Original Article

Survival Rate between Intravenous Adjuvant Chemotherapy in Inpatient and Outpatient Department Settings for Patients with Stage III Colorectal Cancer

Ying-Jing Chen
Ming-Cheng Chen
Joe-Bin Chen
Feng-Fan Chiang
Chou-Chen Chen
Division of Colorectal Surgery, Department of Surgery, Taichung Veterans General Hospital, Taichung, Taiwan

Key Words
Colorectal cancer;
Stage III;
Intravenous chemotherapy;
Out-patient department;
In-patient department;
FOLFOX;
XELOX

Purpose. Adjuvant chemotherapy with oxaliplatin plus fluoropyrimidine for 6 months has become the standard treatment for stage III colorectal cancers since 2004.
Some patients receive intravenous chemotherapy at the inpatient department (IPD) rather than the outpatient department (OPD) because of several reasons, such as commercial health insurance, severe side effects or relatively poor general conditions. In addition, the limited availability of beds causes delayed admissions for those patients who received inpatient chemotherapy. This retrospective study aimed to evaluate the effects of delayed admissions for adjuvant chemotherapy on oncologic results.
Methods. Patients with stage III colorectal cancer who had received more than 6 cycles of intravenous chemotherapy of FOLFOX or XELOX from January 2010 to December 2014 at Taichung Veterans General Hospital, Taichung, Taiwan were enrolled in this retrospective study.
We utilized IBM SPSS ver. 22.0 as the statistical software to run our analysis. The Kaplan-Meier method was used to analyze the disease-free survival (DFS) and overall survival (OS) rates. Statistical results were considered significant when the *p*-value was less than 0.05.
Results. A total of 257 patients were enrolled. Among them, 211 patients were in the OPD group, and 46 patients were in the IPD group. The age between these groups showed a statistically significant difference, and the median age of OPD: IPD was 58 [51-67]: 53 [46-66] ($p = 0.024$). There is no statistical difference in gender, co-morbidities, ECOG PS score, location of tumor, adverse effects, time to initiate chemotherapy and the number of cycles between the 2 groups. Meanwhile, the median duration of chemotherapy (months) and the standardized median duration of chemotherapy were significantly longer for the IPD group than the OPD group (5.75 months [5.32-6.21] vs. 6.44 months [5.75-7.85], $p < 0.001$ and 5.98 months [5.52-6.67] vs. 7.15 months [6.21-8.15], $p < 0.001$). No significant difference in 3-year DFS rate (71.3% vs. 65.7%), 5-year DFS rate (63.1% vs. 58.9%) ($p = 0.697$), and 5-year OS rate (80.7% vs. 84.3%, $p = 0.306$) was found between the OPD and IPD groups.
Conclusion. The treatment duration showed a significant difference between the OPD and IPD groups. However, no statistically significant difference in 3-year/5-year DFS and 5-year OS was found between the two groups. Therefore, even though patients with IPD would have to prolong the interval of the entire treatment, the outcome is non-inferior to that of the OPD group.
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Correspondence to: Dr. Ming-Cheng Chen, Division of Colon & Rectal Surgery, Department of Surgery, Taichung Veterans General Hospital, No. 1650, Sect. 4, Taiwan Boulevard, Taichung 40705, Taiwan. Tel: 886-4-2359-2525; Fax: 886-4-2359-5046; E-mail: vghtc.crs@gmail.com

It is the consensus that surgery plus chemotherapy provide a better outcome than surgery alone in stage II and III colon cancer.[1,2]

The Multicenter International Study of Oxaliplatin/5-Fluorouracil/Leucovorin (FOLFOX) in the Adjuvant Treatment of Colon Cancer (MOSAIC) reported promising results.[3,4] The study collected stage II or III colon cancer patients who had a curative operation, and then compared the outcome of those patients who received chemotherapy 5-fluorouracil/leucovorin (FL) alone or FOLFOX for 6 months. The rate of disease-free survival at 3 years was higher in the group FOLFOX than the FL alone group (78.2% vs.72.9%, p = 0.002).

The National Surgical Adjuvant Breast and Bowel Project (NSABP) C-07 report found improvement in disease-free survival (DFS) in patients with stage III colon cancer.[5,6]

In this study, a better outcome of disease-free survival was noted in FOLFOX group than FL group. Initial phase III trial showed the DFS rates at 3-year/ 4-year were 76.1%/73.2% for FOLFOX and 71.8%/ 67% for FL. HR of FOLX vFL is 0.80 (95% CI 0.69 to 0.93, $p < 0.04$). Further follow-up detail was present in 2011. DFS at 5 years between FOLFOX and FL were 69.4% vs. 64.2% (HR, 0.82; 95% CI, 0.72 to 0.93; $p = .002$). However, there is no significant difference in overall survival between FL and FOLFOX.

Apart from FOLFOX, XELOX (capecitabine and oxaliplatin) would also be the choice of adjuvant therapy for stage III colon cancer.

For those who do not want to receive IV bolus chemotherapy over extended hours, XELOX can also be an alternative. Oral capecitabine has the same efficacy as IV FL in DFS. The study also concluded that capecitabine has fewer grade 3 or 4 side effects of fluoropyrimidine (e.g. diarrhea, hand-foot-syndrome, alopecia, neutropenia, etc.) than FL ($p < 0.001$).[7]

The outcome of DFS for XELOX, a 3-month regimen is not inferior to that of a 6-month regimen (HR: 0.95; 95% CI, 0.85 to 1.06) in the low-risk group. Unfortunately, the benefit of a shorter regimen is not for FOLFOX (HR:1.16; 95% CI, 1.06 to 1.26).[8]

Since a lot of studies support benefit of surgery plus chemotherapy over surgery alone, FOLFOX or XELOX following curative operation was suggested for stage III colorectal patients no matter in OPD or IPD settings.

Due to the long-standing medical development, home-based chemotherapy became another choice for patients.[9,10] The advantages of the out-patient department (OPD) chemotherapy include avoiding hospitalization, lower the cost, administrating drugs safely and effectively, eliminating the commuting time between residence and hospital, saving more time for daily activities or work from home-based chemotherapy, allowing patients to be in a familiar and comfortable environment, having better physical and psychological comfort than the in-patient department (IPD) settings, and higher satisfaction rate.[11,12] Quality of life between two groups was similar.[8]

The advantages of the IPD settings were dealing with professional personnel directly, having immediate response if unpleasant health emergencies should occur, monitoring general conditions more precisely, etc. Instead of IPD treatment, more patients would choose OPD treatment nowadays.

Some patients receive intravenous chemotherapy at the IPD rather than the OPD because of several reasons, such as commercial health insurance coverage of in-patient medical treatment, multiple co-morbidities, and severe side effects from the previous treatment, etc. In addition, the limited availability of beds in our hospital causes delayed admissions for those patients who received inpatient treatment.

A literature mentioned some reasons that cause intercycle delaying of chemotherapy in non-small cell lung cancer (NSCLC), with the highest possibility includes some reasons that are not related to disease or chemotherapy itself.[13] Others include scheduled day of chemotherapy coincide with holiday, patient's infeasible conditions (fever, infection, neutropenia, discomfort or severe adverse effect from last chemotherapy, etc.) or personal reason.

This retrospective study aimed to compare the difference of the OPD and IPD adjuvant chemotherapy, FOLFOX or XELOX, whether there is prolonging duration of chemotherapy in IPD and whether the OS and DFS are affected.

Materials and Methods

Patients

Patients with stage III colorectal cancer who had received 6-12 cycles of intravenous chemotherapy of FOLFOX or XELOX from January 2010 to December 2014 in Taichung Veterans General Hospital, Taichung, Taiwan were enrolled in this retrospective study. The inclusion criteria are (1) Patients with stage III colorectal cancer (with pathologic proof) who received IV FOLFOX or XELOX for 6-12 cycles (2) The total number of chemotherapy cycles was between 6-12, even if the patient had a period of interruption and then restarted the treatment. On the other hands, the exclusion criteria include (1) Double or triple cancers, including other cancer types diagnosed before or after colorectal cancer was diagnosed; (2) FOLFOX or XELOX less than 6 times or more than 12 times; (3) primary chemotherapy regimen other than FOLFOX or XELOX; (4) solely oral chemotherapy; (5) patients who received radiotherapy at any time; (5) under other trials; (6) missing any required data.

Some patients in this study have received chemotherapy in both OPD and IPD. Patients who received FOLFOX or XELOX more than 3 cycles at the OPD are defined as OPD patients, so as IPD patients.

Duration of chemotherapy was calculated from day 14 of the final course of chemotherapy minus day 1 of the 1st cycle of chemotherapy. Because not all patients completed the entire 12 cycles of chemotherapy, standardized duration of chemotherapy was calculated based on (day 14 of the final course of chemotherapy minus day 1 of the 1st cycle of chemotherapy) divided by the number of cycles and then multiplied by 12. The date of case closure is the date of the latest OPD/IPD/ER/examination record at Veterans General Hospital in Taichung (VGHTC), the date of the latest contact record, or the date of death.

Performance status was recorded with Karnofsky scale on our chart, and the score was converted to Eastern Cooperative Oncology Group (ECOG) performance status score accordingly.

Adverse events were evaluated according to National Cancer Institute (NCI) Common Toxicity Criteria.

Survival analysis and statistical methods

Data were collected from the colorectal patients in Taichung Veterans General Hospital. We utilized IBM SPSS ver. 22.0 (SPSS, Inc., Chicago, IL, USA) as the software to run our analysis. The Kaplan-Meier method was used to analyze the DFS and OS rates. Continuous data are expressed as median and interquartile range (IQR). Categorical data are expressed numbers and percentages. Statistical results were considered significant when the p-value was less than 0.05.

Results

Between January 2010 and December 2014, 257 patients with stage III colorectal cancer who had received more than 6 cycles of intravenous chemotherapy of FOLFOX or XELOX were enrolled. Among them, 211 patients were in the OPD group, and 46 patients were in the IPD group. A significant difference in age was found between these groups, with a median age of OPD vs. IPD 58 [51-67] vs. 53 [46-66] (p = 0.024) (Table 1).

Co-morbidities including DM, HTN, MI or CAD and CVD were collected in this study. Diabetes mellitus in OPD and IPD groups was 16.58% vs. 17.39% (p = 0.231); hypertension was 25.59% vs. 26.1% (p = 0.945); myocardial infarction or coronary artery disease was 0.47% vs. 2.17% (p = 0.485) and cardiovascular disease was 6.63% vs. 2.17% (p = 0.090).

ECOG performance status score between two groups were similar. 68.25% vs. 67.39% patients score 0, 19.91% vs. 17.39% score 1, 2.84% vs. 4.35% score 2 and 9.00% vs. 10.87% has unknown score in OPD and IPD, respectively (p = 0.910).

Location tumor site was also compared between OPD and IPD, colon was 58.29% vs. 47.83%, RS colon was 7.58 vs. 8.70% and rectum was 34.12% vs. 43.48% (p = 0.424).

Some of grade 3/4 adverse effects from chemotherapy in OPD vs. IPD were also recorded, neutropenia was 11.4% vs. 15.2% (p = 0.470), peripheral neurotoxicity was 17.1% vs. 15.2% (p = 0.763) and nausea/vomiting was 7.6% vs. 13.0% (p = 0.311). No

significant difference of co-morbidities, tumor locations and PS were noted between two groups.

The median time to initiation of chemotherapy of OPD and IPD was 4.86 vs. 5.07 weeks ($p = 0.392$). 91.9% patients receive chemotherapy within 8 weeks, and 8.06% after 8 weeks in OPD group; 95.7% patients receive chemotherapy within 8 weeks, and 4.35% after 8 weeks in IPD group ($p = 0.541$).

No difference in the median number of cycles of adjuvant chemotherapy received was found between the two groups (12 [10-12] vs. 12 [10-12], $p = 0.932$ (Table 1).

The median duration of chemotherapy (months) and the standardized median duration of chemotherapy showed a statistical difference between the OPD and IPD groups, which were 5.75 [5.32-6.21] vs. 6.44 [5.75-7.85], $p < 0.001$ and 5.98 [5.52-6.67] vs. 7.15 [6.21-8.15], $p < 0.001$ (Table 1).

The 3-year DFS rate between the OPD and IPD groups was 71.3% vs. 65.7% ($p = 0.697$). The 5-year DFS rate was 63.1% vs. 58.9% ($p = 0.697$; Fig. 1). The 5-year OS rate was 80.7% vs. 84.3% ($p = 0.306$; Fig. 2). Both groups showed no statistically significant difference.

Discussion

The strength of this article is that most studies in the past only discussed the efficacy of shortening the duration of the chemotherapy, the number of cycles and the timing of chemotherapy initiation.[5,15-20] It is

Table 1. Baseline demographic of the study sample

	OPD (n = 211)		IPD (n = 46)		*p*-value
Age (Y/O)	58	(51-67)	53	(46-66)	0.024*
Gender					0.417
Female	99	(46.92%)	25	(54.34%)	
Male	112	(53.08%)	21	(45.65%)	
Co-morbidities					
DM	35/211	(16.58%)	8/46	(17.39%)	0.231
HTN	54/211	(25.59%)	12/46	(26.1%)	0.945
MI or CAD	2/211	(0.47%)	1/46	(2.17%)	0.485
CVD	14/211	(6.63%)	1/46	(2.17%)	0.090
ECOG PS score					0.910
0	144	(68.25%)	31	(67.39%)	
1	42	(19.91%)	8	(17.39%)	
2	6	(2.84%)	2	(4.35%)	
Unknown	19	(9.00%)	5	(10.87%)	
Location					0.424
Colon	123	(58.29%)	22	(47.83%)	
RS colon	16	(7.58%)	4	(8.70%)	
Rectum	72	(34.12%)	20	(43.48%)	
Adverse effects (grade 3/4)					
Neutropenia	24/211	(11.4%)	7/46	(15.2%)	0.470
Peripheral neurotoxicity	36/211	(17.1%)	7/46	(15.2%)	0.763
Nausea and vomiting	16/211	(7.6%)	6/46	(13.0%)	0.311
Time to chemotherapy initiation (weeks)	4.86	(4.14-5.86)	5.07	(4.25-5.43)	0.392
< 8 weeks	194	(91.9%)	44	(95.7%)	0.541
≥ 8 weeks	17	(8.06%)	2	(4.35%)	
No. of cycles	12	(10-12)	12	(10-12)	0.932
Duration of chemotherapy (months)	5.75	(5.32-6.21)	6.44	(5.75-7.85)	< 0.001**
Standardized duration of chemotherapy (months)	5.98	(5.52-6.67)	7.15	(6.21-8.15)	< 0.001**

Mann-Whitney U test. Chi-Square test. Fisher's exact test. * $p < 0.05$, ** $p < 0.01$.
Continuous data are expressed as median and IQR. Categorical data are expressed as numbers and percentages.
Abbreviations: OPD: out-patient department; IPD: in-patient department; DM: diabetes mellitus; HTN: hypertension; MI: myocardial infarction; CAD: coronary artery disease; CAD: cardiovascular disease; ECOG PS score: Eastern Cooperative Oncology Group Performance status score.

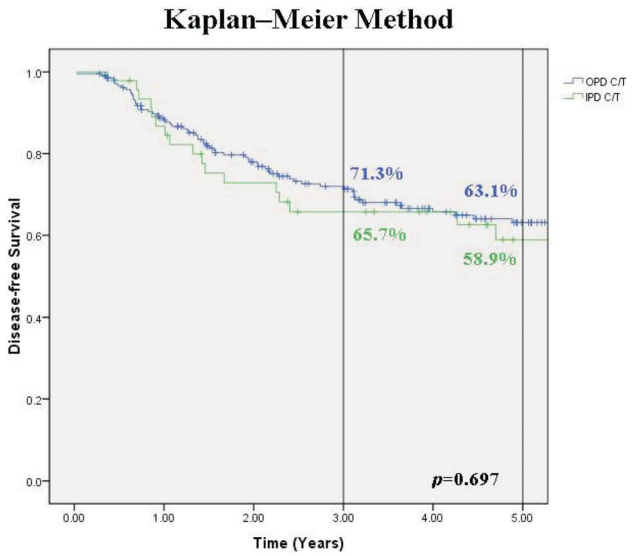

Fig. 1. Kaplan-Meier (K-M) survival curve of disease-free survival. OPD: outpatient department, IPD: inpatient department.

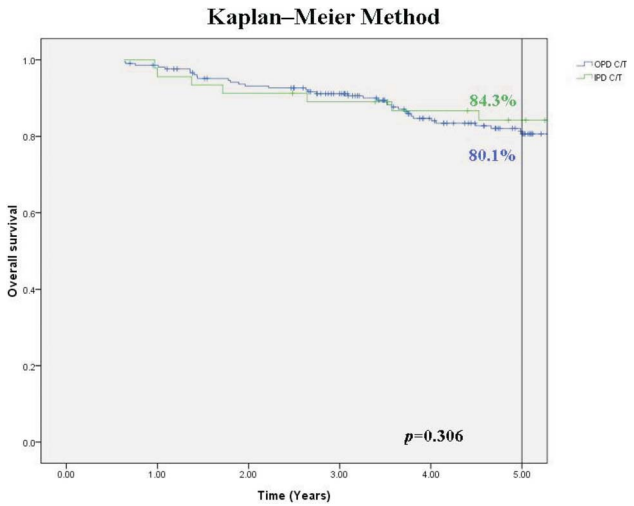

Fig. 2. Kaplan-Meier (K-M) survival curve of overall survival. OPD: outpatient department, IPD: inpatient department.

difficult to find any study about the survival outcome of chemotherapy prolonging. This study revealed that there is no difference in survival outcome between OPD and IPD. Despite the statistical significant difference in treatment duration between the OPD and IPD groups, we did not see the inferior outcome from prolonging the entire treatment schedule.

From this study, we observed that there is no significant difference in gender, co-morbidities, ECOG score, location of tumor site, severe adverse effects, number of cycles and time to initiation of chemotherapy. This probably could explain why there is no difference in survival outcome between two groups.

Although some patients have prolonged duration of treatments, the median time to initiate chemotherapy is < 8 weeks in both groups in our study. Delay of initiation of chemotherapy (≥ 8 weeks) showed poor outcome on overall survival in stage II and III colon cancer patient.[19,20] The median number of cycles of chemotherapy is 12 in these two groups in our study. This result can be ascribed to the fact that most of our patients received enough cycles of treatment. Our 5-year overall survival rate is 80.1% vs. 84.3% in OPD and IPD groups, both outcome are non-inferior to the studies mentioned above. Although our study focused on the result of prolonging treatment. The number of cycles is an important factor for survival.[17,18] As long as the patients receive enough cycles, and if longer intervals between cycles would not affect the treatment efficacy, then patients could rest longer and recover better between cycles at home. It also allows dredging the flow of patients.

The OPD and IPD groups showed a significant difference in age. Commercial health insurance has an age limitation, and the price of insurance premiums increases with age. Higher proportions of patients receive chemotherapy at the IPD only because they have to fulfill the principle of the insurance contract but not because of co-morbidities. Those who could purchase health insurance are probably relatively younger, which could explain why the median age of the IPD group is younger than that of the OPD group.

There are many reasons could cause delay of the treatment, including poor general conditions of the patients such as infection, neutropenia, anemia, or severe side effect. Chemotherapy would be postponed in such conditions not only in IPD patients but also in OPD patients, therefore, this could not explain the delay in IPD. There are only 31 beds are available for CRS patients in VGHTC, which is a medical center. Those who undergo an operation and are in the perioperative period, have postoperative complications and need chemotherapy treatment would share the ca-

pacities. Shortage of beds is surely the major factor for delaying treatment.

One of the limitations of this article is the significant imbalance of patient numbers between the OPD and IPD groups. Considering the deficiency of the hospital beds, some patients that need inpatient chemotherapy were referred to the local hospital. However, a treatment duration difference was still observed between the two groups, with non-inferior outcomes in the IPD group despite having fewer patients than the OPD group. Moreover, the assumption of more patients having commercial insurance in the IPD group is difficult to confirm. And it is hard to prove that shortage of beds is the major reason for delaying chemotherapy in this study, unless more patient data is collected from other oncology department in our hospital.

There are few patients who received chemotherapy in both OPD and IPD settings. Crossed groups for more than three cycles (e.g. an OPD patient received 12 cycles in total, 4 cycles were in IPD and 8 cycles in OPD) may pollute the calculation for the treatment group.

Back to our patient, both OPD and IPD chemotherapy with FOLFOX or XELOX are safe and effective for stage III colorectal cancer patients. Despite of prolonged duration of chemotherapy was noted in IPD patients, those who choose to receive treatment in IPD due to whatever reasons, could keep the way of drug administration without inferior survival outcome.

Conclusion

The significant difference in treatment duration between the OPD and IPD groups did not significantly affect their DFS and OS rates. Therefore, even though IPD patients would have to prolong the interval of the entire treatment, the outcome is non-inferior to that of the OPD group. We can assume if patients received enough cycles, they would get non-inferior results. Our IPD patients do not need to worry about the consequence of delaying treatment. However, we still can do further research for the maximum tolerable intercycle duration that would not affect survival outcomes in the future for possible different treatment strategies.

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Conflict of Interest Statement

The authors declare no conflict of interest in the study.

Role of the Funding Source

The authors declare no role of funding source in the study.

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原　著

第三期大腸直腸癌病人接受門診及住院術後輔助性化學治療的存活率間的比較

陳映菁　陳明正　陳周斌　蔣鋒帆　陳周誠

台中榮民總醫院　大腸直腸外科

目的　為期六個月的術後輔助性化學治療 oxaliplatin 加 fluoropyrimidine，在西元 2004 年起就已經是第三期大腸直腸癌的標準治療。
因為許多不同的因素，例如商業醫療保險，有些病人更傾向於接受住院化療而不是門診化療。但由於床位有限，住院病人必須延遲接受化學治療的狀況很常見。
為了要釐清接受術後輔助性化療的病人是不會因為延遲入院治療而影響到癌症治療的結果，我們做了這個回顧性研究。

方法　此篇回顧性研究蒐集了在 2010 年 1 月到 2014 年 12 月之間被診斷第三期大腸直腸癌的病人，並在台中榮民總醫院接受超過六次的靜脈注射化療 FOLFOX 或 XELOX。統計軟體為 SPSS 第 22 版，我們用 Kaplan-Meier 方法來分析無病存活率及整體存活率。統計結果若 *p* 值小於 0.05 即為統計學上有意義。

結果　總共有 257 個病人被收案，其中門診組有 211 位病人，住院組有 46 位病人。年齡在門診及住院這兩組比較有統計學上的差異，門診病人診斷年齡中位數為 58 歲，住院病人診斷年齡中位數為 53 歲，*p* 值為 0.024。兩組在性別、共病症、ECOG 分數、腫瘤位置、化療副作用、第一次化療開始的時間以及化療次數都沒有統計學上的差異。化療次數中位數兩組皆為 12，*p* 值為 0.932。與此同時，住院組在化療時間 (月) 中位數及標準化化療時間 (月) 的中位都明顯時間較長且有統計學上的意義。門診及住院的化療時間 (月) 分別為 5.75 比 6.44 個月，而標準化化療時間 (月) 中位數則為 5.98 比 7.15 個月，兩者 *p* 值皆 ＜0.001，顯示有統計學上的差異。
三年無疾病存活率為 71.3% (門診) 比 65.7% (住院)，五年無疾病存活率為 63.1% 比 58.9%，*p* 值為 0.679，及五年整體存活率 80.7% 比 84.3%，*p* 值為 0.306，兩者皆無統計學上的差異。

結論　門診及住院化療病人化療時間是有統計學上的差異的，但兩者之間的 3 年、5 年無疾病存活率及 5 年整體存活率是沒有統計學上的差異的。所以即使住院病人化療時間比較長，治療結果也沒有比較差。

關鍵詞　大腸直腸癌、第三期、靜脈注射化學治療、門診、住院、FOLFOX、XELOX。