

ORIGINAL ARTICLE

COVID-19 vaccines and cancer patients: acceptance, attitudes and safety

Gorana Matovina Brko¹, Maja Popovic^{1,2}, Masa Jovic¹, Jelena Radic^{1,2}, Milka Bodlovic Kladar¹, Ivan Nikolic^{1,2}, Vladimir Vidovic¹, Ivana Kolarov Bjelobrk^{1,2}, Biljana Kukic^{1,2}, Svetlana Salma¹, Jelena Litavski¹, Nemanja Petrovic^{1,2}, Bojana Vranjkovic¹, Tatjana Roganovic¹, Maja Ruzic^{2,3}, Tihomir Dugandzija^{2,4}, Lazar Popovic^{1,2}

¹Department for Medical Oncology, Oncology Institute of Vojvodina, Sremska Kamenica, Serbia; ²Faculty of Medicine, University of Novi Sad, Novi Sad, Serbia; ³Clinic for Infectious Diseases, Clinical Center of Vojvodina, Novi Sad, Serbia; ⁴Department for Epidemiology, Oncology Institute of Vojvodina, Sremska Kamenica, Serbia.

Summary

Purpose: Recommendations and guidelines consider cancer patients a high-priority population for COVID-19 immunization. Vaccination process in Serbia began in January 2021 with four available vaccines. We have conducted a cross-sectional study investigating cancer patients' acceptability of anti SARS-CoV2 vaccines.

Methods: The study included 767 patients with solid and hematologic malignancies treated at the Oncology Institute of Vojvodina, Serbia. During July and August 2021 patients filled in an individual paper questionnaire on anti SARS-CoV2 vaccination acceptance, preferences, side effects and information origin. Data on treatment phase, diagnosis and treatment was collected from electronic health records.

Results: During the first six months of vaccination campaign in Serbia 41% (320/767) of the investigated oncology patients received COVID-19 vaccines. The median age of vaccinated patients was 65 years (28-84). Most of them

(75%) were in active treatment of cancer. Half of the unvaccinated patients (52%) wish to get vaccinated after the end of their cancer treatment. Around 10% of the patients definitely refused vaccination. The majority of information on COVID-19 vaccines cancer patients got from their oncologist, television and newspapers. Side effects were reported by 10.93% of the patients after the first dose and 13.31% after the second dose. No serious side effects were reported.

Conclusion: We have confirmed that patients are reluctant of receiving vaccine due to fear of side effects, especially during the active cancer treatment. However, real-world evidence and clinical trials data have gathered enough evidence to reassure any doubts of the patients and their oncologists on safety and efficacy of anti SARS-CoV2 vaccines.

Key words: COVID-19 vaccines, SARS-CoV2, cancer therapies, vaccination

Introduction

Coronavirus disease (COVID-19) global epidemic was announced in March 2020. According to the World Health Organization (WHO) data as of September 1st 2021 there have been globally 218,558,771 confirmed cases and 4,517,240 deaths of COVID-19 [1]. On the other hand, pandemic of malignant diseases continue to smolder in the

world: GLOBOCAN data for 2020 reported over 19 million new cases and close to 20 million cancer deaths [2]. COVID-19 pandemic has imposed a huge impact on health care systems worldwide compromising treatment of diseases other than COVID-19. SARS-CoV2 infection can postpone, interrupt or hinder cancer diagnosis and treatment,

Corresponding author: Lazar Popovic, MD, PhD. Faculty of Medicine, University of Novi Sad, Department for Medical Oncology, Oncology Institute of Vojvodina. Put Doktora Goldmana 4, 21 204 Sremska Kamenica, Serbia.
Tel: +381 638041910; Email: Lazar.popovic@mf.uns.ac.rs
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patients live in a fear of infection, regular follow-up visits and diagnosis can be compromised [3,4]. Oncology patients are in greater risk of developing severe COVID-19, particularly the ones with poor performance status, hematologic malignancies and the ones recently treated with chemotherapy [5,6]. Vaccination against COVID-19 started at the very beginning of 2021. As of 1st September 2021, a total of 5,289,724,918 vaccine doses have been administered in the world [1]. Vaccination campaign in Serbia begun in January 2021, with 4 different anti SARS-CoV2 vaccines available to choose from: Sinopharm (BBIBO), BNT162b2 (Pfizer/BioNtech), Sputnik V (Gam-COVID-Vac), ChAdOx1 nCoV-19 (Oxford/AstraZeneca) [7]. Despite that availability of vaccines in Serbia was high, as of September 1st 2021 40.1% of the Serbian population has been completely vaccinated and 5,882,996, doses have been administered [1]. Guidelines for cancer patients' diagnosis, treatment and follow-up at the time of the COVID-19 pandemic have been available promptly after the beginning of the pandemic and were updated frequently and regularly [8,9]. Even before the vaccination process has started, oncology societies worldwide stated their rec-

ommendations and guidelines for cancer patient vaccination and insisted that they should be considered a high-priority population for COVID-19 immunization [10-12]. Although clinical trials for vaccines included healthy individuals and excluded cancer patients, the data of other vaccines in this patient population were considered and vaccination against SARS-CoV2 was strongly recommended [10-13].

Methods

We have conducted a cross-sectional study investigating cancer patient acceptability of vaccination, vaccine preferences, doubts and fears and reported side effects, considering the phase of cancer treatment. The study included patients with solid and hematologic malignancies that have been treated with systemic therapy or visited medical oncologists for the follow up or consultations from 1st July until 15th August 2021 at the Oncology Institute of Vojvodina, Serbia. Investigated patients were visiting medical oncology inpatient or outpatient departments for treatment, or medical oncologists for follow up and consultations. They were randomly enrolled during their regular visit to the oncology center by agreeing to fill in an individual paper questionnaire

Table 1. Patients population characteristics

Characteristics	All patients <i>n</i> (%)	Vaccinated <i>n</i> (%)	Not vaccinated <i>n</i> (%)
Number of patients	767	320 (41.72)	447 (58.28)
Median age, years (range)	63 (20-86)	65 (28-84)	62 (22-86)
Age group (years)			
18-24	3	0	3 (100)
25-49	160	55 (34.37)	105 (65.63)
50-59	136	50 (36.76)	86 (63.24)
60-69	251	107 (42)	144 (58)
70-79	183	93 (50.82)	90 (49.18)
80-	27	11 (42)	16 (58)
Primary tumor			
Breast cancer	365 (47.59)	158 (43.29)	207 (56.71)
Gastrointestinal cancer ¹	227 (29.59)	87 (38.32)	140 (61.68)
Genitourinary cancer	71 (9.26)	54.93 (39/71)	32 (45.07)
Hematology ²	40 (5.21)	14 (35)	26 (65)
Gynecological cancer	24 (3.13)	11 (45.83)	13 (54.17)
Other ³	40 (5.21)	10 (25)	30 (75)
Previous COVID-19 infections	164 (21.38)	57 (34.76)	107 (65.24)
Previous influenza vaccine	177 (23.07)	109 (61.58)	68 (38.42)
Cancer treatment phase			
Active treatment primary ⁴	297 (41.19)	128 (42.67)	169 (40.14)
Active treatment metastatic ⁵	314 (43.55)	97 (32.33)	217 (51.54)
Follow up	110 (15.26)	75 (25)	35 (8.32)

¹Including hepatobiliary and pancreatic cancers; ²lymphoma and myeloma only; ³head and neck, melanoma, GIST; ⁴Chemotherapy, targeted therapy, hormonal therapy; ⁵chemotherapy, targeted therapy, hormonal therapy, checkpoint inhibitors, tyrosine kinase inhibitors.

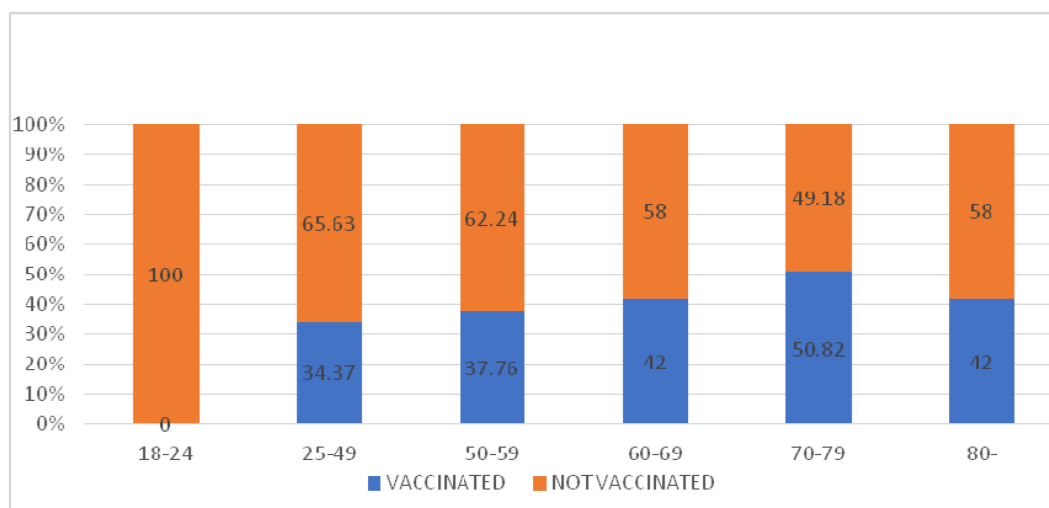


Figure 1. Vaccinated and non vaccinated cancer patients in age groups.

Table 2. The most common side effects after the first and the second dose of vaccines

Side effect	PFIZER n (%)		SINOPHARM n (%)		All vaccines n (%)	
Dose	1 st (77)	2 nd (68)	1 st (205)	2 nd (195)	1 st (320)	2 nd (293)
Pain	13 (16)	22 (15)	3 (1.46)	6 (3.1)	18 (6.14)	24 (8.19)
Fever	4 (5.19)	7.35 (5)	2 (0.97)	0 (0)	11 (3.44)	9 (3)
Chills	5 (6.49)	8.82 (6)	1 (0.49)	1 (0.5)	8 (2.5)	10 (3.12)
Myalgia	2 (2.6)	3 (4.4)	2 (0.98)	2 (1.02)	6 (1.9)	7 (2.18)
Headache	3.9 (3)	3 (4.4)	2 (0.98)	0 (0)	5 (1.56)	3 (0.9)
Diarrhea	0 (0)	1 (1.47)	1 (0.49)	0 (0)	1 (0.31)	1 (0.31)
Allergies	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Other	2 (2.6)	3 (4.41)	0 (0)	0 (0)	2 (0.6)	3 (1)

on previous COVID-19 infection, previous influenza vaccination, anti SARS-CoV2 vaccination acceptance, status and preferences, side effects and information origin. All patients signed an informed consent form and received no financial compensation. The questionnaire was approved by institutional ethics committee. Electronic health records of Oncology Institute of Vojvodina were used to review patient diagnosis and phase of treatment at the time of vaccination. Vaccinated and unvaccinated cancer patients were compared using χ^2 test for categorical variables and Moods median test for median age

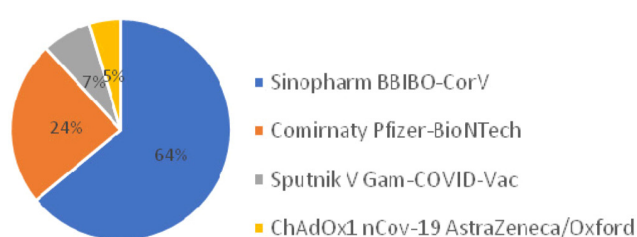


Figure 2. Vaccine choices in cancer patients.

Results

The study included 800 cancer patients who filled in the questionnaires and 767 of them have been valid and analyzable. The analyzed patient population characteristics are listed in Table 1.

When compared to the age groups, one half of the patients aged 70-79 received COVID-19 vaccine. There were no vaccinated patients in the age 18-24 group (Figure 1).

Previous SARS-CoV2 infection was reported by 164 (21.38%) of the investigated cancer patients and 57 (34.76%) of them decided to be vaccinated after the infection. Influenza vaccine received 177 (23.07%) patients at some point in their lifetime and the majority of them (109;61.58%) had COVID-19 vaccine in 2021. The vaccine choices are shown in Figure 2.

Side effects were reported by 35 (10.93%) of the patients after the first dose and 39 (13.31%) after

the second dose. The vaccine with the least side effect reported was Sinopharm (3% and 4.6% patients with side effects after the first and the second dose), while around one quarter of the patients vaccinated with other vaccines had some side effects (Figure 3). None of the investigated patients reported serious side effect of any vaccine.

The most common side effects are listed in Table 2. Data is presented for the whole vaccinated patient population, as well as the two most commonly used vaccines.

Asked why they have decided to vaccinate against COVID-19 187 (58%) of the patients reported they are worried about their own health as well as the health of their loved ones 104 (32.5%), 144 (54%) followed the health recommendations and trusted the science; 113 (35.31%) wished to return to normal life as soon as possible.

Not vaccinated were 447 (58.28%) of the enrolled patients. Half of them (232;51.9%) said they wish to get vaccinated after the end of their cancer treatment, while 79 (17.67%) wanted to get vac-

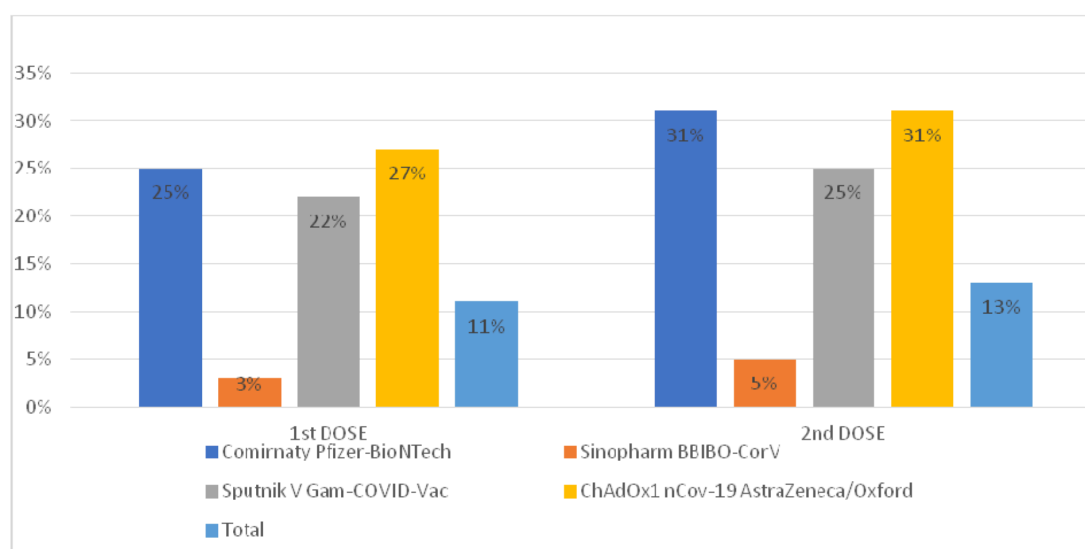


Figure 3. The frequency of the side effects after the first and the second dose.

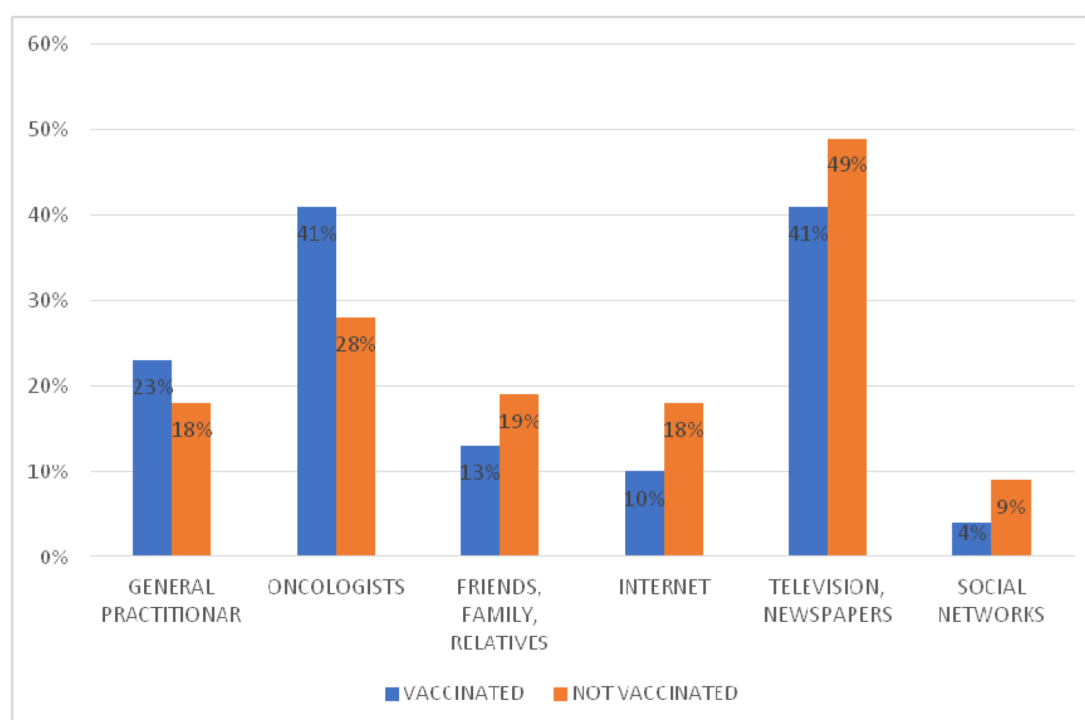


Figure 4. Self-reported information sources on COVID-19 vaccines in cancer patients.

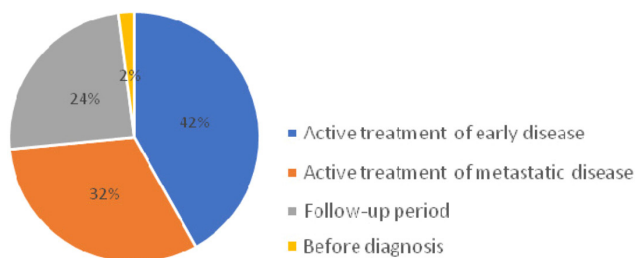


Figure 5. Treatment phase at the time of COVID 19 vaccination.

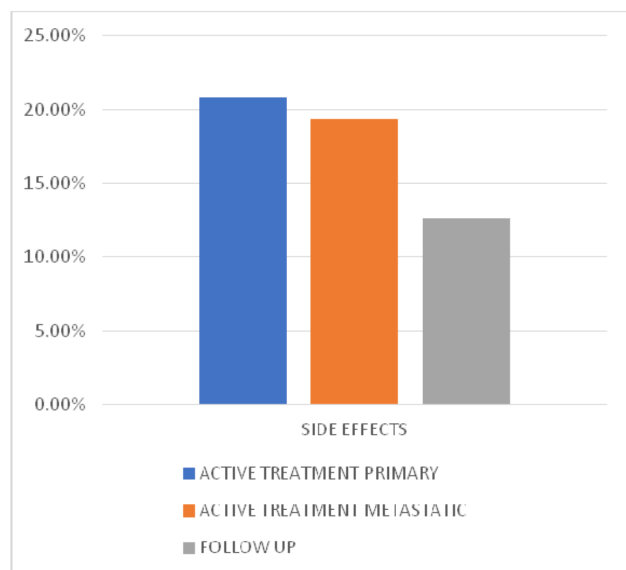


Figure 6. Side effects reported according to cancer treatment phase.

nated as soon as possible. Around 63 (14%) of the patients wished to wait for more data on efficacy and safety of vaccines. There were 79 (17.67%) not vaccinated cancer patients who refused vaccination. Out of 108 patients who responded to the question asking why they did not want to vaccinate 35 (32.41%) said they did not trust available scientific data, 40 (37.04%) were worried about side effects and 40 (37.04%) did not think vaccination is necessary. In the investigated population there were altogether 79 (10.2%) of the patients who definitely refused vaccination. These patients were significantly younger than vaccinated patients: median age 55 vs 65 years ($p=0.0006$).

The majority of the investigated patients who were not vaccinated found the information about COVID-19 vaccines on television and newspapers (212;49%) in comparison with 132 (41%) of the vaccinated patients. Not vaccinated patients also consulted significantly less their oncologist (120;28%) compared to 132 (41%) of vaccinated population ($p=0.003$). Unvaccinated cancer patients also con-

sider social networks, Internet, friends and family as the source of information more frequently than vaccinated cancer patients (Figure 4).

We collected data for the phase of treatment in 306 out of 320 patients who received the vaccine (Figure 5).

Most of the vaccinated cancer patients on active treatment for both early and metastatic disease were treated with hormone therapy or targeted therapies. Thirty patients who were treated with chemotherapy or combined chemo and targeted therapy received vaccines in between cycles of chemo: 10 patients received Pfizer, 19 Sinopharm and one patient received Sputnik V.

In different cancer subgroups most of the patients were equally vaccinated (Figure 6). Only genitourinary cancer patients were vaccinated in over 50% of the cases: 7 patients were vaccinated during tyrosine kinase inhibitor treatment for metastatic clear cell renal cell carcinoma, 20 patients with metastatic prostate cancer during new hormonal agents' treatment and in between chemotherapy cycles. In vaccinated breast cancer group, most of the patients were treated with hormonal therapy, targeted therapy for HER2 positive disease or combination: (67%;106/158). Twelve patients received vaccines in between cycles of chemotherapy. Most of the gastrointestinal cancer patients were vaccinated during the follow up period. Twelve patients were vaccinated in between cycles of chemotherapy. Five patients treated with checkpoint inhibitors were vaccinated in between immunotherapy cycles. None of the patients treated with anti CD20 antibody received vaccine.

Side effects reported according to the treatment phase are presented in Figure 6. Patients in the active treatment of disease had somewhat numerically more side effects reported in comparison to the patients in follow up phase ($p=0.21$).

Discussion

In the beginning of 2021, the national anti-COVID-19 campaign was launched in Serbia with the aim to vaccinate all eligible individuals in the country [6]. Four vaccines were available with free choice of preferred vaccine. Since the very beginning of the campaign during 6 months period prior to our survey, there were no reported vaccine shortages in Serbia. Vaccination was even stimulated by governmental decision to pay 25 euro per vaccinated person [14]. Oncology patients were encouraged to be vaccinated as well, recognized as a priority population [6]. Although it has been expected that the acceptance of vaccination in cancer patients would be higher than in the general population,

according to our data only 41.7% of adult cancer patients were vaccinated for COVID-19 in comparison to 40% of general population in Serbia as of 1st of September 2021 [1]. Data from a French cross-sectional study published in *Annals of Oncology* in the beginning of the vaccination campaign in the world, reported 57% of the oncology patients being interested in receiving COVID-19 vaccine as soon as it was available [15]. Data from a Polish cancer center at the same time period reported 60.3% of oncology patients were interested in receiving the vaccine [16]. These numbers are in concordance with higher vaccination rates in the general population in these countries: 65.72% in France and 50.43% in Poland [1]. Recent reports from an Israeli cancer center in Tel Aviv states 90.55% treated cancer patients received COVID-19 vaccine until April 2021 [17] and 81% in a cancer center in Dublin, Ireland [18]. Lower rates of vaccinated general population were recorded in eastern European countries and Balkans: 17.98% in Bulgaria, 26.98% in Romania, 12.99% in Bosnia and Herzegovina and 41% in Croatia [1]. To our knowledge there are no published data on vaccine acceptance or implementation in cancer patients in these countries. According to Center for Investigative Journalism in Serbia (CINS) and their data collected from the national epidemiology institute, the percentages of vaccinated people in general population in almost all age groups were higher in comparison with our data for cancer patients: 15% ages 18-24; 33.6% ages 25-49; 49.9% ages 50-59; 65.3% ages 60-69; 78.6% ages 70-79; 57.7% in older than 80 [19]. These data suggest inadequate acceptance of vaccine in highly prioritized populations of cancer patients of all age groups.

We have tried to evaluate the reasons for vaccine unacceptance in cancer patients and found that patients are concerned about the safety and efficacy of vaccines, are in fear of side effects and wish to wait for more reliable data, and these are reported concerns in cancer patients in other countries as well [15,16,20,21]. Only 10% of all investigated patients definitely refuse to receive vaccine and this is significantly younger population. Data from other studies suggest similar numbers of vaccine refusal in this patient population: 5.2% in Ireland [17], 16.6% in a French survey [15], and up to 28.8% of Tunisian oncology patients [20]. Half of the patients that were not vaccinated report they want to wait to end cancer treatment, which implies additional fear of side effects that might potentially occur due to cancer treatment. On the other hand, most of the patients who did receive vaccine (75%) were in the active cancer treatment phase, early or metastatic. Due to low rates of vaccinated cancer

patients, possibility exists that even general practitioners and oncologists as well, do not have enough knowledge and information themselves to recommend vaccination during cancer treatment even to the patients treated with hormone therapy and targeted therapies and not only cytotoxic drugs. In our study only 30 patients receiving chemotherapy were vaccinated in between chemotherapy cycles. According to the NCCN recommendations, patients were advised to receive vaccine after recovery of neutrophil count, which mostly occurred two to three days prior to chemotherapy cycle. Delay of vaccination is recommended after high dose chemotherapy with stem cell transplantation and CAR-T cell therapy until 3 months after the end of treatment [12].

None of the investigated patients had serious side effect of the vaccine. There are somewhat numerically but not statistically higher rates of side effects in patients in active treatment of both early cancer and metastatic disease in comparison to patients in the surveillance phase (20.77% and 19.38% vs 12.99%). Monin et al report evidently lower rate of side effects in cancer patients in comparison with healthy controls (46% vs 62% and 29% vs 69%) after the first and second vaccine dose, respectively [22]. The most common side effect was pain at the injection site reported by 18 (6.14%) and 24 (8.19%) patients after the first and the second dose, respectively. Patients reported no serious side effects of any vaccine. These data are consisting with growing real-world evidence justifying safe vaccination of cancer patients during active treatment with immune checkpoint inhibitors, targeted therapy and chemotherapy [22-25].

Both vaccinated and not vaccinated cancer patients mostly reach out for information to their oncologists (41% vs 28%) as well as television and newspapers (41% vs 49%, respectively). This is in concordance with previously reported data emphasizing the importance of oncologists in education and encouragement of cancer patients to receive COVID-19 vaccines [15,16,26]. Public media like television and newspapers often provide inadequate information presenting different experts who are giving their own opinions rather than official recommendations, which leads to uncertainty, fear and confusion in cancer patients and this was observed in the general population as well [27]. This is the main reason why oncologists should find the time to proactively encourage and support cancer patients to be vaccinated.

The other issue that might concern oncologists rather than cancer patients is the efficacy of vaccines in cancer patients on active treatment. There are doubts that effective immune response to

vaccine may lack in this population. Growing evidence of real-world data suggest that seropositivity rates in patients were lower than in the control groups [28-31]. Oostig et al reported results from a multicenter perspective non-inferiority trial, designed to assess the impact of chemotherapy and immunotherapy on immunogenicity and safety of mRNA-1273 vaccines. The results showed that after two vaccine doses the proportion of patients with SARS-CoV-2-binding antibody response is non-inferior when compared to healthy individuals. A significant minority of patients do lack adequate response. Increase in antibody concentration is reported after the second dose [32]. Efficacy in terms of protection from COVID-19 infection was also documented in cancer patients. In a series of 1503 cancer patients, reduced SARS-CoV-2 infection and death were reported after two doses of COVID-19 vaccines, confirming that vaccines do work in actively treated cancer patients [33].

To our knowledge this is the first cross-sectional study that reported cancer patients' acceptance and safety of COVID-19 vaccine in countries

with generally low vaccine acceptance in Europe. The study confirmed that patients are reluctant of receiving vaccine due to fear of side effects, especially during active cancer treatment, and unlike other studies reporting safety data, the majority of patients in this trial received Sinopharm inactivated vaccine. Although cancer patients' population was excluded from registrational vaccine trials, resulting in physicians' insecurity of prescribing vaccine to oncology patients on active treatment, emerging real-world data and clinical trials have gathered enough evidence to reassure any doubts. Vaccines are safe and effective in cancer patients and we should all proactively encourage this frail population to protect their own health and of their loved ones. We all have a great endeavor ahead of us, and this is to reach the end of COVID-19 pandemic as soon as possible.

Conflict of interests

The authors declare no conflict of interests.

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