), primary lesion site, lymphovascular invasion (LVI), perineural invasion (PNI), histology, microsatellite instability (MSI) status, recurrence and early recurrence. Patients were stratified into high-risk and low-risk groups according to National Comprehensive Cancer Network (NCCN) guidelines. No matter whether being high-risk or low-risk patients with stage IIA, all received adjuvant UFUR treatment.

Oncologic outcomes

Disease-free survival rates were defined as the time

from randomization to recurrence of tumor or death, with overall survival rates defined as the time from the date of randomization until the date of death or the last date of follow-up. The definition of early recurrence was local recurrence or distant metastases to occur within 12 months postoperatively.

Follow-up

For recurrence evaluation, the follow-up protocol was according to NCCN guidelines; viz., checking carcinoembryonic antigen (CEA) level every three months in the first 2 years, then every six months for 3 years with abdominal or pelvic (computer tomography) CT every 6-12 months for 5 years, following colonoscopy 1 year after surgery.

Statistical analysis

Differences between categorical variables were determined using Pearson's chi-squared test and survival analysis was conducted using the Kaplan-Meier method with the log-rank test. Statistical significance was set at a p-value of < 0.05. Statistical analyses were performed utilizing SPSS version 30.0 (SPSS Inc., Chicago, IL, USA).

Results

Patient characteristics

From April 2017 to January 2022, 157 patients with a pathohistological diagnosis of stage IIA CRC underwent radical surgery. Totally, 103 patients met the inclusion criteria and 11 patients did not receive adjuvant chemotherapy while 2 patients were lost to follow-up over 1 year; finally, 90 patients entered analysis, and among these, 59 were placed in the low-risk group and 31 in the high-risk group. The CONSORT diagram is presented in Fig. 1.

Summary data regarding baseline characteristics and treatment outcomes are detailed in Table 1. No significant differences in various parameters including sex, age, primary lesion site, histology, microsatellite instability (MSI) status nor adjuvant chemotherapy regimen between two groups were found (all $p > 0.05$).

Outcomes

The cut-off time was till January 2025 and the median follow-up time was 52.5 months (range: 4-81 months). No significant differences were found between low-risk and high-risk patient groups in recurrence (8.5% vs. 19.4%, $p = 0.134$) and early recurrence (5.1% vs. 6.5%, $p = 0.788$). High-risk patients with stage IIA did not exhibit significantly inferior DFS than the low-risk group ($p = 0.112$) (Fig. 2A) but were significantly inferior in OS rates ($p = 0.049$) (Fig. 2B).

Discussions

In this retrospective study, low-risk and high-risk patients with stage IIA CRC with radical surgery followed by adjuvant UFUR treatment were compared. UFUR for the patients with stage II or stage III CRC was reimbursed by the Taiwan National Health Insurance (NHI) system. The results of this retrospective research indicated that there was no significant superiority between low-risk patients with stage IIA CRC and high-risk patients with stage IIA CRC in DFS, recurrence or early recurrence.

Most studies have not demonstrated survival improvement of AC for low-risk stage IIA CRC patients.[26-30] These studies showed lower DFS and OS in high-risk stage IIA CRC compared to low-risk groups. In our study, no significant difference of DFS was found between the two groups, but OS was significantly lower in the high-risk group. One possible reason is that AC is not mainstream treatment for low-risk stage IIA CRC. A previous study showed worse DFS or OS in high-risk stage IIA CRC compared to low-risk stage IIA CRC when both were treated with AC, but only 12.4% of low-risk stage IIA CRC patients received AC in the study.[15]

In the initial data of our study, 87.4% of all stage IIA CRC patients (90 out of 103 patients) received AC

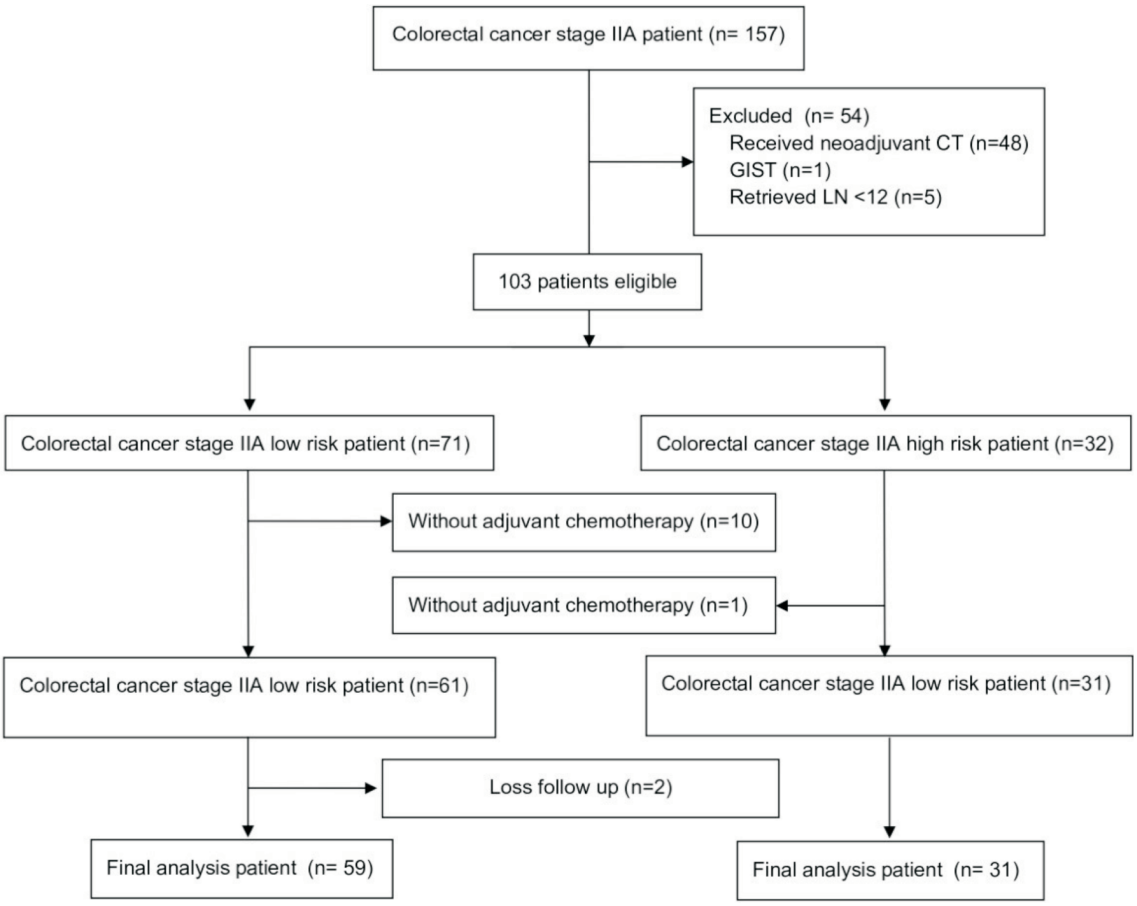

Fig. 1. CONSORT diagram of this study. The final patient number for analysis was 90. Collection was from April 2017 to January 2022, and database was locked for final analysis on January 2025. Median follow-up time was 52.5 months (range 4 to 81 months).

and 96.7% of the low-risk group patients chose UFT because of the Taiwan NHI system. Poorly differentiated histology and PNI have been considered important risk factors for mortality.[19-21] LVI has also been considered as a prognostic factor for OS and DFS although benefit from AC remains controversial.[19,21,22] Although there are few studies comparing OS between low-risk and high-risk groups, these high-risk features might explain the significant difference of OS in our study. One study showed that AC lowered the risk of death by 26% in the low-risk patients and by 24% in the high-risk group.[33] More risk feature comes with worse survival rate but AC can offset this effect to some degree;[33] nevertheless, two studies suggest no survival benefit of AC in low-risk groups.[34,35]

A previous study showed significantly different 5-year DFS between low-risk and high-risk stage IIA CRC patients (92.1% vs. 79.2%, $p = 0.003$),[24] while other studies have shown significantly improved DFS in high-risk groups (DFS with and without AC, 87.3% vs. 78.9%, $p = 0.028$), but not in low-risk groups.[32] This might explain our result of the high-risk group without inferior DFS over that of the low-risk group. Further study is needed to decide AC treatment in these patients.

Limitations

Our study possesses several limitations. Firstly, this is a single-institution retrospective study including only 90 patients, raising the possibility of sampling bias; secondly, the median follow-up time was 52.5 months, possibly making the outcome result less

Table 1. Characteristics of the 90 enrolled patients with stage IIA colorectal cancer

	Total (n = 90)	Low-risk group[1] (n = 59)	High-risk group[2] (n = 31)	*p*-value
Characteristic	n	n (%)	n (%)	
Gender				0.945
Male	46	30 (50.8)	16 (51.6)	
Female	44	29 (49.2)	15 (48.4)	
Age (y/o)				0.413
< 65	46	32 (54.2)	14 (45.2)	
≥ 65	44	27 (45.8)	17 (54.8)	
ECOG performance status				
0 and 1	90	59 (100)	31 (100)	
≥ 2	0	0 (0)	0 (0)	
Sideness				0.121
Right-sided[3] colon	33	25 (42.4)	8 (25.8)	
Left-sided[4] colon	57	34 (57.6)	23 (74.2)	
LVI				< 0.001*
Yes	11	0 (0)	11 (35.5)	
No	79	59 (100)	20 (64.5)	
PNI				< 0.001*
Yes	19	0 (0)	19 (61.3)	
No	71	59 (100)	12 (38.7)	
Histologic grade				< 0.001*
Moderately differentiated	86	59 (100)	27 (87.1)	
Poorly/undifferentiated	4	0 (0)	4 (12.9)	
Bowel obstruction/perforation				< 0.001*
Yes	2	0 (0)	2 (6.5)	
No	88	59 (100)	29 (93.5)	
Histology				0.503
Adenocarcinoma	86	57 (96.6)	29 (93.5)	
Mucinous adenocarcinoma	4	2 (3.4)	2 (6.5)	
MSI status				0.695
High	10	6 (10.2)	4 (12.9)	
Low/stable	80	53 (89.8)	27 (87.1)	
Treatment outcome				
Recurrence				0.134
Yes	11	5 (8.5)	6 (19.4)	
No	79	54 (91.5)	25 (80.6)	
Early recurrence[5]				0.788
Yes	5	3 (5.1)	2 (6.5)	
No	85	56 (94.9)	29 (93.5)	

Note. Data are given as no. (%) except where otherwise noted.
High-risk factors for recurrence: poorly differentiated/undifferentiated histology; lymphatic/vascular invasion; bowel obstruction; < 12 lymph nodes examined; perineural invasion; localized perforation; close, indeterminate, positive margins; or high-tier tumor budding.
† *p*-value was calculated by the Chi-square test for the categorical data. * Statistical significance.
[1] Low risk group: patient without high-risk factors for recurrence. [2] High risk group: patient with high-risk factors for recurrence.
[3] Left-sided colon: descending colon + sigmoid colon + rectosigmoid junction + rectum. [4] Right-sided colon: cecum + ascending colon + transverse colon. [5] Early recurrence within 1 year after operation.
y/o, years old; ECOG, Eastern Cooperative Oncology Group; LVI, lymphovascular invasion; PNI, perineural invasion; MSI, microsatellite instability.

accurate; and thirdly, a better method to determine the treatment strategy could be via comparing outcomes of AC and observation within the same group (low risk or high-risk group). Because of the Taiwan NHI system however, most patients chose oral AC with UFT whether having high- or low-risk disease, as it is

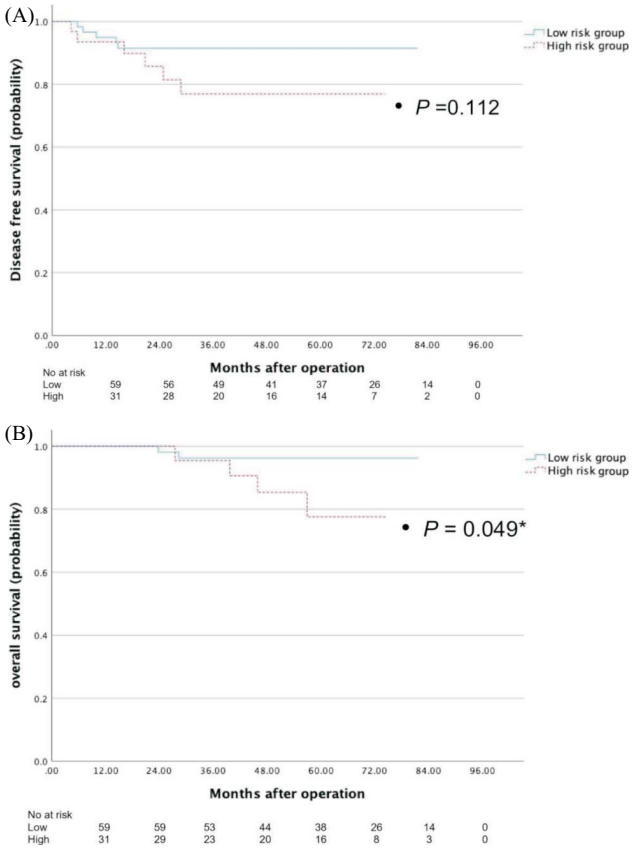

Fig. 2. Cumulative disease-free survival (DFS) rates and overall survival (OS) rates of the 90 enrolled patients with stage IIA CRC, obtained using the Kaplan-Meier method. Difference in DFS and OS were analyzed using the log-rank test. The results demonstrated that (A) The DFS of high-risk patients with stage IIA was not significantly inferior to that of low-risk patients with stage IIA (p = 0.112). (B) The OS of low-risk patients with stage IIA was significantly superior to that of high-risk patients with stage IIA (p = 0.049).

affordable and more convenient for them. Only 11 patients chose observation after operation, thereby raising the possibility of sampling bias. Finally, the latest NCCN guidelines (2024 version) stratified colon cancer to MSS (microsatellite stability) and the MSI-H group. For stages 0-IIB colon cancer with MSI-H, radical surgery alone is suggested whether high-risk features are met or not; accordingly, AC is not suggested for such patients because of lack of efficacy of standard fluorouracil-based therapy.[25] Ten (11.1%) patients with MSI-H colorectal cancer in our study population might have further increased sampling bias.

Conclusion

ASCO guidelines recommend against routine use of AC for patients with low-risk stage IIA disease. NCCN guidelines suggest both observation or UFUR as treatment options followed up by radical surgery for low-risk patients with stage IIA disease. Our results suggested that AC with UFUR was an acceptable treatment option for high-risk stage IIA patients in DFS, but those patients with high-risk still had inferior outcomes in the long-term OS rates in our study. Further prospective studies with extended follow-up durations and substantial sample sizes are warranted to validate our observational results.

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Authors' Contributions

All authors contributed equally to the writing of the manuscript, reviewed any revisions that were made and provided their final approval of the manuscript.

Consent for Publication

Written informed consent was obtained from the patients for the treatment. In addition, written informed consent was obtained from the patients' families for publication of this case report and any accompanying images.

Competing Interests

The authors declare that they have no competing interests.

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原　著

Uracil-tegafur (UFUR) 在低風險和高風險 5 之 IIA 期結直腸癌患者中的臨床意義的比較：單一機構回顧性研究

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目的　以 uracil-tegafur (UFUR) 為基礎的輔助化學治療已多年應用於第三期結直腸癌患者。然而，針對第 IIA 期結直腸癌患者的研究相對較少，且輔助化學治療在第二期結直腸癌中的角色仍具爭議。本研究旨在探討第 IIA 期低風險與高風險患者的最佳治療策略。

方法　本研究回溯性分析 2017 年 4 月至 2022 年 1 月間，157 位接受根治性結直腸癌手術治療之第 IIA 期患者。研究比較接受輔助化學治療之低風險與高風險第 IIA 期患者之無病存活率與存活率。

結果　在性別、年齡、原發病灶位置、組織學類型、微衛星不穩定性狀態及輔助化學治療等臨床參數方面，兩組間無顯著差異 (均 $p > 0.05$)。然而，高風險第二期 A 期患者之總存活率顯著低於低風險組 ($p = 0.049$)，但其無病存活率並無顯著差異 ($p = 0.112$)。

結論　針對高風險第 IIA 期結直腸癌患者，建議施行輔助化學治療，因先前研究已顯示其具益處。本研究結果進一步顯示，對於高風險第 IIA 期患者，以 UFUR 為基礎之輔助化學治療為可接受之選項，其無病存活率並不差於低風險患者，但我們的研究顯示高風險組之總存活率仍是較低。

關鍵詞　Uracil-tegafur (UFUR)、第 IIA 期結直腸癌、輔助化學治療、無病存活率、存活率。