

Original Scientific Article

SARS-COV-2 ANTIGEN SCREENING DURING THE FIRST POST-LOCKDOWN MAJOR MUSIC FESTIVAL IN NOVI SAD, SERBIA, IN JULY 2021

Maja Lazović¹, Veselin Bojat², Vladimir Vuković^{1,3}, Nina Smiljanić², Marija Milić⁴, Radmila Velicki^{1,3}, Nataša Nikolić^{1,3}, Tatjana Pustahija^{1,3}, Mioljub Ristic^{1,3}

¹Institute of Public Health of Vojvodina, Novi Sad, Serbia

²Health Center Novi Sad, Novi Sad, Serbia

³Faculty of Medicine, University of Novi Sad, Novi Sad, Serbia

⁴University of Pristina temporarily settled in Kosovska Mitrovica, Serbia

Abstract. *Many countries have resumed mass gathering events like music festivals, despite potential risk of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmissions. This study aimed to examine the frequency of SARS-CoV-2 infection among visitors to a mass event, the EXIT festival, in relation to the proposed preventive measures. A total of 466 visitors were included in this longitudinal study conducted in Novi Sad, Serbia, during July, 2021. All subjects were tested with RDT-Ag test for the presence of SARS-CoV-2 virus at the beginning of the study and seven days after. Basic socio-demographic and epidemiological data were collected through a questionnaire. The average age of participants was 28.34 ± 8.87 years with the majority of men (53.7%). There were 170 (36.5%) vaccinated participants. A 97.1% in vaccinated and 92.2% in unvaccinated group, reported to regularly wear a protective mask ($p=0.029$). At the second cross-sectional testing, 354 subjects were tested, of which 150 (42.4%) were vaccinated. There was no statistically significant difference in application of preventive measures during and after the festival, in respect to vaccination status of the participants. Twenty participants (5.6%) reported some of the COVID-19-like symptoms in the first seven days after visiting the festival, but no COVID-19 infection was confirmed at the RDT-Ag testing. Despite the potential effectiveness of applied preventive measures such as RDT-Ag screening, mask-wearing and vaccination, additional caution is needed when holding these events during a period of high SARS-CoV-2 transmission, as well as when the new virus variants emerge in community.*

Key words: COVID-19, preventive measures, RDT-Ag testing, mass event, EXIT festival.

Introduction

Mass gatherings represent an assembling of a larger number of people at a certain location, in a certain period of time and for a certain purpose, and as such are associated with an increased risk for the health of participants due to various factors [1,2]. During the COVID-19 pandemic, mass gatherings posed a significant public health challenge given the close contact between visitors, bringing to the increased risk of the SARS-CoV-2 virus transmitting to the susceptible population [3–5]. A recent review of the available literature showed that the most important factors associated with the risk of SARS-CoV-2 transmission are a longer duration of the mass event, organization of the indoor events and non-compliance with the preventive measures, while on the other hand, there was no correlation between the size of the event and the higher risk of SARS-CoV-2 transmission [5–7].

Governments of most countries in the world developed different strategies for organizing mass gatherings based on two fundamental approaches: cancelling or limiting mass gatherings, or limiting the number of visitors

to these events [3,4]. The cancellation of most mass events in the first year of the COVID-19 pandemic had a huge impact not only on social aspects of human functioning but also on the economy of many countries [8]. The availability of COVID-19 vaccines in combination with other public health measures (e.g., mask wearing, physical distancing, disinfection) and better knowledge of the duration of immunity after COVID-19 infection have significantly changed the situation in many countries and indicated that SARS-CoV-2 transmission in the population can be controlled [9–14]. Thanks to this growing knowledge and the daily increase in coverage of vaccination against COVID-19, mass gatherings were allowed in many countries around the world [9,10].

The World Health Organization continues to underline the importance of mass gatherings (sports events, concerts, celebrations, etc.) on the intensity of transmission of COVID-19, especially in the vulnerable population in which there is limited immunity to this infection [15]. However, in countries where the epidemiological situation allows reopening and mass gatherings to occur, after a period of restrictions on movement, it is crucial to ensure that all decisions on the organization of mass events are based on the risk assessment of the intensity of virus transmission in population and include immuniza-

Correspondence to: Maja Lazović
Institute of Public Health of Vojvodina, Futoška 121, 21000 Novi Sad
E-mail: maja.lazovic@izjzv.org.rs
Received May 7th, 2022 / Accepted May 18th, 2022

tion in compliance with the adequate preventive measures [15]. Of concern is the fact that a large percentage of population in many countries has not been vaccinated yet. In addition, new variants of SARS-CoV-2 are emerging, which are more contagious than the previous ones and against which somewhat lower effectiveness of several vaccines has been observed [9,10,16,17]. As asymptomatic individuals and patients with a mild clinical presentation of COVID-19 significantly contribute to the transmission of SARS-CoV-2 in the community, screening testing of unvaccinated individuals, regardless of signs or symptoms of COVID-19, is an important approach to prevent and control the outbreak of COVID-19 in the population [11]. The use of RDT-Ag (rapid diagnostic test for detection of SARS-CoV-2 antigen) as the screening strategy is a suitable measure because of the lower testing costs and quickly available results, as well as the high specificity and some lower sensitivity of these tests in the early stages of SARS-CoV-2 infection when the infected person is the most contagious [11]. The use of a RDT-Ag as a screening test as part of a prevention strategy is important because of the short time required to obtain results, high specificity and sensitivity in the early stages of infection when viral load is at the highest, reduced sensitivity as the disease progresses and SARS-CoV-2 transmission becomes lower [11,18].

A number of studies investigating the effectiveness of comprehensive preventive measures during mass gatherings, such as the vaccination, wearing protective face masks, systematic RDT-Ag test screening, adequate ventilation of the indoor area and appropriate hygiene, have indicated the safety of mass gatherings and low risk of SARS-CoV-2 transmission, only if all prescribed preventive measures against COVID-19 are implemented [9,19–21]. Therefore, the aim of our study was to examine the frequency of SARS-CoV-2 infection in a representative sample of visitors to a mass event, the EXIT music festival in relation to the applied preventive measures.

Material and Methods

Study Design

This longitudinal study was conducted in the period from July 8, 2021 to July 17, 2021 in the City of Novi Sad, Serbia, where the data of repeated measurements from the same sample of participants in two time periods, were collected. The study included visitors of the EXIT music festival, which is traditionally held outdoor, every year during July, at the Petrovaradin Fortress in Novi Sad, Serbia. The necessary sample size was calculated using the G-power program v. 3.1.6 [22] considering an alpha error of 5%, study strength of 0.80, a 95% confidence interval, and an average number of the EXIT festival visitors, which was around 50,000 people annually, in the previous 5 years. Thus, the calculated necessary sample size was 382 participants, but due to the probability of the lost to follow-up, the sample size was increased by 20%,

so that at the beginning of the study a total of 466 visitors were included.

Special preventive measures were active at the festival site. Entry to the festival was allowed only for visitors who met at least one of the following conditions: 1. A proof of complete vaccination schedule, i.e. received two doses of any of the available vaccines against COVID-19, and more than 14 days have passed since the second dose; 2. A certificate of the previous COVID-19 in the last six months before the festival visit with a positive specific SARS-COV2 IgG antibody test; or 3. A negative RT-PCR (reverse transcription polymerase chain reaction) or RDT-Ag, not older than 48 hours before the visit. The same conditions applied to the visitors and organizers of the festival. Also, body temperature was measured before entering the festival, and hand sanitizers were available at several points at the festival site.

For the purpose of investigating the effectiveness of applied preventive measures, all visitors were monitored for seven days. The first cross-sectional testing was conducted at the beginning of the study, during the days of the festival, on July 8, 9 and 10, 2021. Basic socio-demographic data (gender, age, level of education, marital status) and epidemiological data (travel abroad in the past 14 days, presence of COVID-19 symptoms, contact with a confirmed case of COVID-19, previous COVID-19 infection and date of illness, presence of chronic diseases, vaccination status and type of COVID-19 vaccine received, adequate use of a protective face mask, and adherence to other prevention measures) were obtained through a specially designed questionnaire. The second cross-sectional testing was conducted one week after the first, i.e. on July 15, 16 and 17, 2021. The questionnaire provided additional epidemiological data on the potential risk of exposure to COVID-19 in the days after the festival (occurrence of COVID-19 symptoms in the days after the festival, contact with a confirmed case of COVID-19 in the days after the festival visit, regularity and duration of the use of a protective face mask in the days after visiting the festival, regular use of a protective face mask during the festival, staying in indoor space with a large number of people in the days after visiting the festival, adherence to other preventive measures in the days after visiting the festival, and the time spent at the EXIT festival).

Laboratory Methods

All enrolled subjects were tested with the RDT-Ag (STANDARD Q COVID-19 Ag Test, SD Biosensor, Gyeonggi-do, South Korea) [18] for the presence of SARS-CoV-2 virus in a sample of throat and nose swabs at the beginning of the study and seven days after the first test, regardless of their vaccination status. The seventh day is set for retesting because it represents the period in which laboratory confirmation can be obtained in about 95% of those infected with SARS-CoV-2 virus, when virus excretion is greatest and when the possibility of virus detection by antigen test is the greatest [23].

During the first visit to the EXIT festival, nasopharyngeal swab samples were collected by the trained healthcare workers from the Health Center Novi Sad together with the supervision of the study investigators, before entering the festival, and an RDT-Ag test was performed immediately at the sampling site. Respondents who were tested positive on the first test were excluded from the current study, isolated in the red area, and referred to the COVID-19 respiratory center of the Health Center Novi Sad for further diagnostics and treatment, in accordance with the current professional and methodological instructions of the Institute of Public Health of Serbia.

Study participants with a negative first RDT-Ag were invited by e-mail or telephone to the second test, seven days apart, when testing was performed with the same type of RDT-Ag test, at the Health Center Novi Sad.

Statistical Analysis

Descriptive statistics with the mean and standard deviation (SD) for continuous variables and absolute frequencies and percentage (%) for categorical variables were used for the data presentation. The Kruskal-Wallis test, Mann Whitney - U test, and Chi-squared test were used to examine the differences between continuous and categorical variables, where appropriate. The level of statistical significance was set at $p < 0.05$. Data were analyzed using the SPSS Windows user package, version 19.

Ethical Considerations

The Ethics Committee of the Health Center Novi Sad approved the study protocol under the number 21/14-1, from July 7, 2021. The approval was also obtained from the director of the Health Center Novi Sad (decision number 21/14-2, from July 8, 2021). All visitors who agreed to participate in the study, and who met one or more inclusion criteria for this research study were informed about the purpose and the aim of the study, and gave their written consent to participate. Each participant was assigned with a special study code which was then entered in the questionnaire used in the research as well as on the samples taken, in order to make the research process anonymous. Only the main study investigators knew the personal data of the respondents. All data were thus fully anonymized before the analyses were conducted.

Results

In the first cross-sectional testing, a positive RDT-Ag was obtained from two participants who were then excluded from the study monitoring, thus, a total of 466 subjects were included in the study, of whom 170 (36.5%) were vaccinated and 296 (63.5%) were unvaccinated (Table 1).

Out of 464 participants that gave information on sex, the majority (53.7%) were male. The average age of the respondents tested on the first day of arrival at the EXIT

festival was 28.34 ± 8.87 years, where the youngest respondent was 15 and the oldest was 58 years old. Of 170 participants that were vaccinated, a 48.8% received Pfizer-BioNTech BNT162b2 vaccine, 30.6% received Sinopharm BBIBP-CorV, 11.2% Oxford-AstraZeneca ChAdOk1 nCoV-19, 8.2% Gamaleya Research Institute Gam-COVID-Vac, 0.6% were vaccinated with the Moderna mRNA-1273, while the one remaining participant (0.6%) did not provide data on the vaccine type. The vaccinated participants were on average 5.3 years older (mean = 31.70, SD=10.54 years) in respect to unvaccinated participants (mean = 26.41, SD = 7.08 years) ($p = 0.001$). The majority (44.1%) of vaccinated participants belonged to the 21-30 age group followed by 31-40 (18.2%) and 41-50 (18.2%) group, while in the unvaccinated group, the majority (52.7%) were in 21-30 years group, followed by the youngest group, 15-20 (23%) ($p < 0.001$). A total of 50.2% of the participants were single, with 42.9% in vaccinated group and 54.4% in unvaccinated ($p < 0.001$). Regarding the level of formal education, majority (47.1%) in the vaccinated group had primary/secondary school education followed by participants with a university degree (40.6%) while in the unvaccinated participants inversion was noted and the majority (45.9%) had university degree followed by 42.9% of participants with primary/secondary level education ($p = 0.533$). Around 7% of vaccinated participants reported having some chronic disease with respect to just 2% in the unvaccinated group ($p = 0.007$). A total of 9.4% of vaccinated participants reported travelling abroad in respect to just 3% of unvaccinated ($p = 0.004$). Also, significantly higher percent (27.1%) of vaccinated participants reported having had a COVID-19 in the past in comparison to just 18.2% of unvaccinated participants ($p = 0.026$). The majority of participants reported wearing a protective mask adequately, i.e. 97.1% and 92.2% in vaccinated and unvaccinated group, respectively ($p = 0.024$). High percent of participants (above 97%) in both groups reported adherence to other preventive measures against the spread of COVID-19. Sex of the participants, level of education, contact with a person with COVID-19 symptoms or with those who had laboratory confirmation of COVID-19 were similarly distributed in the vaccinated and unvaccinated persons without significance differences ($p > 0.05$).

At the second cross-sectional testing, seven days from the first, 24% of the respondents were lost to follow-up, thus, a total of 354 participants were included, of which 150 (42.4%) were vaccinated and 204 (57.6%) were not vaccinated. There was no statistically significant difference in the application of the proposed preventive measures and activities during and after the EXIT festival, with respect to the vaccination status of the participants, as reported in the Table 2.

The majority of participants (68.6%) did not wear a face mask at the festival, but 87.6% reported having worn a mask after the festival and until the moment of testing. Most of the participants avoided staying indoors with a large number of people (78.8%) and applied other pre-

ventive measures, like physical distancing, hand washing and disinfection (92.1%). Only one unvaccinated respondent reported having been in contact with a person with a confirmed COVID-19. That participant also reported the presence of symptoms that may indicate

COVID-19 that appeared in the first days after visiting the EXIT festival (fever, sore throat, fatigue, runny nose), but his RDT-Ag was negative at the second cross-sectional testing, performed seven days after visiting the festival.

Table 1 Socio-demographic and epidemiological characteristics of participants tested at the first day of arrival at the EXIT festival, Novi Sad, Serbia

Variables	Total (n=466), n (%)	Vaccination status		p-value*
		Vaccinated (n=170), n (%)	Unvaccinated (n=296), n (%)	
Sex				
Male	250 (53.7)	90 (52.9)	160 (54.1)	0.905
Female	214 (45.9)	79 (46.5)	135 (45.6)	
Missing	2 (0.4)	1 (0.6)	1 (0.3)	
Age (years), mean (SD)	28.34±8.87	31.70±10.54	26.41±7.08	0.001
Age group				
15-20	91 (19.5)	23 (13.6)	68 (23.0)	<0.001
21-30	231 (49.6)	75 (44.1)	156 (52.7)	
31-40	89 (19.1)	31 (18.2)	58 (19.6)	
41-50	44 (9.4)	31 (18.2)	13 (4.4)	
51-60	11(2.4)	10 (5.9)	1 (0.3)	
Marital status				
Single	234 (50.2)	73 (42.9)	161 (54.4)	<0.001
In a relationship / extramarital	155 (33.3)	51 (30.0)	104 (35.1)	
Married	75 (16.1)	44 (25.9)	31 (10.5)	
Missing	2 (0.4)	2 (1.2)	0 (0)	
Level of education				
Primary / secondary school	207 (44.4)	80 (47.1)	127 (42.9)	0.533
Higher education	54 (11.6)	21 (12.3)	33 (11.2)	
University degree	205 (44.0)	69 (40.6)	136 (45.9)	
Having any chronic disease				
Yes	18 (3.9)	12 (7.1)	6 (2.0)	0.007
No	448(96.1)	158 (92.9)	290 (98.0)	
Traveling abroad				
Yes	25 (5.4)	16 (9.4)	9 (3.0)	0.004
No	441 (94.6)	154 (90.6)	287 (97.0)	
Contact with a person/s with COVID-19 symptoms				
Yes	3 (0.7)	2 (1.2)	1 (0.3)	0.415
No	462 (99.1)	168 (98.8)	294 (99.4)	
Missing	1 (0.2)	0 (0)	1 (0.3)	
Contact with the confirmed COVID-19 case/s				
Yes	2 (0.4)	2 (1.2)	0 (0.0)	0.131
No	463 (99.4)	168 (98.8)	295 (99.7)	
Missing	1 (0.2)	0 (0)	1 (0.3)	
Pre-existing COVID-19 infection				
Yes	100 (21.5)	46 (27.1)	54 (18.2)	0.026
No	366 (78.5)	124 (72.9)	242 (81.8)	
Wearing a mask adequately				
Yes	438 (94.0)	165 (97.1)	273 (92.2)	0.024
No	27 (5.8)	4 (2.3)	23 (7.8)	
Missing	1 (0.2)	1 (0.6)	0 (0)	
Adherence to other preventive measures[#]				
Yes	455 (97.6)	167 (98.2)	288 (97.3)	0.232
No	10 (2.2)	2 (1.2)	8 (2.7)	
Missing	1 (0.2)	1 (0.6)	0 (0)	

*Significant results (p<0.05) are presented in bold. [#]Other preventive measures included: physical distancing, hand washing and disinfection.

Table 2 Adherence to the preventive measures in participants tested seven days after the EXIT festival visit, according to their vaccination status, Novi Sad, Serbia

Variables	Total (n=354) n (%)	Vaccination status		p-value
		Vaccinated (n=150), n (%)	Unvaccinated (n=204), n (%)	
Wearing a mask at the festival				
Yes	110 (31.1)	52 (34.7)	58 (28.4)	0.219
No	243 (68.6)	97 (64.7)	146 (71.6)	
Missing	1 (0.3)	1 (0.6)	0 (0)	
Wearing a mask after the festival and until the moment of testing				
Yes	310 (87.6)	133 (88.7)	177 (86.8)	0.394
No	43 (12.1)	16 (10.7)	27 (13.2)	
Missing	1 (0.3)	1 (0.6)	0 (0)	
Staying indoors with a large number of people				
Yes	74 (20.9)	27 (18.0)	47 (23.0)	0.270
No	279 (78.8)	122 (81.3)	157 (77.0)	
Missing	1 (0.3)	1 (0.7)	0 (0)	
Use of other preventive measures [#]				
Yes	326 (92.1)	141 (94.0)	185 (90.7)	0.453
No	26 (7.3)	8 (5.3)	18 (8.8)	
Missing	2 (0.6)	1 (0.7)	1 (0.5)	
Contact with the confirmed COVID-19 case/s				
Yes	1 (0.3)	0 (0.0)	1 (0.5)	0.576
No	353 (99.7)	150 (100.0)	203 (99.5)	

[#]Use of other preventive measures included: physical distancing, hand washing and disinfection

Table 3 Presence of the COVID-19-like symptoms from the day after the EXIT festival, by vaccination status of the participants, Novi Sad, Serbia

Vaccination status against COVID-19	Total (n=354), n (%)	COVID-19-like symptoms from the day after the festival		p-value
		No (n=334), n (%)	Yes (n=20), n (%)	
Vaccinated	150 (42.4)	142 (42.5)	8 (40.0)	0.825
Unvaccinated	204 (57.6)	192 (57.5)	12 (60.0)	

Table 4 Adherence to proposed preventive measures in participants tested seven days after the EXIT festival visit, according to the presence of COVID-19-like symptoms, Novi Sad, Serbia

Variables	Total (n=354), n (%)	Without COVID-19 symptoms (n=334), n (%)	With COVID-19 symptoms (n=20), n (%)	p-value
Wearing a mask at the festival				
Yes	110 (31.1)	106 (31.7)	4 (20.0)	0.523
No	243 (68.6)	227 (68.0)	16 (80.0)	
Missing	1 (0.3)	1 (0.3)	0 (0)	
Wearing a mask after the festival and until the moment of testing				
Yes	310 (87.6)	292 (87.4)	18 (90.0)	0.925
No	43 (12.1)	41 (12.3)	2 (10.0)	
Missing	1 (0.3)	1 (0.3)	0 (0)	
Staying indoors with a large number of people				
Yes	74 (20.9)	73 (21.9)	1 (5.0)	0.189
No	279 (78.8)	260 (77.8)	19 (95.0)	
Missing	1 (0.3)	1 (0.3)	0 (0)	
Using other preventive measures [#]				
Yes	326 (92.1)	308 (92.2)	18 (90.0)	0.847
No	26 (7.3)	24 (7.2)	2 (10.0)	
Missing	2 (0.6)	2 (0.6)	0 (0)	
Contact with the confirmed COVID-19 case/s				
Yes	1 (0.3)	0 (0.0)	1 (5.0)	0.057
No	353 (99.7)	334 (100)	19 (95.0)	

[#]Use of other preventive measures included: physical distancing, hand washing and disinfection

Twenty participants (5.6%), all of which were tested negative at the first RDT-Ag test, reported that they had some of the symptoms that may indicate COVID-19 infection in the first seven days after visiting the festival (Supplementary Table 1). Nasal congestion and runny nose, along with coughing and chest pain were the most common symptoms reported by these participants. Fever, malaise, diarrhoea, nausea, and headache were reported less frequently. In general, subjects reported the presence of multiple symptoms simultaneously. No significant difference in vaccination status was observed between those who reported having some of the symptoms that may indicate COVID-19 infection (40% were vaccinated and 60% were unvaccinated) and those who did not (42.5% were vaccinated and 57.5% were unvaccinated) ($p = 0.825$) (Table 3). Finally, among these participants, tested by the RDT-Ag test after seven days after visiting the EXIT festival, no COVID-19 infection was confirmed.

Adherence to several preventive measures in participants with and without COVID-19-like symptoms is reported in the Table 4.

No statistical difference ($p > 0.05$) was found in behaviors like wearing a mask at the festival, wearing a mask after the festival and until the moment of testing, staying indoors with a large number of people, using other preventive measures, and contact with the confirmed COVID-19 case/s, between the two observed groups. Finally, there was no statistically significant difference ($p = 0.173$) in the mean hours spent during the festival between visitors with (22.55 ± 15.35 hours) and those without COVID-19-like symptoms (18.06 ± 14.24 hours) (data are not shown).

Discussion

The results of our analysis indicate that in the group of respondents negative on the first antigen test performed on the first day of their visit to the EXIT festival, during which they applied strict measures to prevent the spread of SARS-CoV-2 virus, there was no confirmed COVID-19, by the RDT-Ag testing, in the period of seven days after the visit to the festival. Specifically, at the second screening using RDT-Ag test, which was performed on the seventh day after the first, the test results remained negative in all subjects regardless of their vaccination status. About 5% of respondents reported symptoms that may indicate COVID-19 infection within seven days of visiting the festival, but the result of an RDT-Ag in these subjects remained negative.

Our results coincide with the results of several studies published worldwide [9, 19–21]. Namely, it was noticed that mass gathering outdoor events, regardless of the location, if organized in a way that allows strict control of the SARS-CoV-2 virus transmission and application of all prescribed preventive measures, carry a low risk of the SARS-CoV-2 transmission [9, 19–21]. A recent systematic review, which included 11 studies examining the risks of COVID-19 in visitors to various mass events, in-

dicated that strict application of preventive measures and their control can reduce, but not completely eliminate the risk for SARS-CoV-2 transmission among visitors [9]. Using mathematical models and data from studies conducted so far, it is estimated that an hour of stay at the theater performances, business conferences, football matches or an outdoor music events leads to 0.6 to 1.7 COVID-19 infections per 100,000 visitors, while an hour time spent at dance events and indoor concerts and festivals where visitors dance outdoors leads to 1.8 to 4.3 COVID-19 infections per 100,000 visitors [9]. Several studies emphasized the importance of a multilevel approach to the control of SARS-CoV-2 transmission, which involves the application of several preventive measures simultaneously. Thus, it becomes essentially difficult to determine the effectiveness of any measure individually [9, 24–30]. In our study, we noticed that there was no difference in the occurrence of the disease, more precisely, there was no confirmed COVID-19 infection in the participants of our study, regardless of their vaccination status.

At most mass events in the world, preventive measures that provide means for hand disinfection, wearing face masks, providing adequate ventilation, health examination and contact tracing are implemented [24–31]. In certain circumstances, the quarantine measure before visiting the event was applied to the visitors of mass events [25, 27, 31]. With increasing coverage of immunization against COVID-19 and the availability of different vaccines, the approach to organizing mass events has changed [9]. From June 2021, many countries around the world began to "open up" and allow the organization of mass events, requiring visitors to have a certificate of vaccination, or a certificate of a previous COVID-19 infection not older than six months, or a negative RDT-Ag or PCR test not older than 48 hours [9, 19–21].

It has been previously known that the use of RDT-Ag helps in the control of the COVID-19 in schools, in professional sports competitions, in health and social institutions, and mass gatherings around the world [11, 21, 32, 33]. Although data on the high effectiveness of the RDT-Ag strategy are increasingly available, caution should be placed when interpreting test results, as the sensitivity of RDT-Ag, especially in asymptomatic individuals widely ranged from 41.2% to 93.3%, depending on the type of RDT-Ag [11, 34–36]. Also, the sensitivity of the rapid antigen test is lower if the prevalence of COVID-19 in the population is lower, so repeated testing of the population of interest is recommended in such situations in order to increase the sensitivity of the applied RDT-Ag for the virus detection [11, 34–36]. On the other hand, RDT-Ag testing is a very useful method, because the results are quickly available (approximately after 10–15 minutes), due to their high specificity (positive persons can be immediately classified as positive) can be used on the swab sampling site ("point-of-care", "near patient"), while the use of PCR testing such as the gold standard, is much more expensive, requires more time, special equipment and machines, and specially trained staff [11, 18, 34–36].

Results from several studies indicate that the application of a one-day screening RDT-Ag the day before a concert or other mass event, the use of face masks and adequate and forced room ventilation can prevent high rates of SARS-CoV-2 infection in the organization of a mass event indoors, and in situations where maintaining the physical distance among visitors is not possible and when vaccination coverage in the population is low, i.e. less than 10% [19, 20, 36]. However, the results of various studies have shown that mass gatherings with preventive measures have a limited impact on SARS-CoV-2 virus transmission and on the increase of the COVID-19 incidence in the population, if the current incidence in the community is low [9, 36]. Otherwise, the impact of mass gathering on SARS-CoV-2 transmission and an increase in COVID-19 morbidity in the population would be significant and could contribute to an increase in morbidity of up to about 23% [9, 36]. A major problem around the world is the spread of the new variant of the virus, like delta and omicron variants, which were found to be more contagious than previous variants of SARS-CoV-2 virus and that also could break through the immune barrier acquired after COVID-19 infection or vaccination [16,37]. Thus, it is very important to consider this when organizing mass events, given that during July 2021, when organizing several major public events in Massachusetts, a slight increase in the incidence of COVID-19 was observed among the residents, even among those vaccinated, and in 90% of patients from the sample, the delta variant of SARS-CoV-2 was isolated [5].

Our study has some limitations. Firstly, we had no control group of respondents who did not attend the EXIT festival and therefore we could not compare the differences in disease rates between the exposed to the event and those that were not exposed. Secondly, even though the EXIT festival is an international festival with visitors from all over the world, we included only visitors that are residents of Serbia, since it was necessary to conduct a repeated RDT-Ag testing seven days after the festival ended, which would not be possible to conduct for the international visitors since the majority of them travelled back to their homeland countries as soon as the festival finished. Thirdly, during the time of the festival, the

number of COVID-19 cases in the population of the city of Novi Sad as well as the Republic of Serbia was low, and thus the circulation of the virus in the population was low, which could indirectly affect the lower risk of spreading the virus among EXIT festival visitors and consequently the absence of the COVID-19 [38]. Also, the low prevalence of COVID-19 in the population at the time of the study could potentially affect the lower sensitivity of the RDT-Ag. Finally, a slightly smaller number of subjects responded to the follow-up call for the second RDT-Ag testing compared to the calculated sample size. However, we argue that this reduction in sample size did not significantly affect our findings.

Despite these limitations, the results of our study and their comparability with the previous findings from the literature are important since they imply the possibility of a good control of the SARS-CoV-2 transmission and COVID-19 at the mass events during the COVID-19 pandemic. Also, our findings indicate that the organization of mass events is accompanied by a low risk of disease if the recommended preventive measures are applied and strictly controlled. In line with this, there was no increased number of COVID-19 cases in Novi Sad, in community, after the EXIT festival finished. The results of our study should be interpreted in the light of the intensity of SARS-CoV-2 virus transmission in the population, the emergence of new virus variants and their characteristics. Finally, current results lead to the conclusion that with good organization and following the preventive measures during a visit to a mass event, the risk of COVID-19 associated with a mass event is not significantly higher than that estimated in the population, at the time.

Acknowledgment. *The authors would like to thank all the participants enrolled in this study and all the colleagues from the Health Center Novi Sad that contributed to the realization of this study. Finally, our gratitude also goes to the Projekt Lab Novi Sad for the provided technical support.*

Funding. *This study was supported by the City of Novi Sad and the EXIT foundation. The funders had no role in the study design, analysis, and interpretation of the data; preparation of the manuscript nor decision to submit the manuscript for publication.*

References

1. World Health Organization. Public Health for Mass Gatherings: Key Considerations. World Heal Organ. 2015. Available: <https://apps.who.int/iris/handle/10665/162109>
2. Tavan A, Tafti AD, Nekoie-Moghadam M, et al. Risks threatening the health of people participating in mass gatherings: A systematic review. *J Educ Health Promot.* 2019;8: 209. doi:10.4103/jehp.jehp_214_19
3. McCloskey B, Zumla A, Ippolito G, Blumberg L, Arbon P, Cicero A, et al. Mass gathering events and reducing further global spread of COVID-19: a political and public health dilemma. *Lancet.* 2020;395: 1096–1099. doi:10.1016/S0140-6736(20)30681-4
4. World Health Organization. Key planning recommendations for mass gatherings in the context of COVID-19: interim guidance, first issued 14 February 2020, third update 4 November 2021. 2020. Available: <https://apps.who.int/iris/handle/10665/332235>
5. Brown CM, Vostok J, Johnson H, et al. Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021. *MMWR Morb Mortal Wkly Rep.* 2021;70: 1059–1062. doi:10.15585/mmwr.mm7031e2
6. COVID-19 Health System Response Monitor. Which strategies are countries using for mass gatherings and community events and how have they changed throughout the pandemic? – Cross-Country Analysis. 2021 [cited 2 May 2022] pp. 30–31. Available: <https://analysis.covid19healthsystem.org/index.php/2021/03/02/which-strategies-are-countries-using-for-mass-gatherings-and-community-events-and-how-have-they-changed-throughout-the-pandemic/>

7. World Health Organization. Holding gatherings during the COVID-19 pandemic: WHO policy brief, 2 August 2021. World Heal Organ. 2021. Available: <https://www.who.int/publications/i/item/holding-gatherings-during-the-covid-19-pandemic-who-policy-brief-2-august-2021>
8. Harris M, Kreindler J, El-Osta A, Esko T, Majeed A. Safe management of full-capacity live/mass events in COVID-19 will require mathematical, epidemiological and economic modelling. *J R Soc Med.* 2021;114: 290–294. doi:10.1177/01410768211007759
9. Health Information and Quality Authority. Evidence summary of public health measures to limit the transmission of SARS-CoV-2 at mass gatherings Health Information and Quality Authority Evidence summary of public health measures to limit the transmission of SARS-CoV-2 at mass gatherings. 2021.
10. World Health Organization. Critical preparedness, readiness and response actions for COVID-19: interim guidance, 27 May 2021. 2021; 16 p. Available: <https://apps.who.int/iris/handle/10665/341520>
11. Centers for Disease Control and Prevention. Overview of Testing for SARS-CoV-2, the virus that causes COVID-19. In: Cdc.Gov [Internet]. 2022 [cited 2 May 2022]. Available: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Ftesting%2Fexpanded-screening-testing.html
12. Haas EJ, Angulo FJ, McLaughlin JM, et al. Impact and effectiveness of mRNA BNT162b2 vaccine against SARS-CoV-2 infections and COVID-19 cases, hospitalisations, and deaths following a nationwide vaccination campaign in Israel: an observational study using national surveillance data. *Lancet.* 2021;397: 1819–1829. doi:10.1016/S0140-6736(21)00947-8
13. Ministry of Health of the State of Israel. Israel to Lift All Coronavirus Restrictions. 2021 [cited 2 May 2022]. Available: <https://www.gov.il/en/departments/news/23052021-02>
14. Lumley SF, O'Donnell D, Stoesser NE, et al. Antibody Status and Incidence of SARS-CoV-2 Infection in Health Care Workers. *N Engl J Med.* 2021;384: 533–540. doi:10.1056/NEJMoa2034545
15. World Health Organization. Coronavirus disease (COVID-19): Mass gatherings. In: World Health Organization [Internet]. 2021 [cited 2 May 2022]. Available: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-covid-19-mass-gatherings>
16. European Centre for Disease Prevention and Control. Assessing SARS-CoV-2 circulation, variants of concern, non-pharmaceutical interventions and vaccine rollout in the EU/EEA, 15th update. Stockholm; 2021. Available: <https://www.ecdc.europa.eu/en/covid-19/timeline-ecdc-response>.
17. Bolze A, Luo S, White S, et al. SARS-CoV-2 variant Delta rapidly displaced variant Alpha in the United States and led to higher viral loads. *Cell Reports Med.* 2022;3: 100564. doi:10.1016/j.xcrm.2022.100564
18. Ristić M, Nikolić N, Čabarkapa V, Turkulov V, Petrović V. Validation of the STANDARD Q COVID-19 antigen test in Vojvodina, Serbia. *PLoS One.* 2021;16: e0247606. doi:10.1371/journal.pone.0247606
19. Llibre J, Revollo B, Blanco I, et al. SARS-CoV-2 transmission in an indoor mass-gathering live music event. A randomized clinical trial. 2021. doi:10.21203/RS.3.RS-244584/V1
20. Revollo B, Blanco I, Soler P, et al. Same-day SARS-CoV-2 antigen test screening in an indoor mass-gathering live music event: a randomised controlled trial. *Lancet Infect Dis.* 2021;21: 1365–1372. doi:10.1016/S1473-3099(21)00268-1
21. Estelle CD, Perl TM. To Test or Not to Test: COVID-19 Prevention Strategies to Keep Large Gatherings Safe. *Ann Intern Med.* 2021;174: 1470–1471. doi:10.7326/M21-2976
22. Heinrich Heine University Düsseldorf. G*Power: Statistical Power Analyses for Mac and Windows. In: Version 3.1.9.4 Germany [Internet]. 2019 [cited 2 May 2022]. Available: <https://www.psychologie.hhu.de/arbeitsgruppen/allgemeine-psychologie-und-arbeitspsychologie/gpower>
23. Peng B, Zhou W, Pettit RW, et al. Reducing COVID-19 quarantine with SARS-CoV-2 testing: a simulation study. *BMJ Open.* 2021;11: e050473. doi:10.1136/bmjopen-2021-050473
24. Department for Digital Culture Media & Sport (UK). Information for ticket holders attending the Euro 2020 Events Research Programme matches 2021. 2021. Available: <https://www.gov.uk/government/publications/information-for-ticket-holders-attending-the-euro-2020-events-research-programmematches/information-for-ticket-holders-attending-the-euro-2020-events-research-programme-matches#taking-part-in-the-event>
25. UEFA EURO 2020 Amsterdam. Negative test required for stadium entry 2021. Available: <https://euro2020amsterdam.nl/en/testen-wedstrijdbezoekuefa-euro-2020-in-amsterdam%0A>
26. Hashim HT, Babar MS, Essar MY, Ramadhan MA, Ahmad S. The Hajj and COVID-19: How the Pandemic Shaped the World's Largest Religious Gathering. *Am J Trop Med Hyg.* 2021;104: 797–799. doi:10.4269/ajtmh.20-1563
27. Job S, Kapoor M, Panda PK, Mohan L, Ravikant . COVID-19 Prevention Protocol for an Organised Mass Gathering-An Essential Requisite in Pandemic and Post-Pandemic Phase. *J Clin Diagnostic Res.* 2021. doi:10.7860/jcdr/2021/47856.14713
28. Jokhdar H, Khan A, Asiri S, Motair W, Assiri A, Alabdulaali M. COVID-19 Mitigation Plans During Hajj 2020: A Success Story of Zero Cases. *Heal Secur.* 2021;19: 133–139. doi:10.1089/hs.2020.0144
29. Moritz S, Gottschick C, Horn J, et al. The risk of indoor sports and culture events for the transmission of COVID-19. *Nat Commun.* 2021;12: 5096. doi:10.1038/s41467-021-25317-9
30. Schade W, Reimer V, Seipenbusch M, Willer U, Hübner EG. Viral aerosol transmission of SARS-CoV-2 from simulated human emission in a concert hall. *Int J Infect Dis.* 2021;107: 12–14. doi:10.1016/j.ijid.2021.04.028
31. Hagemann G, Hu C, Al Hassani N, Kahil N. Infographic. Successful hosting of a mass sporting event during the COVID-19 pandemic. *Br J Sports Med.* 2021;55: 570–571. doi:10.1136/bjsports-2020-103511
32. Pedersen L, Lindberg J, Lind RR, Rasmusen H. Reopening elite sport during the COVID-19 pandemic: Experiences from a controlled return to elite football in Denmark. *Scand J Med Sci Sports.* 2021;31: 936–939. doi:10.1111/sms.13915
33. Pray IW, Ford L, Cole D, et al. Performance of an Antigen-Based Test for Asymptomatic and Symptomatic SARS-CoV-2 Testing at Two University Campuses — Wisconsin, September–October 2020. *MMWR Morb Mortal Wkly Rep.* 2021;69: 1642–1647. doi:10.15585/mmwr.mm695152a3
34. Pilarowski G, Lebel P, Sunshine S, et al. Performance Characteristics of a Rapid Severe Acute Respiratory Syndrome Coronavirus 2 Antigen Detection Assay at a Public Plaza Testing Site in San Francisco. *J Infect Dis.* 2021;223: 1139–1144. doi:10.1093/infdis/jiaa802
35. Johansson MA, Quandelacy TM, Kada S, et al. SARS-CoV-2 Transmission From People Without COVID-19 Symptoms. *JAMA Netw Open.* 2021;4: e2035057. doi:10.1001/jamanetworkopen.2020.35057
36. Llibre JM, Videla S, Clotet B, Revollo B. Screening for SARS-CoV-2 Antigen Before a Live Indoor Music Concert: An Observational Study. *Ann Intern Med.* 2021;174: 1487–1488. doi:10.7326/M21-2278
37. Public Health England. SARS-CoV-2 variants of concern and variants under investigation in England - Technical briefing 31. Sage. 2021 [cited 2 May 2022]. Available: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/993879/Variants_of_Concern_VOC_Technical_Briefing_15.pdf
38. Government of the Republic of Serbia. COVID-19 [In Serbian]. Available: <https://www.srbija.gov.rs/sekcija/453027/covid-19.php>