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ORIGINAL ARTICLE

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Safety of anti-SARS-CoV-2 messenger RNA vaccine in lung cancer patients undergoing anticancer chemotherapy: A multicenter, prospective, observational, patient-reported outcome study

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Abstract

Background: COVID-19 incidence is high in patients with cancer. The fatality rate was high for the Delta variant, necessitating infection prevention by vaccination. This study evaluated the safety of a SARS-CoV-2 vaccine in patients with advanced lung cancer receiving anticancer therapy.

Methods: We prospectively enrolled patients receiving anticancer drugs for advanced lung cancer and planning SARS-CoV-2 vaccination. Early side effects within 7 days of vaccination were evaluated using patient-reported outcome (PRO) surveys. Chi-square test and multivariate logistic regression analyses were used.

Results: Post-vaccination PROs were collected from 406 patients (252 were males). The mean age was 72 years. Treatment at the time of initial vaccination included chemotherapy, immune checkpoint inhibitors (ICI), a combination of chemotherapy and ICI, targeted therapy including tyrosine kinase inhibitors, and others in 115, 93, 45, 147, and six cases, respectively. The vaccines administered were BNT162b2 and mRNA273 in 361 and three cases, respectively and unknown in 42 cases. A total of 16.1% of patients developed fever (38°C) after the second mRNA vaccination (95% confidence interval: 12.6%–20.1%). This rate is comparable to data previously reported in 120 patients and slightly higher than that of healthy participants of the BNT162b2 study. Patients receiving treatment with cytotoxic anticancer agents were more likely to have high fever. Multivariate analysis showed no correlation between fever frequency and patient background. No serious initial adverse events due to vaccination were observed.

Conclusions: Anti-SARS-CoV-2 mRNA vaccination is safe; however, post-vaccination fever is more common in patients undergoing lung cancer treatment than in healthy individuals.

KEYWORDS
anticancer drugs, COVID-19, lung cancer, SARS-CoV-2, vaccine safety

INTRODUCTION

Since 2020, outbreaks of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections have been occuring worldwide. The severity of COVID-19 varied by variant, but the Delta variant had a higher severity rate.[1] Several drugs, including steroids and antiviral and anti-interleukin-6 drugs, have been used to treat COVID-19. Although antiviral drugs and antibody cocktail therapy were effective in preventing disease severity in the Delta variant,[2,3] their prophylaxis

against disease severity is less effective in the Omicron variant.[4–6] Although vaccine efficacy is low in the Omicron variant,[1,7] booster inoculations can be used to generate neutralizing antibodies.[6,8] Vaccination can also prevent disease severity in people infected with the Omicron variant.[1] The usefulness of a messenger RNA (mRNA) vaccine has already been reported,[9,10] and BNT162b2 and mRNA-1273 are typical SARS-CoV-2 mRNA vaccines currently in use worldwide.

Patients with cancer are at higher risk of developing COVID-19 and have a higher rate of severe disease[11,12]; therefore, preventation of SARS-CoV-2 infection is important. SARS-CoV-2 infection is severe in patients with lung cancer.[13–16] Vaccination is recommended for these patients by the Center for Disease Control and Prevention and National Comprehensive Cancer Network.[17,18]

The SARS-CoV-2 vaccine has a high incidence of side effects such as fever even in healthy individuals, however, there are few serious adverse events.[9,10] Patients with chronic inflammatory diseases receiving immunosuppressive treatment experience the same side effects from vaccines as those of healthy individuals.[19] Seroconversion with SARS-CoV-2 mRNA vaccines can be achieved in patients with cancer.[20] Although some studies have reported the safety of SARS-CoV-2 mRNA vaccines in patients with cancer,[21] there are case reports of cytokine release syndrome.[22] We designed a prospective observational pilot study to test the safety of an anti-SARS-CoV-2 mRNA vaccine in patients with lung cancer undergoing anticancer drug treatment. In these patients, especially those receiving cytotoxic anticancer drugs, fever was more frequent, but no serious adverse events were observed.[23] The analysis of patient-reported outcome (PRO) for all patients enrolled in the study is now complete and is reported here.

METHODS

This article is an update of a previous report on the safety of a SARS-CoV-2 vaccine in 120 lung cancer cases undergoing cancer chemotherapy, with an increased number of cases, and the Methods are the same as in the previous report.[23]

Ethics statements

All participants provided written informed consent. This study was approved by the relevant institutional review board (National Hospital Organization Iwakuni Clinical Center Institutional Review Board, Iwakuni, Yamaguchi, Japan) (no.: 0262) and was conducted in compliance with the Declaration of Helsinki and Ethical Guidelines for Medical and Health Research Involving Human Subjects. The study protocol has been registered on the website of the University Hospital Medical Information Network, Japan (protocol ID: UMIN000043918).

Study design and participants

This multicenter, prospective, observational study, the OLCSG2102 study, included patients with advanced lung cancer, receiving anticancer therapies such as chemotherapy, immune checkpoint inhibitors (ICIs), and molecular targeted therapies. Patients who met the following eligibility criteria were enrolled at seven hospitals in Japan: age ≥ 20 -years, diagnosis of unresectable cancer or recurrent lung cancer, treatment with anticancer drugs, and scheduled SARS-CoV-2 vaccination. Patients with a history of COVID-19 disease and/or SARS-CoV-2 vaccination, inappropriate for SARS-CoV-2 vaccination, or with an estimated prognosis of <2 months were excluded. Although we did not specify the vaccine to be used, the majority of vaccines used in Japan at the time of patient enrollment in this study were BNT162b2, with some mRNA-1273 also being used. No changes between the first and second vaccines were allowed during the enrollment period.

Outcomes

Based on the PRO survey, the coprimary outcomes were the frequency of fever and other side reactions 7 days after the second dose of SARS-CoV-2 vaccination. The secondary outcomes included the frequency of fever and other side reactions 7 days after the first dose of SARS-CoV-2 vaccination, incidence of post-vaccination grade 3 or worse immune-related adverse events (irAEs) in patients receiving ICIs, incidence of post-vaccination COVID-19, and overall and progression-free survival of patients receiving anticancer drug therapy. Axillary temperature was measured in degrees Celsius.

Data collection

The side reaction rating scale for the vaccine was based on the BNT162b2 report.[9] Data on local and systemic reactions and medication use were collected from the patients who had been surveyed for 7 days after each vaccination. Pain at the injection site was assessed according to the following scale: mild, does not interfere with activity; moderate, interferes with activity; severe, prevents daily activity; and grade 4, emergency department visit or hospitalization. Redness and swelling were measured according to the following scale: mild, 2.0–5.0 cm in diameter; moderate, >5.0–10.0 cm in diameter; severe, >10.0 cm in diameter; and grade 4, necrosis or exfoliative dermatitis (for redness) and necrosis (for swelling). The scales of systemic events were as follows: fatigue, headache, chills, muscle pain, joint pain (mild, does not interfere with activity; moderate, some interference with activity; or severe, prevents daily activity), vomiting (mild, 1–2 times in 24 h; moderate, >2 times in 24 h; or severe, requires intravenous hydration), and diarrhea (mild, 2–3 loose stools in 24 h; moderate, 4–5 loose stools in 24 h; or

severe, ≥6 loose stools in 24 h). Grade 4 for all events indicated an emergency department visit or hospitalization. Vaccine-related side effects were reported daily by the patients on a predistributed questionnaire. The patients measured and recorded their body temperature daily for 8 days from the day before vaccination to day 7 after vaccination.

Statistical analysis

Data from the BNT162b2 clinical trial showed that the frequency of fever >38°C after the second vaccination was 11% in patients aged ≥56 years.[9] We assumed that a 10% increase in the frequency of fever >38°C in patients, undergoing treatment for lung cancer, was acceptable. Accordingly, we estimated the required number of patients for the early safety assessment to be 104, with a one-sided significance level of 0.05 and a power of 80%.

Differences were assessed using an analysis of variance or a chi-square test. Adjusted odds ratios were calculated using multivariate logistic regression analysis with the following covariates: sex, age, smoking history, presence of respiratory complications, and type of treatment. All statistical analyses were performed using a standard software package (STATA version 17). The significance threshold was set at $p < 0.05$ for two-sided unpaired tests.

RESULTS

Between April 8, 2021 and August 31, 2021, 500 patients undergoing lung cancer treatment were enrolled to assess vaccine safety and irAEs. Of the 500 registered, 406 PROs were recovered. All patients received two doses of the vaccine. Patient characteristics are presented in Table 1. The median age was 72.0 years (range, 42–91 years), and 252 were males (62%) and 154 females (38%). There were 265 (65%) smokers. All patients had advanced lung cancer, and the histological subtypes were mostly adenocarcinomas ($n = 305$). Treatments received for lung cancer at the time of the first vaccination were chemotherapy, ICIs, a combination of chemotherapy and ICIs, targeted therapies such as tyrosine kinase inhibitors, and other treatments in 115, 93, 45, 147, and six patients, respectively. Four patients changed their treatment regimen between the first and second vaccinations. In this study, 361 of the 406 patients received the BNT162b2 vaccine (Table 1).

Systemic reactions to the first and second vaccinations are shown in Figures S1 and 1, respectively. The frequency of fever >38°C after the first and second (primary outcome) vaccinations were 2.49% and 16.1% (95% confidence interval [CI]: 12.6%–20.1%), respectively. The frequency of fever for each treatment regimen is shown in Table 2. Fever after the second vaccination was slightly more frequent with chemotherapy regimens and less frequent with targeted therapy. The most frequent systemic reactions after the second vaccination were myalgia (52.9% [95% CI: 47.9%–57.8%]) and fatigue (49.9% [95% CI: 44.9%–54.9%]), and no significant difference was observed according to treatment regimens. The local reactions after the first and second vaccinations are shown in Figures S2 and 2, respectively. After the second vaccination, 53.9% (95% CI: 48.9%–58.9%) of patients had pain at the injection site; however, no significant difference was observed between different treatment regimens. Overall, no serious adverse events were observed in this study, and the treatment schedule was not postponed in any patient due to vaccine-related side effects.

Medications, such as steroids and antipyretics, had a negligible effect on fever response (Table S1). In the univariate analysis, fever was less frequent in patients aged ≥75 years, with Eastern Cooperative Oncology Group Performance Status 1 (ECOG PS1) or higher, and in patients treated with molecular targeted therapy; however, it was

TABLE 1 Patient characteristics

Characteristic	Number of patients	%
Total	406	100
Age (years)		
Median (range)	72 (42–91)	
Sex		
Male/Female	252/154	62.1/37.9
ECOG-PS		
0/1/2	148/253/5	36.5/62.3/1.2
Smoking status		
Never smoked/smokers/unknown	140/265/1	34.5/65.2/0.2
Histology		
Ad/Sq/NOS/SCLC/unknown	305/51/36/12/2	75.1/12.6/8.9/3.0/0.5
Vaccine		
BNT162b2/mRNA-1273/unknown	361/3/42	88.9/0.7/10.3
Treatment (first vaccination)		
Chemotherapy	115	28.3
ICI	93	22.9
Chemotherapy plus ICI	45	11.1
Targeted therapy	147	36.2
Unknown	6	1.5
Treatment (second vaccination)		
Chemotherapy	116	28.6
ICI	95	23.3
Chemotherapy plus ICI	42	10.3
Targeted therapy	146	36.0
Unknown	7	1.7

Abbreviations: Ad, adenocarcinoma; ECOG-PS, Eastern Cooperative Oncology Group Performance Status; ICI, immune checkpoint inhibitor; mRNA, messenger RNA; NOS, not otherwise specified; SCLC, small cell lung cancer; Sq, squamous cell carcinoma.

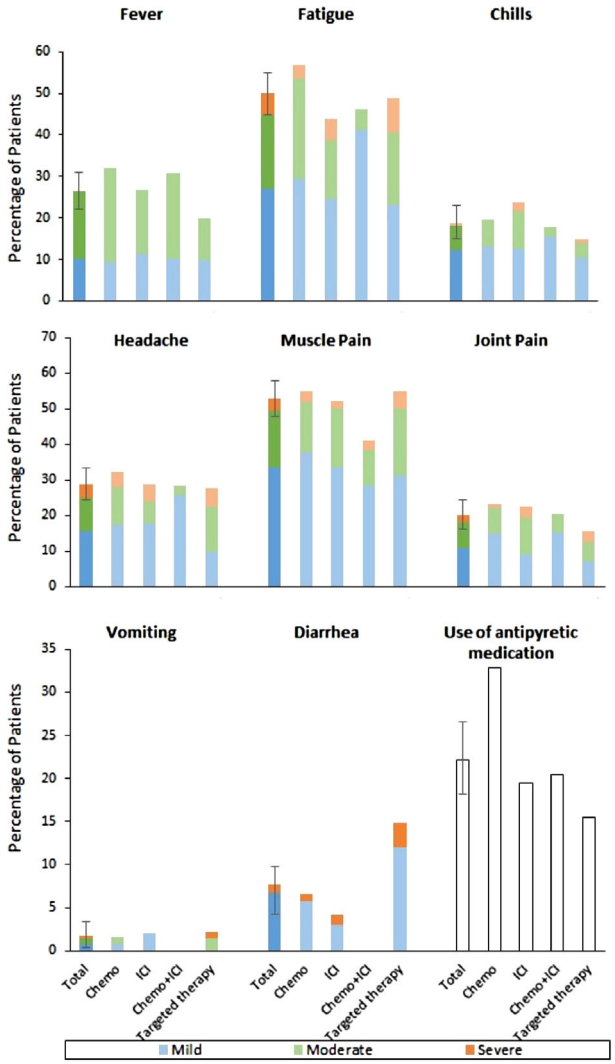

FIGURE 1 Systemic reactions reported after the second vaccination by treatment regimen. ICI, immune checkpoint inhibitor; Chemo, chemotherapy

TABLE 2 Frequency of fever after the second vaccination according to treatment regimen

Treatment regimen	Frequency	95% CI
Chemotherapy ($N = 111$[a])	21.6%	14.4%–30.4%
ICI ($N = 92$)	16.3%	9.4%–25.5%
Chemotherapy plus ICI (N = 45)	20.0%	9.6%–34.6%
Targeted therapy ($N = 144$*)	10.4%	5.9%–16.6%

Abbreviations: CI, confidence interval; ICI, immune checkpoint inhibitor.
[a]Three patients had missing values (one in a chemotherapy group and two in a targeted therapy group).

more frequent in patients treated with cytotoxic anticancer agents, but no significant difference was found in multivariate analysis (Table S2). Patients treated with cytotoxic anticancer drugs had a higher frequency of fever, and those receiving targeted therapy had a lower frequency of fever, although the difference was not significant (Table 2, S2).

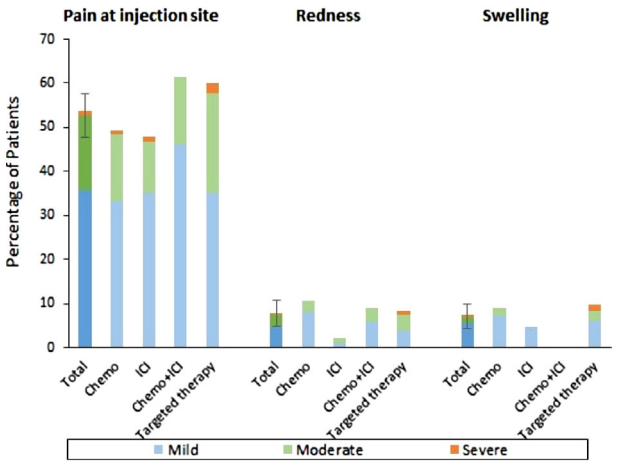

FIGURE 2 Local reactions reported after the second vaccination by treatment regimen. ICI, immune checkpoint inhibitor; Chemo, chemotherapy

No patients were reported to have developed COVID-19 during the observation period of this study.

DISCUSSION

In the present study, the frequency of fever >38°C after the second vaccination (primary outcome) was 16.1%. Our study, similar to our previously reported pilot data,[23] suggests that the risk is higher in patients with lung cancer who are receiving, or will receive, anticancer therapy than in healthy participants. In that study, more men were reported to have fever, but the current results showed no significant difference between men and women for the frequency of fever. We believe this is due to the small number of cases in the previous study, which eliminated the significant difference that might have been observed by chance.

The present study also showed a higher frequency of fever in the group treated with cytotoxic anticancer agents compared with those treated with ICI or targeted therapy, although the difference was not significant. This was also the case in the previous study. The timings of cytotoxic anticancer drug treatment and vaccination was not analyzed in this study due to most of the missing data. However, the similar trend to the previous data suggests that patients undergoing treatment with cytotoxic anticancer agents should still be aware of side effects.

Serious complications (cerebral and myocardial infarction) due to vaccination during immunotherapy have been reported in recent years.[24,25] Long-term data are being collected in this study to determine whether vaccination does not increase irAE in patients on immune checkpoint inhibitor therapy, and this will be reported again in the future.

In conclusion, vaccine-related side effects tend to increase in patients with lung cancer undergoing cytotoxic chemotherapy. However, short-term side effects are comparable to those observed in healthy individuals. This cohort

study provided data on the safety of using the anti-SARS-CoV-2 mRNA vaccine in patients with advanced lung cancer receiving anticancer therapies, such as chemotherapy, ICIs, and targeted therapy.

In conclusion, the anti-SARS-CoV-2 mRNA vaccine is safe; however, post-vaccination fever is more common in patients undergoing lung cancer treatment than in healthy individuals.

AUTHOR CONTRIBUTIONS

D.H.: Conceptualization, Investigation, Methodology, Writing review & editing; T.T.: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Validation, Writing original draft, Writing review & editing; K.N.: Conceptualization, Formal analysis, Investigation, Methodology, Writing review & editing; T.K.: Conceptualization, Investigation, Methodology, Writing review & editing; S.K.: Investigation, Writing review & editing; S.T.: Investigation, Writing review & editing; K.I.: Investigation, Writing review & editing; K.C.: Investigation, Writing review & editing; K.K.: Investigation, Writing review & editing; N.O.: Conceptualization, Data curation, Investigation, Methodology, Writing review & editing; Y.M.: Writing review & editing; K.K.: Writing review & editing. All author approved the final version to be submitted.

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CONFLICT OF INTEREST

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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