Efficacy of the mRNA SARS-CoV-2 vaccine in cancer patients during systemic therapy. A single-centre experience

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Introduction. A novel coronavirus, causing severe acute respiratory syndrome 2 (SARS-CoV-2) has spread globally since its emergence in December 2019. The mRNA SARS-CoV-2 vaccines have been proven to be an efficient and safe disease control means among adult patients without immunocompromising conditions. However, cancer patients were among the group of people that was initially excluded from the registration trials.

Material and methods. 60 patients, enrolled to this study, had been voluntarily vaccinated either with the BNT162b2 or mRNA-1273 SARS-CoV-2 vaccine between March and June 2021 and have been undergoing systemic treatment in the Clinical Oncology Unit of the University Clinical Center of the Medical University of Silesia in Katowice, Poland. Patients received 2 injections of vaccine 21 days apart and were tested with Elecsys® Anti-SARS-CoV-2 immunoassay (Roche Diagnostics, France) for the presence of anti-S-protein antibodies in the patients’ serum. The serum samples were collected 2 to 8 weeks after receiving the second dose of vaccine.

Results. The BNT162b2 vaccine was administered to 57 patients, while the mRNA-1273 vaccine – to 3 patients. Seroconversion was achieved in 83.33% of patients. The median amount of anti-S-protein antibodies was 75.9 U/ml. There were no statistically significant differences in terms of age between the group with seroconversion and the group without seroconversion (Mann-Whitney U-test \( p = 0.762 \)). There was no statistically significant correlation between neither the BMI (Spearman test, \( p = 0.079 \)) nor age (Spearman test, \( p = 0.762 \)) and anti-S-protein antibody levels. Just as the diagnosis (primary tumor localization), clinical stage, type of modality (chemotherapy, chemoradiotherapy, immunotherapy) and the goal of treatment (radical, palliative) were not statistically significant in terms of anti-S-protein antibody levels.

Conclusions. Due to the high number of unresponsive or poorly responsive results, patients undergoing systemic therapy should be advised to maintain other measures of disease control such as distancing, usage of masks. Nevertheless, implementing mRNA SARS-CoV-2 vaccines in immunocompromised patients during systemic therapy is reasoned, valuable and safe.

Key words: cancer patients, systemic therapy, SARS-CoV-2, COVID-19, SARS-CoV-2 vaccine


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**Introduction**

A novel coronavirus, causing severe acute respiratory syndrome 2 (SARS-CoV-2) has spread globally since its emergence in December 2019, affecting our lives dramatically [1]. Until now it has infected 650 million people worldwide [2]. Since then, governments have applied several control measures such as distancing, usage of masks, testing of exposed or symptomatic patients, isolation of symptomatic patients and vaccination programs.

The mRNA SARS-CoV-2 vaccines have been proven to be an efficient and safe disease control means among adult patients without immunocompromising conditions. Their effectiveness has been reported to oscillate around 95%. However, cancer patients were among the group of people that was initially excluded from the registration trials [3, 4]. Therefore, vaccine efficacy among patients in this group remains unclear.

What is more, cancer patients are also at greater risk of COVID-19 infection and worse outcomes of treatment [5, 6]. Therefore, it is implied that SARS-CoV-2 vaccination of patients treated with antineoplastic drugs should be prioritized [7, 8]. That is why the Ministry of Health in Poland in 05.03.2021 implemented guidelines encouraging cancer patients to be the first group of patients vaccinated in Poland, beside elderly citizens and health care workers [9].

**Material and methods**

There were 60 patients who were enrolled in this study. We have included the patients who were voluntarily vaccinated either with BNT162b2 or mRNA-1273 SARS-CoV-2 vaccine between March and June 2021, according to the Polish SARS-CoV-2 vaccination program conducted by the Polish Ministry of Health and were currently undergoing systemic treatment.

There were 60 patients included in the statistical analysis – 36 women and 24 men. Demographic details are presented in table I.

**Results**

There were 60 patients included in the statistical analysis – 36 women and 24 men. Demographic details are presented in table I.

The BNT162b2 vaccine was administered to 57 patients, while the mRNA-1273 vaccine – to 3 patients. Seroconversion, defined as the amount of anti-S-protein antibodies above 0.80 U/ml was achieved in 83.33% of patients. The median amount of anti-S-protein antibodies was 75.9 U/ml, (min.

<table>
<thead>
<tr>
<th>Table I. Demographic data</th>
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<tbody>
<tr>
<td><strong>Parameter</strong></td>
</tr>
<tr>
<td>sex</td>
</tr>
<tr>
<td>age (years)</td>
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<tr>
<td></td>
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<tr>
<td></td>
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<tr>
<td>weight (kg)</td>
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<td></td>
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<tr>
<td>BMI (kg/m²)</td>
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</tbody>
</table>
According to registration trials, the mRNA SARS-CoV-2 vaccine is an effective and safe mean of disease control. Its efficacy was determined at to be 95% (BNT162b2 vaccine) and 94.1% (mRNA-1,273 vaccine).

Those studies as the primary end points had serologic or virologic evidence of SARS-CoV-2 infection or presence of COVID-19 symptoms [3, 4]. We have based our study on detecting seroconversion after at least 2 weeks of receiving the second dose of the vaccination. It was detected in 83.33% of tested patients and there were no statistically significant differences within secondary analyses performed in this study. This stands in accordance with other studies conducted on patients with immunocompromised conditions. In Barrière’s et al. study, 47.5% of patients had anti-S-seroconversion after 3 to 4 weeks, and 95.2% after 6 to 8 weeks after the second dose of the vaccination. What is more, antibody levels were significantly lower compared to the control group consisting of people with no known immunocompromising condition [10].

In Monin’s et al. study, seroconversion after the first dose of the vaccination was observed in 35% of cancer patients and in 95% after the booster – 21 days after the 1st injection [11]. According to Adddeo et al., seroconversion was observed in 94% of patients after the receipt of two doses of vaccine [12].

Differences between our study and the cited examples may be caused by used methodology. We did not differentiate between patients tested after 2 or 8 weeks after
Due to the high number of unresponsive or poorly responsive results, patients undergoing systemic therapy should be advised to maintain other measures of disease control such as social distancing and the use of masks. Swab testing of asymptomatic patients should be considered before admission to the hospital. The duration of immunity after receiving a 2-dose regimen remains unknown and requires further studies.

Conflict of interest: none declared. Elecsys® Anti-SARS-CoV-2 immunoassay tests were provided by Roche.

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Table V. Comparison of study results

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Seroconversion in cancer patients</th>
<th>Seroconversion in the control group</th>
<th>Malignancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Addeo et al. [12]</td>
<td>2021</td>
<td>94%</td>
<td>–</td>
<td>solid tumor and hematologic malignancies</td>
</tr>
<tr>
<td>Ariamanesh et al. [15]</td>
<td>2021</td>
<td>86.9%</td>
<td>–</td>
<td>hematologic malignancies</td>
</tr>
<tr>
<td>Bamière et al. [10]</td>
<td>2021</td>
<td>95.2%</td>
<td>–</td>
<td>solid tumor</td>
</tr>
<tr>
<td>Cai et al. [16]</td>
<td>2022</td>
<td>83.3%</td>
<td>96.3%</td>
<td>solid tumor</td>
</tr>
<tr>
<td>Massarweh et al. [17]</td>
<td>2021</td>
<td>90%</td>
<td>100%</td>
<td>solid tumor</td>
</tr>
<tr>
<td>Monin et al. [11]</td>
<td>2021</td>
<td>95%</td>
<td>100%</td>
<td>solid tumor</td>
</tr>
<tr>
<td>Schmueli et al. [18]</td>
<td>2021</td>
<td>84.1%</td>
<td>98.9%</td>
<td>solid tumor</td>
</tr>
<tr>
<td>Waldhorn [19]</td>
<td>2021</td>
<td>79%</td>
<td>84%</td>
<td>solid tumor</td>
</tr>
<tr>
<td>Yasin et al. [20]</td>
<td>2022</td>
<td>85.2%</td>
<td>97.5%</td>
<td>solid tumor</td>
</tr>
<tr>
<td>this study</td>
<td>2023</td>
<td>83.33%</td>
<td>–</td>
<td>solid tumor</td>
</tr>
</tbody>
</table>

the 2nd dose of the vaccine. Agbarya et al. provided data suggesting that up to 23.3% of patients were seronegative after the second dose of the vaccination [13]. Those results are also compliant with a systemic review by Tran et al. In their study, there were 21 works included providing data from a total of 2,309 patients with solid cancer. Seroconversion after the second dose of the vaccine was observed in 91–97% of patients [14]. The comparison of study results are presented in table V.

We did not observe any association between the seroconversion rate and age or chemotherapy in our study, which stands in contrast with a study by Yasim et al. [20]. This may be due to differences in the patient population size enrolled in the studies, which was larger in Yasim’s study. Similar effects were also detected in studies by Massarweh et al., Ariamanesh et al. and Buttiron Webber et al. [15, 17, 21]. The results of this study are also similar to studies on the influenza vaccination in patients undergoing chemotherapy [22, 23]. The goal of treatment (radical or palliative) or the patients’ age did also not affect the results of the vaccination [23]. In our study there was no correlation between BMI and the amount of anti-S antibodies detected. In the large prospective study by Nilles et al., after adjusted analysis there was no evidence of increased seroprevalence with increasing BMI among tested patients. There was also no statistically significant differences between seropositive obese and non-obese patients in terms of peak SARS-CoV-2 IgG titers [24].

Unfortunately, some patients did not follow the Ministry of Health recommendations and had themselves vaccinated within 2 days of finishing the last dose of systemic treatment. There were seven cases of such practice in our study, but only in one case was anti-S-protein antibodies undetectable (a 68-year-old male patient, treated with chemotherapy due to CS III lung cancer, sequential chemoradiation).

Conclusions
Due to the high number of unresponsive or poorly responsive results, patients undergoing systemic therapy should be advised to maintain other measures of disease control such as social distancing and the use of masks. Swab testing of asymptomatic patients should be considered before admission to the hospital. The duration of immunity after receiving a 2-dose regimen remains unknown and requires further studies.

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