

World Journal of *Clinical Cases*

World J Clin Cases 2022 November 6; 10(31): 11214-11664



Contents

Thrice Monthly Volume 10 Number 31 November 6, 2022

REVIEW

- 11214** Diabetes and skin cancers: Risk factors, molecular mechanisms and impact on prognosis
Dobrică EC, Banciu ML, Kipkorir V, Khazeei Tabari MA, Cox MJ, Simhachalam Kutikuppala LV, Găman MA
- 11226** Endocrine disruptor chemicals as obesogen and diabetogen: Clinical and mechanistic evidence
Kurşunoğlu NE, Sarer Yurekli BP
- 11240** Intestinal microbiota in the treatment of metabolically associated fatty liver disease
Wang JS, Liu JC

MINIREVIEWS

- 11252** Lactation mastitis: Promising alternative indicators for early diagnosis
Huang Q, Zheng XM, Zhang ML, Ning P, Wu MJ
- 11260** Clinical challenges of glycemic control in the intensive care unit: A narrative review
Sreedharan R, Martini A, Das G, Aftab N, Khanna S, Ruetzler K
- 11273** Concise review on short bowel syndrome: Etiology, pathophysiology, and management
Lakkasani S, Seth D, Khokhar I, Touza M, Dacosta TJ
- 11283** Role of nickel-regulated small RNA in modulation of *Helicobacter pylori* virulence factors
Freire de Melo F, Marques HS, Fellipe Bueno Lemos F, Silva Luz M, Rocha Pinheiro SL, de Carvalho LS, Souza CL, Oliveira MV
- 11292** Surgical intervention for acute pancreatitis in the COVID-19 era
Su YJ, Chen TH

ORIGINAL ARTICLE

Clinical and Translational Research

- 11299** Screening of traditional Chinese medicine monomers as ribonucleotide reductase M2 inhibitors for tumor treatment
Qin YY, Feng S, Zhang XD, Peng B

Case Control Study

- 11313** Covered transjugular intrahepatic portosystemic stent-shunt *vs* large volume paracentesis in patients with cirrhosis: A real-world propensity score-matched study
Dhaliwal A, Merhzad H, Karkhanis S, Tripathi D

Retrospective Cohort Study

- 11325** Endoscopic submucosal tunnel dissection for early esophageal squamous cell carcinoma in patients with cirrhosis: A propensity score analysis
Zhu LL, Liu LX, Wu JC, Gan T, Yang JL

Retrospective Study

- 11338** Nomogram for predicting overall survival in Chinese triple-negative breast cancer patients after surgery
Lin WX, Xie YN, Chen YK, Cai JH, Zou J, Zheng JH, Liu YY, Li ZY, Chen YX
- 11349** Early patellar tendon rupture after total knee arthroplasty: A direct repair method
Li TJ, Sun JY, Du YQ, Shen JM, Zhang BH, Zhou YG
- 11358** Coxsackievirus A6 was the most common enterovirus serotype causing hand, foot, and mouth disease in Shiyang City, central China
Li JF, Zhang CJ, Li YW, Li C, Zhang SC, Wang SS, Jiang Y, Luo XB, Liao XJ, Wu SX, Lin L
- 11371** Dynamic changes of estimated glomerular filtration rate are conversely related to triglyceride in non-overweight patients
Liu SQ, Zhang XJ, Xue Y, Huang R, Wang J, Wu C, He YS, Pan YR, Liu LG
- 11381** C-reactive protein as a non-linear predictor of prolonged length of intensive care unit stay after gastrointestinal cancer surgery
Yan YM, Gao J, Jin PL, Lu JJ, Yu ZH, Hu Y

Clinical Trials Study

- 11391** Dan Bai Xiao Formula combined with glucocorticoids and cyclophosphamide for pediatric lupus nephritis: A pilot prospective study
Cao TT, Chen L, Zhen XF, Zhao GJ, Zhang HF, Hu Y

Observational Study

- 11403** Relationship between lipids and sleep apnea: Mendelian randomization analysis
Zhang LP, Zhang XX
- 11411** Efficacy and safety profile of two-dose SARS-CoV-2 vaccines in cancer patients: An observational study in China
Cai SW, Chen JY, Wan R, Pan DJ, Yang WL, Zhou RG

Prospective Study

- 11419** Pressure changes in tapered and cylindrical shaped cuff after extension of head and neck: A randomized controlled trial
Seol G, Jin J, Oh J, Byun SH, Jeon Y

Randomized Controlled Trial

- 11427** Effect of intradermal needle therapy at combined acupoints on patients' gastrointestinal function following surgery for gastrointestinal tumors
Guo M, Wang M, Chen LL, Wei FJ, Li JE, Lu QX, Zhang L, Yang HX

SYSTEMATIC REVIEWS

- 11442** Video-assisted bystander cardiopulmonary resuscitation improves the quality of chest compressions during simulated cardiac arrests: A systemic review and meta-analysis

Pan DF, Li ZJ, Ji XZ, Yang LT, Liang PF

META-ANALYSIS

- 11454** Efficacy of the femoral neck system in femoral neck fracture treatment in adults: A systematic review and meta-analysis

Wu ZF, Luo ZH, Hu LC, Luo YW

- 11466** Prevalence of polymyxin-induced nephrotoxicity and its predictors in critically ill adult patients: A meta-analysis

Wang JL, Xiang BX, Song XL, Que RM, Zuo XC, Xie YL

CASE REPORT

- 11486** Novel compound heterozygous variants in the LHX3 gene caused combined pituitary hormone deficiency: A case report

Lin SZ, Ma QJ, Pang QM, Chen QD, Wang WQ, Li JY, Zhang SL

- 11493** Fatal bleeding due to an aorto-esophageal fistula: A case report and literature review

Ćeranić D, Nikolić S, Lučev J, Slanić A, Bujas T, Ocepek A, Skok P

- 11500** Tolvaptan ameliorated kidney function for one elderly autosomal dominant polycystic kidney disease patient: A case report

Zhou L, Tian Y, Ma L, Li WG

- 11508** Extensive right coronary artery thrombosis in a patient with COVID-19: A case report

Dall'Orto CC, Lopes RPF, Cancela MT, de Sales Padilha C, Pinto Filho GV, da Silva MR

- 11517** Yokoyama procedure for a woman with heavy eye syndrome who underwent multiple recession-resection operations: A case report

Yao Z, Jiang WL, Yang X

- 11523** Rectal cancer combined with abdominal tuberculosis: A case report

Liu PG, Chen XF, Feng PF

- 11529** Malignant obstruction in the ileocecal region treated by self-expandable stent placement under the fluoroscopic guidance: A case report

Wu Y, Li X, Xiong F, Bao WD, Dai YZ, Yue LJ, Liu Y

- 11536** Granulocytic sarcoma with long spinal cord compression: A case report

Shao YD, Wang XH, Sun L, Cui XG

- 11542** Aortic dissection with epileptic seizure: A case report

Zheng B, Huang XQ, Chen Z, Wang J, Gu GF, Luo XJ

- 11549** Multiple bilateral and symmetric C1-2 ganglioneuromas: A case report
Wang S, Ma JX, Zheng L, Sun ST, Xiang LB, Chen Y
- 11555** Acute myocardial infarction due to Kounis syndrome: A case report
Xu GZ, Wang G
- 11561** Surgical excision of a large retroperitoneal lymphangioma: A case report
Park JH, Lee D, Maeng YH, Chang WB
- 11567** Mass-like extragonadal endometriosis associated malignant transformation in the pelvis: A rare case report
Chen P, Deng Y, Wang QQ, Xu HW
- 11574** Gastric ulcer treated using an elastic traction ring combined with clip: A case report
Pang F, Song YJ, Sikong YH, Zhang AJ, Zuo XL, Li RY
- 11579** Novel liver vein deprivation technique that promotes increased residual liver volume (with video): A case report
Wu G, Jiang JP, Cheng DH, Yang C, Liao DX, Liao YB, Lau WY, Zhang Y
- 11585** Linear porokeratosis of the foot with dermoscopic manifestations: A case report
Yang J, Du YQ, Fang XY, Li B, Xi ZQ, Feng WL
- 11590** Primary hepatic angiosarcoma: A case report
Wang J, Sun LT
- 11597** Hemorrhagic shock due to ruptured lower limb vascular malformation in a neurofibromatosis type 1 patient: A case report
Shen LP, Jin G, Zhu RT, Jiang HT
- 11607** Gastric linitis plastica with autoimmune pancreatitis diagnosed by an endoscopic ultrasonography-guided fine-needle biopsy: A case report
Sato R, Matsumoto K, Kanzaki H, Matsumi A, Miyamoto K, Morimoto K, Terasawa H, Fujii Y, Yamazaki T, Uchida D, Tsutsumi K, Horiguchi S, Kato H
- 11617** Favorable response of primary pulmonary lymphoepithelioma-like carcinoma to sintilimab combined with chemotherapy: A case report
Zeng SY, Yuan J, Lv M
- 11625** Benign paroxysmal positional vertigo with congenital nystagmus: A case report
Li GF, Wang YT, Lu XG, Liu M, Liu CB, Wang CH
- 11630** Secondary craniofacial necrotizing fasciitis from a distant septic emboli: A case report
Lee DW, Kwak SH, Choi HJ
- 11638** Pancreatic paraganglioma with multiple lymph node metastases found by spectral computed tomography: A case report and review of the literature
Li T, Yi RQ, Xie G, Wang DN, Ren YT, Li K

- 11646** Apnea caused by retrobulbar anesthesia: A case report
Wang YL, Lan GR, Zou X, Wang EQ, Dai RP, Chen YX
- 11652** Unexplained septic shock after colonoscopy with polyethylene glycol preparation in a young adult: A case report
Song JJ, Wu CJ, Dong YY, Ma C, Gu Q
- 11658** Metachronous isolated penile metastasis from sigmoid colon adenocarcinoma: A case report
Yin GL, Zhu JB, Fu CL, Ding RL, Zhang JM, Lin Q

ABOUT COVER

Editorial Board Member of *World Journal of Clinical Cases*, Muhammad Hamdan Gul, MD, Assistant Professor, Department of Internal Medicine, University of Kentucky, Chicago, IL 60657, United States.
hamdan3802@hotmail.com

AIMS AND SCOPE

The primary aim of *World Journal of Clinical Cases* (WJCC, *World J Clin Cases*) is to provide scholars and readers from various fields of clinical medicine with a platform to publish high-quality clinical research articles and communicate their research findings online.

WJCC mainly publishes articles reporting research results and findings obtained in the field of clinical medicine and covering a wide range of topics, including case control studies, retrospective cohort studies, retrospective studies, clinical trials studies, observational studies, prospective studies, randomized controlled trials, randomized clinical trials, systematic reviews, meta-analysis, and case reports.

INDEXING/ABSTRACTING

The WJCC is now abstracted and indexed in Science Citation Index Expanded (SCIE, also known as SciSearch®), Journal Citation Reports/Science Edition, Current Contents®/Clinical Medicine, PubMed, PubMed Central, Scopus, Reference Citation Analysis, China National Knowledge Infrastructure, China Science and Technology Journal Database, and Superstar Journals Database. The 2022 Edition of Journal Citation Reports® cites the 2021 impact factor (IF) for WJCC as 1.534; IF without journal self cites: 1.491; 5-year IF: 1.599; Journal Citation Indicator: 0.28; Ranking: 135 among 172 journals in medicine, general and internal; and Quartile category: Q4. The WJCC's CiteScore for 2021 is 1.2 and Scopus CiteScore rank 2021: General Medicine is 443/826.

RESPONSIBLE EDITORS FOR THIS ISSUE

Production Editor: *Xu Guo*; Production Department Director: *Xiang Li*; Editorial Office Director: *Jin-Lei Wang*.

NAME OF JOURNAL

World Journal of Clinical Cases

ISSN

ISSN 2307-8960 (online)

LAUNCH DATE

April 16, 2013

FREQUENCY

Thrice Monthly

EDITORS-IN-CHIEF

Bao-Gan Peng, Jerzy Tadeusz Chudek, George Kontogeorgos, Maurizio Serati, Ja Hyeon Ku

EDITORIAL BOARD MEMBERS

<https://www.wjgnet.com/2307-8960/editorialboard.htm>

PUBLICATION DATE

November 6, 2022

COPYRIGHT

© 2022 Baishideng Publishing Group Inc

INSTRUCTIONS TO AUTHORS

<https://www.wjgnet.com/bpg/gerinfo/204>

GUIDELINES FOR ETHICS DOCUMENTS

<https://www.wjgnet.com/bpg/GerInfo/287>

GUIDELINES FOR NON-NATIVE SPEAKERS OF ENGLISH

<https://www.wjgnet.com/bpg/gerinfo/240>

PUBLICATION ETHICS

<https://www.wjgnet.com/bpg/GerInfo/288>

PUBLICATION MISCONDUCT

<https://www.wjgnet.com/bpg/gerinfo/208>

ARTICLE PROCESSING CHARGE

<https://www.wjgnet.com/bpg/gerinfo/242>

STEPS FOR SUBMITTING MANUSCRIPTS

<https://www.wjgnet.com/bpg/GerInfo/239>

ONLINE SUBMISSION

<https://www.f6publishing.com>



Observational Study

Efficacy and safety profile of two-dose SARS-CoV-2 vaccines in cancer patients: An observational study in China

Sheng-Wei Cai, Jin-Yan Chen, Rong Wan, De-Jian Pan, Wei-Lin Yang, Ren-Gui Zhou

Specialty type: Medicine, research and experimental

Provenance and peer review: Unsolicited article; Externally peer reviewed

Peer-review model: Single blind

Peer-review report's scientific quality classification

Grade A (Excellent): 0
Grade B (Very good): B
Grade C (Good): C
Grade D (Fair): 0
Grade E (Poor): 0

P-Reviewer: Dey J, India; Shahid M, Pakistan

Received: July 21, 2022

Peer-review started: July 21, 2022

First decision: August 4, 2022

Revised: August 16, 2022

Accepted: September 21, 2022

Article in press: September 21, 2022

Published online: November 6, 2022



Sheng-Wei Cai, De-Jian Pan, Wei-Lin Yang, Ren-Gui Zhou, Department of Oncology, The 904th Hospital of Joint Logistic Support Force, Wuxi 214044, Jiangsu Province, China

Jin-Yan Chen, Department of Disinfection and Supply, The 904th Hospital of Joint Logistic Support Force, Wuxi 214044, Jiangsu Province, China

Rong Wan, Department of Quality Control, The 904th Hospital of Joint Logistic Support Force, Wuxi 214044, Jiangsu Province, China

Corresponding author: Rong Wan, BHMS, Chief Nurse, Department of Quality Control, The 904th Hospital of Joint Logistic Support Force, No. 101 Xingyuan North Road, Wuxi 214044, Jiangsu Province, China. yings2007@21cn.com

Abstract

BACKGROUND

The new coronavirus severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has produced a global pandemic of coronavirus disease 2019 (COVID-19), resulting in modifications to public health policies on a universal scale. SARS-CoV-2 vaccine has evolved as the most effective and secure way for protecting healthy individuals against COVID-19. Patients with cancer were excluded from clinical trials due to their increased COVID-19 risk and current immunosuppressing therapy. Safety and effectiveness evidence is insufficient for SARS-CoV-2 vaccination in cancer patients.

AIM

To assess the efficacy and safety of two-dose SARS-CoV-2 vaccines in cancer patients.

METHODS

A multicenter observational study was performed at ten Chinese hospitals between January 1, 2021 and December 31, 2021. Each participant in the research received two doses of vaccination. A total of 215 healthy people were screened and 132 eligible patients with cancer were recruited. In order to verify the safety of the second dose of the vaccine, a side-effect report was compiled. Two weeks following the second vaccination dose, subjects underwent an analogous questionnaire survey. Utilizing a magnetic particle-based chemiluminescence immunoassay, serum levels of anti-SARS-CoV-2 immunoglobulin G (IgG) antibodies were measured to determine the effectiveness of vaccination. IgG

levels ≥ 10 AU/mL were considered seropositive.

RESULTS

All the 347 eligible patients completed the follow-up, and anti-SARS-CoV-2 IgG antibodies were detected. Local pain at the injection location was the most common side effect mentioned by all responders, with an increased incidence in cancer patients than the healthy people after the second dose vaccine (17.2% *vs* 9.1%; $P = 0.035$). There was no significant difference in headache, urticaria, or other adverse reactions between patients with cancer and healthy people. In the group of cancer patients, the seropositivity incidence was 83.3%, while it was 96.3% in the group of healthy people. In the group of cancer patients, the seropositivity incidence and antibody levels were significantly lower ($P < 0.001$). This analysis showed a poorer response rate in patients on active immunosuppressive treatment and elderly cancer patients.

CONCLUSION

Two-dose Chinese vaccines are effective and safe in cancer patients. However, further research is required on the efficacy in elderly cancer patients and those on active immunosuppressive treatment.

Key Words: SARS-CoV-2; Vaccine; Cancer; COVID-19; Immunotherapy

©The Author(s) 2022. Published by Baishideng Publishing Group Inc. All rights reserved.

Core Tip: Newer strains of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have made the ongoing global coronavirus disease 2019 pandemic critical. Patients with cancer form a high-risk group, as those with active cancer or those treated with immunosuppressive therapies are more likely to be infected by SARS-CoV-2. Our study indicated the efficacy and safety of two-dose SARS-CoV-2 vaccines in cancer subjects.

Citation: Cai SW, Chen JY, Wan R, Pan DJ, Yang WL, Zhou RG. Efficacy and safety profile of two-dose SARS-CoV-2 vaccines in cancer patients: An observational study in China. *World J Clin Cases* 2022; 10(31): 11411-11418

URL: <https://www.wjgnet.com/2307-8960/full/v10/i31/11411.htm>

DOI: <https://dx.doi.org/10.12998/wjcc.v10.i31.11411>

INTRODUCTION

The new coronavirus severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has produced a global pandemic of coronavirus disease 2019 (COVID-19), resulting in modifications to public health policies and causing many patient deaths worldwide[1]. As of April 2, 2022, 47583 cases of COVID-19 have been diagnosed and 13436 patients have been dead in China. SARS-CoV-2 vaccine was considered to be the preventive way of accomplishing sufficient herd immunity against SARS-CoV-2 infection to eventually stop the COVID-19 pandemic. More than 3.2 billion doses of SARS-CoV-2 vaccine have been administered until April 2, 2022 in China, and almost 1.28015 billion Chinese have undergone SARS-CoV-2 vaccination.

Patients with cancer have been recognized as a highly vulnerable group, and it is of important significance to clarify the risk and efficacy of vaccination as patients with active cancer or those treated with immunosuppressing therapies are more likely to be infected by SARS-CoV-2 and develop severe illness if infected[2,3]. Even though, there is a higher mortality in cancer patients than in healthy people [4]. However, it is unknown whether COVID-19 vaccination is effective and safe for cancer patients as almost all vaccine-evaluated clinical trials excluded cancer patients[5]. Current recommendations suggest cancer patients to undergo SARS-CoV-2 vaccination against COVID-19, despite the absence of solid data on the effectiveness and safety of these vaccines in cancer patients[6].

Therefore, we aimed to clarify and compare the efficacy and safety of SARS-CoV-2 vaccines between cancer patients and non-cancer individuals. The findings would improve clinical care, protect these vulnerable patient populations, and help the government to formulate corresponding policies.

MATERIALS AND METHODS

Study design and patients

This is a multicenter observational study performed at ten Chinese hospitals from January 1, 2021 to December 31, 2021. We screened 215 healthy people and 132 eligible patients with cancer were recruited. All healthy people and cancer patients underwent double-dose SARS-CoV-2 vaccination. China has released SARS-CoV-2 inactivated vaccines from the Beijing Institute of Biological Products, Wuhan Institute of Biological Products, and Sinovac. Two weeks after the second vaccination dose, an identical survey was completed online or by telephone to report side effects. Using a magnetic particle-based chemiluminescence immunoassay, serum levels of anti-SARS-CoV-2 immunoglobulin G (IgG) antibodies were measured to determine the efficacy of vaccination. The safety and efficacy in cancer patients after double-dose SARS-CoV-2 vaccination were evaluated. The study was approved by the Clinical Research Ethics Committees of Anhui Medical University Affiliated with Wuxi Clinical College (Approval number: YXLL-2020-003).

The trial was explained to participants, their family members, or legal counsel. The patients' competency was then evaluated based on their appropriate time allocation, location, and personality, as well as their comprehension of the presentation. All potential participants provided written informed consent.

Assessments

Approximately two weeks after the second vaccination dose, an analogous telephone or online questionnaire was performed. Vaccine recipients were asked if they had experienced any similar signs like: Fatigue, localized soreness, or injection site edema. Additionally, they were allowed to report symptoms not listed in the survey. We also recorded the baseline characteristics of the study population including treatment delivery, data collection, and outcome assessment. Additionally, 5 mL of peripheral venous blood was collected from subjects, centrifuged at 2500 rpm for 10 min, and stored at -80 °C. SARS-CoV-2 specific IgG antibodies were evaluated by the magnetic particle chemiluminescence method. iFlash 3000 (YHLO, China) and IgG antibody detection Kit (YHLO, China) were used to quantify IgG antibody levels following the manufacturer's instructions. An IgG level ≥ 10 AU/mL was considered seropositive.

Statistical analysis

The differences in continuous variables, expressed as the mean $\pm$ SD, between the two groups were tested by the student's *t*-test or Mann-Whitney *U* test. Categorical variables are represented as *n* (%), and were compared by the chi-squared test or Fisher's exact test and continuous data by the Wilcoxon rank-sum test. In calculating the mean difference or risk ratios with 95% confidence intervals, *P*-values < 0.05 were judged as statistical significance. Statistical analyses were performed with SPSS Statistics (v. 20, IBM, Chicago, IL). No interim analysis was included in the assessments. Data overseeing was performed by the 904th Hospital of PLA.

RESULTS

Baseline patient characteristics

A total of 347 subjects underwent assessment between January 1, 2021 and December 31, 2021. Among them, 215 healthy people were screened and 132 eligible patients with cancer were recruited. All 347 eligible subjects completed the follow-up, and anti-SARS-CoV-2 IgG antibodies were detected. **Table 1** depicts the demographics and features of the study subjects.

Adverse effects and safety evaluation

Two doses of SARS-CoV-2 vaccines were administered to cancer patients to evaluate their safety. All adverse effects were recorded for the second dose. According to the cancer patient group, total side effects occurred in 28.8% of those who received the second dose of the vaccination, and 34.4% in healthy adults. The incidence of side effects reported after the second dose had no significant difference between the two groups (*P* = 0.215). The most frequent adverse events were tiredness (15.9%), headache (12.9%), and local pain (9.1%) in the cancer patients, while the first three common adverse were local pain (17.2%), headache (12.1%), and fever (10.7%) in the healthy people. The rate of local pain was significantly higher in the healthy people than in the cancer patients (*P* = 0.035, **Table 2**), and the incidence of tiredness was increased significantly in the cancer patients than in the healthy people (*P* = 0.045, **Table 2**). The incidence of other adverse effects showed no significant difference between the two groups (*P* > 0.05, **Table 2**).

Efficacy evaluation

The identification of SARS-CoV-2 specific IgG antibodies 2 wk after the administration of the second

Table 1 Demographic and baseline characteristics of the study population in the two groups

	Healthy	Cancer	P value
Number	215	132	
Age			< 0.001
mean $\pm$ SD	46.2 $\pm$ 8.1	58 $\pm$ 5.4	
Sex			0.12
Male	137 (63.7%)	73 (55.3%)	
Female	78 (36.3%)	59 (44.7%)	
History of hypertension			0.17
Yes	69 (32.1%)	52 (39.4%)	
No	146 (67.9%)	80 (60.6%)	
Smoking history			0.06
Yes	50 (23.3%)	43 (32.6%)	
No	165 (76.7%)	89 (67.4%)	
BMI	27.5 $\pm$ 1.5	26.9 $\pm$ 1.2	< 0.001
Diabetes mellitus			0.01
Yes	21 (9.8%)	25 (18.9%)	
No	194 (90.2%)	107 (81.1%)	
Coronary disease			0.22
Yes	15 (7.0%)	5 (3.8%)	
No	200 (93.0%)	127 (96.2%)	
Respiratory disease			0.19
Yes	11 (5.1%)	3 (2.3%)	
No	204 (94.9%)	129 (97.7%)	
Type of vaccine			0.69
Sinovac	133 (61.9%)	85 (64.4%)	
Beijing biological	49 (22.8%)	25 (18.9%)	
Wuhan biological	33 (15.3%)	22 (16.7%)	

BMI: Body mass index.

dosage was used to determine whether or not two doses of SARS-CoV-2 vaccination was effective in preventing infection with the virus. Cancer patients had a seropositivity rate of 83.3% and a median antibody level of 25.8 AU/mL. Seropositivity rate was 96.3% and median antibody level was 31.6 AU/mL in healthy individuals. Cancer patients had significantly lower seropositivity rate and antibody levels when compared with the non-cancer group ($P < 0.001$, Table 3). We also found no significant variation in the antibody values among different vaccines in both cancer patients and healthy people ($P > 0.05$, Table 3). Additionally, the immune response may be reduced by chemotherapy and immunotherapy. As a result of active chemotherapy, immunotherapy, and targeted therapy, 66.7%, 74.1%, and 83.3% of patients were seropositive, respectively, as compared to 94.1% in non-treated patients. The efficacy of vaccination was decreased significantly in patients on chemotherapy, immunotherapy, and targeted therapy compared to non-treated patients (Table 4, $P > 0.05$).

DISCUSSION

In this multicenter study, cancer patients were studied to determine the short-term side effects and effectiveness of SARS-CoV-2 vaccines given that current cancer treatments may have an effect on these outcomes. After receiving the second dose, there was not a statistically significant variation in the incidence of adverse responses between the groups. According to the findings of this study, as

Table 2 Adverse effect after the first and second doses of the vaccine

Characteristic	Healthy	Cancer	P value
Overall incidence	34.4% (74/215)	28.0% (37/132)	0.215
Tired	8.8% (19)	15.9% (21)	0.045
Headache	12.1% (26)	12.9% (17)	0.829
Local pain	17.2% (37)	9.1% (12)	0.035
Fever	10.7% (23)	7.6% (10)	0.336
Erythema	8.4% (18)	6.8% (9)	0.600
Myalgia	7.0% (15)	6.1% (8)	0.739
Diarrhea	5.1% (11)	5.3% (7)	0.939
Nausea	7.4% (16)	3.8% (5)	0.166
Chills	3.7% (8)	3.8% (5)	0.975

Table 3 Vaccine features and antibody levels of the study population

Characteristic	Healthy	Cancer	P value
Antibody level (mean $\pm$ SD)	31.6 $\pm$ 4.8	25.8 $\pm$ 3.2	< 0.001
Seropositivity			< 0.001
Positive ($\geq$ 10 AU/mL)	96.3% (207/215)	83.3% (110/132)	
Negative (< 10 AU/mL)	3.7% (8/215)	16.7% (22/132)	
Type of vaccine			0.206
Sinovac	97.0% (159/164)	83.2% (89/107)	
Beijing biological	95.5% (42/44)	78.9% (15/19)	
Wuhan biological	85.7% (6/7)	85.7% (6/7)	

Table 4 Seropositivity rates of cancer patients after severe acute respiratory syndrome coronavirus 2 vaccination according to treatment status

Characteristic	Seropositivity
No therapy	94.1% (43/51)
Targeted therapy	83.3% (30/36)
Immunotherapy	74.1% (20/27)
Chemotherapy	66.7% (12/18)

compared to healthy people, the cancer patients had a lower rate of local pain and a higher rate of tiredness. The incidence of other adverse effects was also compared between the two groups, but there were no significant difference between them. We also found an 83.3% seropositivity rate in the cancer patients and a 96.3% seropositivity rate in healthy people. Antibody levels and seropositivity rates were significantly lower among cancer patients than among healthy subjects. Hence, our study indicated that two dosages of SARS-CoV-2 vaccine administration is effective and safe in cancer subjects.

Because of the large number of people who were vaccinated with SARS-CoV-2 vaccine, more and more studies have focused on the rate of vaccine-related adverse effects[7,8]. A latest systematic review that comprised eleven studies found that all adverse responses after COVID-19 vaccine administration were mild to moderate, and that few severe reactions were not connected to the vaccination[7]. Since there was no clear efficacy and safety evaluation for cancer patients after SARS-CoV-2 vaccine administration in China, high vaccine hesitancy was exhibited in the cancer patients. A European and Hong Kong survey also indicated that most cancer patients were unwilling to be vaccinated or hesitated[9,10]. The present study demonstrated that patients suffering from cancer were not at risk when given the SARS-CoV-2 vaccine, and showed no increase in the rate of vaccine-related adverse effects. The results were similar to the previous studies in different countries and on different SARS-CoV-2 vaccines[1].

Shulman *et al*[2] also reported that patients with cancer were compared with those without cancer in reported adverse events, and active cancer treatment had little impact on adverse event profiles.

The most common symptom reported by healthy people was local pain at the injection site, which was significantly less common among cancer patients. It could be that cancer patients have a higher tolerance for pain after long-term treatment by intravenous injection. Additionally, tiredness was the most common complaint of cancer patients, and its incidence was higher significantly than that in the healthy people. Maybe, patients with cancer suffer from fatigue due to advanced age and weakened bodies than those in the general population. Hence, cancer patients need more rest after SARS-CoV-2 vaccine injection.

For efficacy evaluation, the seropositivity rate was as low as 83.3% in cancer patients, which was significantly lower than that in healthy people in this study. Further antibody detection showed that patients with cancer had lower IgG antibody levels than individuals without cancer. Ariamanesh *et al* [11] reported that the seropositivity rate also decreased in patients with malignancies. Similar results also were demonstrated in a Turkey study[1]. In a recent study, Goshen-Lago *et al*[12] reported that the SARS-CoV-2 BNT162b2 vaccine appeared to be safe and achieve satisfactory serologic status in patients with cancer.

Meanwhile, immune reactions to SARS-CoV-2 vaccination can vary depending on the stage of cancer therapy that the patient is currently receiving. In the present study, the lowest seropositivity rate was 66.7% after active chemotherapy treatment. Cancer patients who are receiving vigorous chemotherapy and immunotherapy may have a reduced cellular immune reaction, which could be the cause of this immunity suppression. Hence, whether additional doses or strengthened vaccine injections are required needs to be explored in future studies.

There were a few shortcomings with this research. To start, the sample size was low, therefore further research with larger sample sizes is required to investigate the efficacy and safety of SARS-CoV-2 vaccines in cancer patients. Second, we evaluated the efficacy of participants just by detecting the IgG antibody levels, and IgM antibody levels should be assessed in the future study. Third, the current investigation only covered the short-term side effects and efficacy of SARS-CoV-2 vaccines in patients with cancer. To evaluate the effects of vaccines and antibody levels in the prevention of disease, a long-term investigation is required.

CONCLUSION

According to the presented findings, two-dose SARS-CoV-2 vaccines in cancer patients are effective and safe. The most prevalent side effects among cancer patients are fatigue, headaches, and localized pain. Cancer patients' seropositivity rates and IgG antibody levels are lower than those of healthy individuals. Active chemotherapy and immunotherapy maybe affect the effectiveness of vaccines. However, the long-term effects of these vaccines are stills unclear. Further studies with larger populations of cancer patients undergoing two-dose SARS-CoV-2 vaccines should be performed.

ARTICLE HIGHLIGHTS

Research background

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine has evolved as the most effective and secure way for protecting healthy individuals against coronavirus disease 2019 (COVID-19). Patients with cancer have been recognized as a highly vulnerable group, and it is of important significance to clarify the risk and efficacy of vaccination. We aimed to clarify and compare the efficacy and safety of SARS-CoV-2 vaccines between cancer patients and non-cancer individuals.

Research motivation

The new coronavirus SARS-CoV-2 has produced a global pandemic of COVID-19, and SARS-CoV-2 vaccine was considered to be a preventive way of accomplishing sufficient herd immunity against SARS-CoV-2 infection to eventually stop the COVID-19 pandemic. Current recommendations suggest cancer patients to undergo SARS-CoV-2 vaccination against COVID-19, but safety and effectiveness evidence is insufficient for SARS-CoV-2 vaccination in cancer patients.

Research objectives

The present observational study was conducted to assess the efficacy and safety of two-dose SARS-CoV-2 vaccines in cancer patients.

Research methods

This multi-center observational study enrolled 132 eligible patients with cancer. Two weeks following

the second vaccination dose, subjects underwent an analogous questionnaire survey. Utilizing a magnetic particle-based chemiluminescence immunoassay, serum levels of anti-SARS-CoV-2 immunoglobulin G (IgG) antibodies were measured to determine the effectiveness of vaccination. IgG levels ≥ 10 AU/mL were considered seropositive.

Research results

Local pain at the injection site was the most common side effect, and its incidence was higher in cancer patients than the healthy people (17.2% *vs* 9.1%; $P = 0.035$). No significant difference in headache, urticaria, or other adverse reactions was noted between patients with cancer and healthy people. The seropositivity incidence and antibody levels were significantly lower in cancer patients ($P < 0.001$). This analysis showed a relatively poorer response rate in patients on active immunosuppressive treatment and elderly cancer patients.

Research conclusions

It is effective and safe to accept two-dose Chinese vaccines in cancer patients. Future studies are needed to focus on the efficacy of these vaccines in elderly cancer patients and those on active immunosuppressive treatment.

Research perspectives

Further studies with larger populations of cancer patients undergoing two-dose SARS-CoV-2 vaccination should be performed. Longer follow-up is needed to clarify the long-term efficacy and safety profile of two-dose SARS-CoV-2 vaccines in cancer patients.

ACKNOWLEDGEMENTS

We thank Jiangsu Brilliant Biological Technology Co., Ltd. for providing technical and linguistic help.

FOOTNOTES

Author contributions: Cai SW and Chen JY contributed equally to this work; Cai SW, Wan R, Pan DJ, and Chen JY designed the research study; Cai SW, Wan R, and Chen JY performed the research; Pan DJ, Yang WL, Zhou RG, and Chen JY contributed new reagents and analytic tools; Cai SW, Zhou RG, and Chen JY analyzed the data and wrote the manuscript; and all authors have read and approved the final manuscript.

Institutional review board statement: The study was approved by the Clinical Research Ethics Committees of Anhui Medical University Affiliated with Wuxi Clinical College (Approval number: YXLL-2020-003).

Informed consent statement: Before anyone was allowed to take part in the research project, we made sure that they (or their legal counsel) have provided informed consent to conduct the study.

Conflict-of-interest statement: All the authors report no relevant conflicts of interest for this article.

Data sharing statement: On reasonable request, the corresponding author can provide access to the utilized and processed datasets for this study.

STROBE statement: The authors have read the STROBE Statement-checklist of items, and the manuscript was prepared and revised according to the STROBE Statement-checklist of items.

Open-Access: This article is an open-access article that was selected by an in-house editor and fully peer-reviewed by external reviewers. It is distributed in accordance with the Creative Commons Attribution NonCommercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: <https://creativecommons.org/licenses/by-nc/4.0/>

Country/Territory of origin: China

ORCID number: Rong Wan 0000-0002-5575-7292; Wei-Lin Yang 0000-0002-9564-6132.

S-Editor: Wang JJ

L-Editor: Wang TQ

P-Editor: Wang JJ

REFERENCES

- 1 **Yasin AI**, Aydin SG, Sümbül B, Koral L, Şimşek M, Geredeli Ç, Öztürk A, Perkin P, Demirtaş D, Erdemoglu E, Hacibekiroğlu İ, Çakır E, Tanrikulu E, Çoban E, Özcelik M, Çelik S, Teker F, Aksoy A, Furat ST, Tekin Ö, Kalkan Z, Türken O, Oven BB, Dane F, Bilici A, Isikdogan A, Seker M, Türk HM, Gümüş M. Efficacy and safety profile of COVID-19 vaccine in cancer patients: a prospective, multicenter cohort study. *Future Oncol* 2022; **18**: 1235-1244 [PMID: 35081732 DOI: 10.2217/fon-2021-1248]
- 2 **Shulman RM**, Weinberg DS, Ross EA, Ruth K, Rall GF, Olszanski AJ, Helstrom J, Hall MJ, Judd J, Chen DYT, Uzzo RG, Dougherty TP, Williams R, Geynisman DM, Fang CY, Fisher RI, Strother M, Huelsmann E, Adige S, Whooley PD, Zarrabi K, Gupta B, Iyer P, McShane M, Yankey H, Lee CT, Burbure N, Laderman LE, Giurintano J, Reiss S, Horwitz EM. Adverse Events Reported by Patients With Cancer After Administration of a 2-Dose mRNA COVID-19 Vaccine. *J Natl Compr Canc Netw* 2022; **20**: 160-166 [PMID: 35130494 DOI: 10.6004/jnccn.2021.7113]
- 3 **Liang W**, Guan W, Chen R, Wang W, Li J, Xu K, Li C, Ai Q, Lu W, Liang H, Li S, He J. Cancer patients in SARS-CoV-2 infection: a nationwide analysis in China. *Lancet Oncol* 2020; **21**: 335-337 [PMID: 32066541 DOI: 10.1016/S1470-2045(20)30096-6]
- 4 **Hwang JK**, Zhang T, Wang AZ, Li Z. COVID-19 vaccines for patients with cancer: benefits likely outweigh risks. *J Hematol Oncol* 2021; **14**: 38 [PMID: 33640005 DOI: 10.1186/s13045-021-01046-w]
- 5 **Jackson LA**, Anderson EJ, Rouphael NG, Roberts PC, Makhene M, Coler RN, McCullough MP, Chappell JD, Denison MR, Stevens LJ, Puijssers AJ, McDermott A, Flach B, Doria-Rose NA, Corbett KS, Morabito KM, O'Dell S, Schmidt SD, Swanson PA 2nd, Padilla M, Mascola JR, Neuzil KM, Bennett H, Sun W, Peters E, Makowski M, Albert J, Cross K, Buchanan W, Pikaart-Tautges R, Ledgerwood JE, Graham BS, Beigel JH; mRNA-1273 Study Group. An mRNA Vaccine against SARS-CoV-2 - Preliminary Report. *N Engl J Med* 2020; **383**: 1920-1931 [PMID: 32663912 DOI: 10.1056/NEJMoa2022483]
- 6 **Garassino MC**, Vyas M, de Vries EGE, Kanesvaran R, Giuliani R, Peters S; European Society for Medical Oncology. The ESMO Call to Action on COVID-19 vaccinations and patients with cancer: Vaccinate. Monitor. Educate. *Ann Oncol* 2021; **32**: 579-581 [PMID: 33582237 DOI: 10.1016/j.annonc.2021.01.068]
- 7 **Medeiros KS**, Costa APF, Sarmiento ACA, Freitas CL, Gonçalves AK. Side effects of COVID-19 vaccines: a systematic review and meta-analysis protocol of randomised trials. *BMJ Open* 2022; **12**: e050278 [PMID: 35210336 DOI: 10.1136/bmjopen-2021-050278]
- 8 **Chen J**, Cai Y, Chen Y, Williams AP, Gao Y, Zeng J. Nervous and Muscular Adverse Events after COVID-19 Vaccination: A Systematic Review and Meta-Analysis of Clinical Trials. *Vaccines (Basel)* 2021; **9** [PMID: 34452064 DOI: 10.3390/vaccines9080939]
- 9 **Barrière J**, Gal J, Hoch B, Cassuto O, Leysalle A, Chamorey E, Borchellini D. Acceptance of SARS-CoV-2 vaccination among French patients with cancer: a cross-sectional survey. *Ann Oncol* 2021; **32**: 673-674 [PMID: 33529740 DOI: 10.1016/j.annonc.2021.01.066]
- 10 **Chan WL**, Ho YT, Wong CK, Choi HC, Lam KO, Yuen KK, Kwong D, Hung I. Acceptance of COVID-19 Vaccination in Cancer Patients in Hong Kong: Approaches to Improve the Vaccination Rate. *Vaccines (Basel)* 2021; **9**: 792 [PMID: 34358208 DOI: 10.3390/vaccines9070792]
- 11 **Ariamanesh M**, Porouhan P, PeyroShabany B, Fazilat-Panah D, Dehghani M, Nabavifard M, Hatami F, Fereidouni M, Welsh JS, Javadinia SA. Immunogenicity and Safety of the Inactivated SARS-CoV-2 Vaccine (BBIBP-CorV) in Patients with Malignancy. *Cancer Invest* 2022; **40**: 26-34 [PMID: 34634986 DOI: 10.1080/07357907.2021.1992420]
- 12 **Goshen-Lago T**, Waldhorn I, Holland R, Szwarcwort-Cohen M, Reiner-Benaim A, Shachor-Meyouhas Y, Hussein K, Fahoum L, Baruch M, Peer A, Reiter Y, Almog R, Halberthal M, Ben-Aharon I. Serologic Status and Toxic Effects of the SARS-CoV-2 BNT162b2 Vaccine in Patients Undergoing Treatment for Cancer. *JAMA Oncol* 2021; **7**: 1507-1513 [PMID: 34236381 DOI: 10.1001/jamaoncol.2021.2675]



Published by **Baishideng Publishing Group Inc**
7041 Koll Center Parkway, Suite 160, Pleasanton, CA 94566, USA

Telephone: +1-925-3991568

E-mail: bpgoffice@wjgnet.com

Help Desk: <https://www.f6publishing.com/helpdesk>

<https://www.wjgnet.com>

