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The safety assessment of COVID-19 vaccine injection in patients with colorectal cancer.

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Background: With the unprecedented morbidity and mortality associated with the COVID-19 pandemic, vaccine against COVID-19 has been more and more popularized in general population. However, the safety of COVID-19 vaccine injection in patients with malignant tumors, such as colorectal cancer (CRC), remains unclear. **Methods:** During January 2021 and January 2022, 148 CRC patients treated in the department of colorectal surgery in the Sixth Affiliated Hospital of Sun Yat-sen University were enrolled in this cohort. The clinical data and COVID-19 vaccine injection outcome data was collected and analyzed retrospectively. Patients who received at least one dose of COVID-19 vaccine injection were set as an observation group and those who did not get any vaccine injection were set as a control group. The median follow-up time was 8.0 months, vaccine-related adverse events (VRAEs) were collected by questionnaire. The disease progression status of CRC was also compared between the two groups. **Results:** Eighty-three CRC (male: female 44:39) patients enrolled in this study have got at least one dose of COVID-19 vaccine injection, with a median follow-up time of 8.0 (2.0–13.0) months and no VRAEs reported. Among the vaccinated patients, 51 patients were injected with inactivated vaccine (Sinovac Life Sciences Co., Ltd.), 10 patients were vaccinated with inactivated vaccine (Beijing Institute of Biological Products Co., Ltd.), others were injected another inactivated vaccine (Chengdu Institute of Biological Products Co., Ltd.). The reasons of the 65 patients (male: female 36:29) who did not injected COVID-19 vaccine including: 53 patients had a concern that vaccination will affect the progress of CRC, 8 patients had a concern of old age to get vaccinated and 4 patients did not give any reason. As for disease progression, 14 patients in the observation group had tumor recurrence or progression, while 8 patients in control group reported tumor recurrence or progression, with a median follow-up time of 8.0 (2.0–13.0) months. There was no significant difference in short-term disease progression between the observation group and the control group ($P = 0.439$). **Conclusions:** Under the background of COVID-19 pandemic and vaccination of general population, it might be necessary for the patients with malignant disease, such as CRC, to get vaccinated due to whose weaken immune system. COVID-19 vaccine injection is safe for CRC patients and COVID-19 vaccination would not affect the patients' prognosis. Research Sponsor: National Natural Science Foundation of China [Grant No. 81972885] and the 1010 project of the 6th Affiliated Hospital of Sun Yat-sen University [1010CG (2020)-20].