Original Article

Compare the Treatment Outcome between Stivarga and Lonsurf in Metastatic Colorectal Cancer: A Single Center Experience

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Key Words
Lonsurf;
Stivarga;
Colorectal cancer;
Progression-free survival;
Overall survival

Purpose. Both Lonsurf (Trifluridine/Tipiracil) and Stivarga (Regorafenib) were used in metastatic colorectal cancer patients as a late-line treatment. Although those these two agents were proved having benefits for the metastatic colorectal patients, there only few studies direct compare the effect of them. This study was aimed at finding the difference of outcome between two treatment groups.

Methods. Patients with mCRC treated by Lonsurf or Stivarga in our department from January 2017 to September 2023 were retrospectively enrolled. Patients' age, gender, tumor site, metastasis site, etc. were collected. The Kaplan-Meier method was used to analyze the progression-free survival and overall survival rates. Statistical results were considered significant when the *p*-value was less than 0.05.

Results. Totally 226 patients were included in this study, with fifty-two in Lonsurf group and 154 in Stivarga group. There is no significant difference between two groups of gender, age, tumor site or metastasis site, but patient in Lonsuf group had higher combined therapy rate (57.7% vs. 34.5%, $p = 0.003$). The Lonsurf group also had higher treatment image response rate (11.5% vs. 3.4%, $p = 0.022$), but there was no significant difference of progression-free survival and overall survival between two groups.

Conclusions. In our study, despite there are significant difference in combined therapy rate and treatment image response rate in two groups, the long-term outcome of progression free survival and overall survival had no significant difference between two treatment groups. Limitations exist such as retrospective study design and less case in single institution. Further subgroup analysis including combined therapy regimen and subsequent therapy regimen may be needed to identify the treatment efficacy.

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As the third prevalent malignancy worldwide, over 1.9 million new colorectal cancer (CRC) cases and 930,000 deaths were estimated in 2020.[1]

In Taiwan, there were 16238 cases of newly diagnosed CRC with a high incidence rate (69.47/100,000), and a mortality rate of 28.48/100,000 was recorded in 2021.[2]

About 33% of patients with CRC will develop

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metastases either at presentation or during follow-up.[3] Fluoropyrimidine-based cytotoxic chemotherapy has long been the mainstay of treatment.[4]

Despite chemotherapy plus target therapy had been proved benefit for metastatic colorectal cancer (mCRC),[5,6] refractory mCRC still had poor prognosis with dropped survival.

Thus, two oral form medications: Lonsurf (Trifluridine/Tipiracil) and Stivarga (Regorafenib) had been proved to prolong the survival of refractory mCRC as a third- to fourth-line treatment.

Stivarga had been approved by the U.S Food and Drug Administration (FDA) since September 27, 2012. The CORRECT trial revealed that median overall survival was 6.4 months in the regorafenib group versus 5.0 months in the placebo group ($p = 0.0052$) and demonstrated a 51% reduction in the risk of disease progression or death (hazard ratio: 0.49, 95% CI: 0.42-0.58, $p < 0.0001$).[7] The following trial including CONCUR trial which emphasizing in Asian patient also proved that Stivarga had a benefit for these Asian patient.[8]

Lonsurf had been approved by FDA since September 22, 2015. Patients treated with Lonsurf lived an average of 7.1 months compared to 5.3 months for those who received a placebo pill. And the average progression free survival (PFS) with Lonsurf vs. placebo were 2.0 months vs. 1.7 months.[9] Following study in real world settings still confirm the benefits of Lonsurf for those MCRC patients.[10,11]

Both oral agents were proved had benefit for mCRC patients as second-line therapy, but less research direct compare these two agents' efficacy. The exciting research which comparing these two medications in mCRC still had controversial results.[12-15]

Thus, this study was aimed at comparing the different groups of treatment strategy of these two medicines for mCRC patients in clinical practice.

Method

Patient

This was a single center retrospective study conducted at Taichung Veterans General Hospital, Taiwan.

We collected the clinical data of patients who had metastatic colorectal cancer (mCRC) and treated with Stivarga or Lonsurf, from July 1, 2017. to September 30, 2023. The last following date was February 29, 2024.

Patients' basic characteristics including age, gender, BSA, primary tumor site, metastases site and KRAS status were collected for further analysis.

Treatment

Patient with Stivarga and/or Lonsurf treatment was included, and the combination regimen, including fluoropyrimidine, oxaliplatin, irinotecan, the anti-vascular endothelial growth factor (anti-VEGF) such as bevacizumab, or the anti-epidermal growth factor receptor (anti-EGFR) such cetuximab or panitumumab, were also collected.

Patient treated with Stivarga had dosage range from 80 mg to 160 mg daily for first 21 days, then had a 7-day period of rest.

The treatment of Lonsurf was 30-35 mg/m^2 twice daily during active treatment days (Days 1 to 5 and 8 to 12 of each 28-day treatment cycle).

The duration of treatment was calculated and recorded for further analysis. The treatment response was defined as image regression according to RECIST criteria.

Statistical analysis

For patients' characteristics, t-test was used for continuous variables and Chi-square test was used for categorical variables.

Overall survival (OS) was defined as the length of time from first time of treatment (Stivarga or Lonsurf) to the date of death or last follow up. Progression free survival (PFS) was defined as the length of time between start of treatment and the time of disease progression.

The OS and PFS were estimated using Kaplan-Meier method.

Significance was established at $p \leq 0.05$.

All the statistical analyses were performed using SPSS Statistics software version 26.0.

Result

Totally 226 patients were included in this study, 52 (23%) patients were Lonsurf group and 174 (77%) were Stivarga group.

The mean age [SD] of Lonsurf vs. Stivarga group was 63.83 [12.01] vs. 61.78 [10.67] (p = 0.239), and the mean BSA [SD] of Lonsurf vs. Stivarga group was 1.60 [0.18] vs. 1.64 [0.19] (p = 0.229). No significant difference between two groups of patients (Table 1).

Other patient's categorical characteristics we analyzed were similar between Lonsurf vs. Stivarga group. The gender of male was 51.9% vs. 62.6% (p = 0.166).

The most primary tumor site were sigmoid colon and rectum, which was 42.3% and 38.5% in Lonsurf group, and 34.5% vs. 43.1% in Stivarga group respectly. There is no significant difference of the primary tumor site between the two groups (p = 0.767).

We analyzed each site of metastasis, the most metastasis site of all patients were liver and lung, 141 [62.4%] patients had liver metastasis and with 132 [60.2%] patients had lung metastasis.

The proportion of the patient with liver metastasis in Lonsurf vs. Stivarga group was 32 [61.5%] vs. 109 [62.6%] (p = 0.885). Patients with lung metastasis in Lonsurf vs. Stivarga group was 29 [55.8%] vs. 107 [61.5%] (p = 0.459).

The number of patients with other metastasis site, including bone, ovary, peritoneum, etc., were also analyzed in Lonsurf group and Stivarga group, without significant statistical differences between two groups.

KRAS mutation number was analyzed between two groups without significant differences, 29 [56.9%] vs. 101 [58.4%] (p = 0.847).

More patient had combined therapy in Lonsurf group vs. Stivarga group, the number of patients was 30 [57.7%] vs. 60 [34.5%] (p = 0.003).

We compare the outcomes of two groups, and the treatment image response rate was 11.5% vs. 3.4% (p = 0.022), which had significant differences (Table 2).

However, the median of PFS and OS in Lonsurf group were 2.53 months [95% CI: 1.99-3.07] and 8.31 months [95% CI: 5.30-11.33]. The median of PFS and OS in Stivarga group were 2.76 months [95% CI: 2.37-3.15] and 8.15 months [95% CI: 6.56-9.73]. No

Table 1. Demographics

	Lonsurf (n = 52)	Stivarga (n = 174)	Total	p value
Gender				0.166[a]
Male	27 (51.9%)	109 (62.6%)	136 (60.2%)	
Female	25 (48.1%)	65 (37.4%)	90 (39.8%)	
Mean age [SD]	63.83 [12.011]	61.78 [10.672]		0.239[b]
Mean BSA	1.6046 [0.17560]	1.6395 [0.18516]		0.229[b]
Tumor site				0.552[a]
Colon	32 (61.5%)	99 (56.9%)		
Rectum	20 (38.5%)	75 (43.1%)		
Metastasis				
Liver	32 (61.5%)	109 (62.6%)		0.885[a]
Lung	29 (55.8%)	107 (61.5%)		0.459[a]
Bone	5 (9.6%)	21 (12.1%)		0.627[a]
Peritoneal carcinomatosis	9 (17.3%)	48 (27.6%)		0.134[a]
Adrenal	2 (3.8%)	4 (2.3%)		0.543[a]
Urniary system	1 (1.9%)	6 (3.5%)		0.801[a]
Distant lymph node	18 (34.6%)	66 (37.9%)		0.664[a]
Ovary	3 (5.8%)	3 (1.7%)		0.111[a]
Local recurrence	7 (13.5%)	35 (20.1%)		0.279[a]
KRAS mutant	29 (56.9%)	101 (58.4%)		0.847[a]
Combined therapy	30 (57.7%)	60 (34.5%)		0.003[a]*

[a] Pearson's Chi-square test. [b] Independent t-test.

Table 2. Compare the treatment response of two groups

	Lonsurf (n = 52)	Stivarga (n = 174)	Total	*p* value
Treatment response				0.022[a]*
Yes	6 (11.5%)	6 (3.4%)	12 (5.3%)	
No	46 (88.5%)	168 (96.6%)	214 (94.7%)	

[a] Pearson's Chi-square test.

significant difference of PFS and OS between two groups ($p = 0.968$ and $p = 0.908$) (Figs. 1, 2).

Discussion

For mCRC patients who have experienced failure with previous systemic treatments, Lonsurf and Stivarga are the new options for subsequent treatment.

Both agents have been proven effective in prolonging overall survival and improving disease control.[16] However, there have been fewer studies emphasizing which one is superior.

Previous studies showed that the efficacy was similar between Lonsurf and Stivarga treatment, including a large sample study published in JNCCN.[14] But the study of Anuj K. Patel et al.[17] had revealed that patients treated with Lonsurf had better tumor response and disease control than patients treated with Stivarga.

Our study had similar patient basic characteristics between two groups, including age, gender, primary tumor site, metastasis site and number, even KRAS status. It represents there is less selection bios from physician's preferences of medicine selection according to patient characteristics.

Besides monotherapy use, Lonsurf had been used as combined therapy with other agent.[18,19] Study of Prager GW et al. showed that it is better combine Lonsurf and Bevacizumab treatment in refractory mCRC patient than Lonsurf only, it was approved by FDA.[20]

Although only Lonsurf had plus bevacizumab had been approved by FDA, some studies showed Stivarga plus other agents can still get better efficacy.[21,22] Thus, our clinical practice included regimens of combined therapy with agents such as 5-FU, irinotecan, oxaliplatin, capecitabine and bevacizumab.

Our study showed that there was more patient underwent combined therapy in Lonsurf group with significant differences, it may be because of the above reasons, and could affect the treatment outcomes. Al-

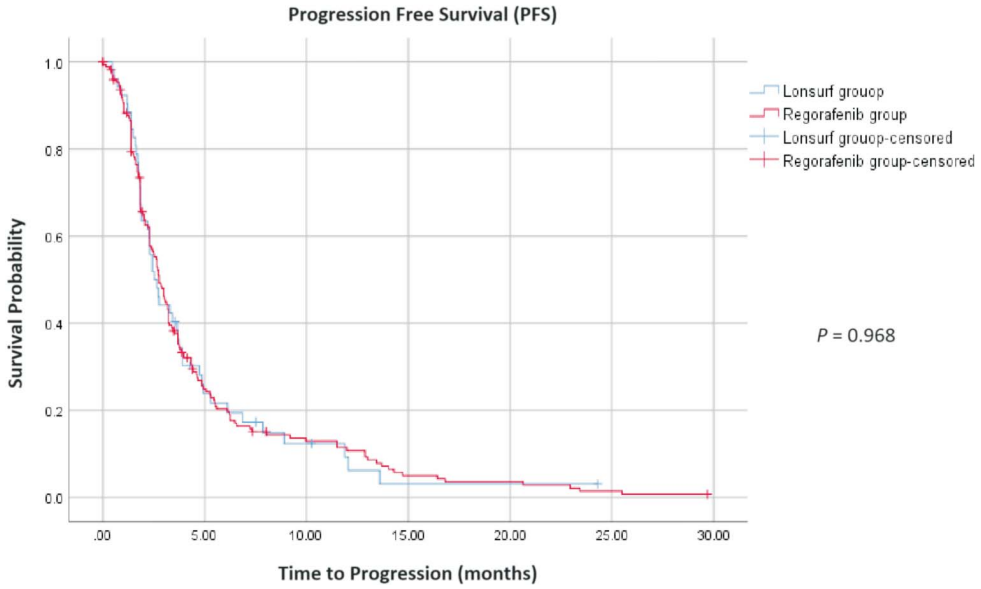

Fig. 1. Progression free survival: Lonsurf vs. Stivarga.

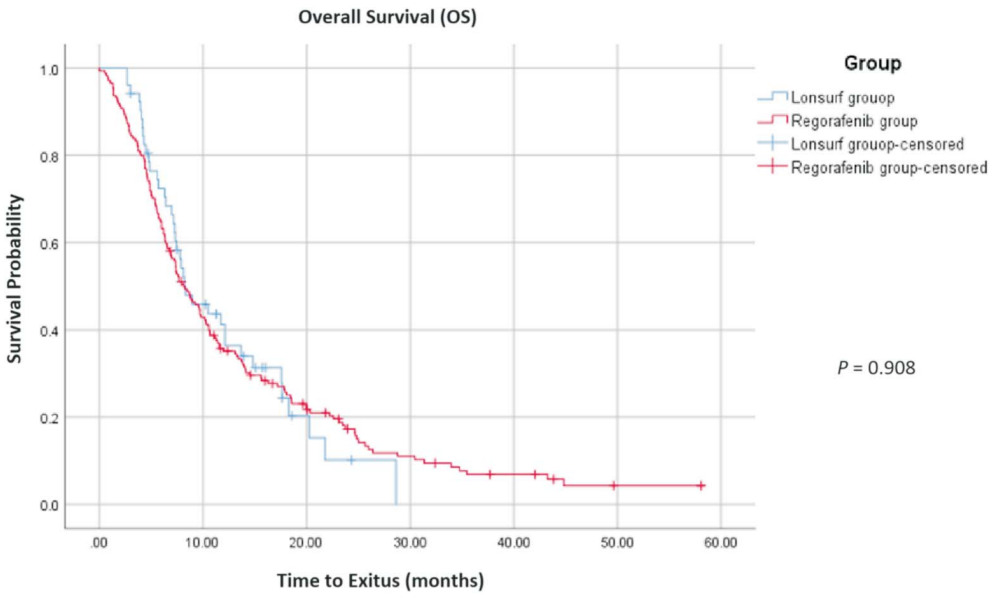

Fig. 2. Overall survival: Lonsurf vs. Stivarga.

though there is no significant difference in PFS and OS analysis, further study to evaluate outcomes between mono- or combined therapy, even Lonsurf followed by Stivarga or the reverse regimen should be needed.

In present study, although the two groups had similar progression-free survival and overall survival, Lonsurf seem to had higher treatment image response rate than Stivarga. It is similar with previous mentioned study.[17] The explanation should be that patient with Stivarga treatment may had a higher portion with stable disease (SD) of RECIST criteria, so the PFS or OS could reached Lonsurf group outcome despite a lower image response rate. This was a real-world retrospective study, the image scan follow up could not always be arranged in a fixed duration. Some study had showed that tumor marker was an accurate evaluation despite compare to image evaluation,[23] it may be consider as an acceptable disease status evaluation for further study design. In addition, PET evaluation was commonly used in colorectal cancer follow up evaluation, and shift the RECIST to PERCIST may lead to a more precise evaluation.[24] Thus, further analysis design for treatment response with different definition will be needed.

The Lonsurf group and Stivarga group had median of PFS: 2.53 and 2.76 months in our study. These results were similar with other previous studies,[25-27] but slightly less than those studies. We thought that it was because the definition of disease progression. Most study define the disease progression as image findings which showed tumor size progression. Otherwise, in our study, elevated serum tumor marker and tumor sized progression in image exam were both consider the disease progression. It could lower the progression free survival rate and results in such consequence. To designs an analysis under same criteria may have a reliable comparison with the results of other studies.

Like most other research, there was no significant OS between the Lonsurf treatment group and Stivarga treatment group. The median OS in present study were 8.31 months [95% CI: 5.30-11.33] of Lonsurf group and 8.15 months [95% CI: 6.56-9.73] of Stivarga group. It seem to be obviously longer than the OS of initial clinical trials and some other articles. In real world clinical practice, both Lonsurf and Stivarga could be used as combined therapy with other agents, even used as the sequential treatment followed another one if disease progression or the patient intolerance.[28-30] Further distribute the patient to more subgroups such as combined therapy or not, or even different groups with sequential therapy of Lonsurf/Stivarga or Stivarga/Lonsurf, will be needed to analyze which treatment

protocol wound had better outcomes.[31]

Limitations of present study exist. First, it was a retrospective non-randomized study, and the sample sized was related small due to single center research. These findings may not lead to a rigid conclusion due to above reasons. Second, both image and chemistry finding were considered when we collected the data of treatment response and disease progression in this our study. It may make the results of present study be difficult in comparing with other studies. Third, although limited combined therapy regimens were approved, different regimen of combined therapy were used during clinical practice, but we had not completed record the therapy type of each patient. The significant difference of efficacy or outcomes may be blocked due to none of subgroup analysis.

Conclusion

For Lonsurf and Stivarga, the treatment efficacy of disease image response had significant differences in our study. However, the follow up progression free survival and the overall survival showed no difference between two group. A prospective randomized study, with combined therapy and sequential therapy type subgroup analysis, should be arranged to figure out which treatment protocol benefit these metastatic colorectal cancer patients most.

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原　著

Lonsurf 以及 Stivarga 在治療轉移性大腸直腸癌病患預後之比較：單一機構之經驗研究

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目的　Lonsurf 以及 Stivarga 都被做為轉移性大腸直腸癌病患的後線治療藥物。雖然兩者都已經證實對於轉移性大腸直腸癌病患有益處，卻只有少數的研究嘗試直接比較兩種藥物效果的差異。因此，這篇研究希望能找出兩種治療方式的預後差異。

方法　此研究回朔性收錄了從 2017 年 1 月到 2023 年 9 月，在本醫院接受了 Lonsurf 或 Stivarga 治療的轉移性大腸直腸癌病患。病患的年紀、腫瘤位置、轉移位置等資料皆被收錄，並利用 Kaplan-Meier 分析兩種治療之存活率，顯著差異定義為 p 值小於 0.05。

結果　共 226 個病患收入此研究分析，其中 52 個為 Lonsurf 組別，174 個為 Stivarga 組別。性別、年紀、腫瘤位置、轉移位置等在兩組之間並無顯著差異。在 Lonsurf 治療的組別，有較高的合併治療比率以及較高的治療影像反應陽性之比率，但在疾病無惡化存活率以及整體存活率的比較中，兩者並無顯著差異。

結論　在此篇研究中，儘管 Lonsurf 組有較高的合併治療比率以及藥物治療影像反應陽性比率，兩組治療的疾病無惡化存活率以及整體存活率並沒有顯著差異。此篇研究存有回朔性研究及單一機構小樣本的統計限制。進一步的研究設計將合併治療或接續治療分組並分析也許能分辨出不同治療組合方式的效果差異。

關鍵詞　朗斯福、癌瑞格、大腸直腸癌、疾病無惡化存活率、整體存活率。