Safety of Pfizer-BioNTech COVID-19 mRNA Vaccine in the Elderly

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Abstract

Background. COVID-19 is an infectious viral disease that has affected more than 234 million people and has caused almost 4.8 million deaths worldwide. A patient's age is the most important factor influencing the risk of severe course of the disease. The elderly usually suffer from many ailments, and therefore, polypharmacy is a common phenomenon among them. Our paper presents the initial results of the analysis of adverse effects in the group of older people in the context of participants' pharmacotherapy.

Methods. The information concerning post-vaccination adverse effects, COVID-19 in the past and current pharmacotherapy was collected from 200 people aged 60 years or older. Statistical analysis was performed using StatSoft Statistica 13.1 software.

Results. Twenty-three participants reported adverse effects after vaccination. Statistical analysis of groups with and without adverse effects revealed significant differences in age, cardiovascular drugs, neurological and psychiatric drugs, analgesics, gastrointestinal drugs, supplements, and vitamins.

Conclusions. Obtained results suggest the need to study the potential effect of ongoing pharmacotherapy on the safety and effectiveness of vaccination.

Backgruound

According to the WHO (World Health Organization) data, COVID-19 (coronavirus disease 2019) has affected more than 234 million people and has caused almost 4.8 million deaths worldwide [1]. The risk factors for the severe course of the disease include male sex, obesity, smoking, and comorbid and chronic conditions; however, age is the most important factor [2-6]. Older people are at risk of COVID-19 complications and death: according to CDC data, 80% of COVID-19 deaths in United States were in patients aged 65 years or older [7]. Therefore, vaccination of this age group has been a top priority [8]. It is a very heterogenic group, with many ailments, using various pharmacotherapy. They often use drugs with a complex mechanism of action which may influence the vaccination-related adverse effects. Our paper presents the initial results of the analysis of adverse effects in the group of older people in the context of participants' pharmacotherapy.

Methods

The research was a retrospective study carried out on 200 participants aged 60 years or older who received two doses of the COVID-19 mRNA vaccine (Pfizer). Information was collected concerning:

1. adverse effects observed after vaccination,
2. COVID-19 in the past,
3. pharmacotherapy used by the participants.

As the study was a retrospective analysis of data from medical documentation, no approval from ethics committee was necessary. Informed consent was obtained from all participants of the study.

The participants were divided into two groups based on the presence (group 1) or absence (group 2) of vaccination adverse effects. Statistical analysis was performed using StatSoft Statistica 13.1 software. Student's t-test was used to calculate significance concerning the age of participants. Pearson's chi-square with Yates correction was applied to calculate differences concerning participants' sex and pharmacotherapy. Phi coefficient was calculated to assess the strength of association between variables.

Results

Twenty-three people reported adverse effects after vaccination (group 1) while 177 (group 2) did not. The most common adverse effects included fatigue, fever and pain at the injection site (Table 1).

Table 1
The most common adverse effects observed in the studied population
after vaccination with the Pfizer COVID-19 mRNA vaccine.

Adverse Effect	Number of cases	%
fatigue	12	52,17%
fever	11	47,83%
pain at injection side	9	39,13%
pain (muscle, joint, head)	7	30,43%
increased BP (blood pressure) and pulse	4	17,39%
chills	4	17,39%
local oedema at injection site	3	13,04%
nausea	2	8,70%
impaired concentration and memory	2	8,70%
tinnitus, hearing impairment	1	4,35%

The participants' age ranged from 60 to 92 (average 70.37 +/- 6,44). The average age was significantly higher in group 2 (70.88 vs 66.43 years; $p=0,002$; Figure 1a). Table 2 presents the results of the statistical analysis of categorical variables. The groups did not differ concerning the sex and COVID-19 course in the past. Statistically significant difference was found for the following drug groups (Figure 1b-f): cardiovascular drugs (strong association), neurological and psychiatric drugs (weak association), analgesics (weak association), gastrointestinal drugs (weak association) and supplements and vitamins (moderate association). In all the above cases, group 2 was using the drugs more frequently than group 1.

Table 2
Statistical analysis of categorical variables in the studied population.
Statistically significant results presented with bold font.

	Adverse effects after vaccination		p	Phi coefficient
	Group 1 yes (%)	Group 2 no (%)		
Sex			0,3320	-0,08
male	7 (30,43)	77 (43,50)		
female	16 (69,57)	100 (56,50)		
Covid19 in the past			0,7978	0,00
yes	3 (13,04)	24 (13,56)		
no	20 (86,96)	153 (86,44)		
Cardiovascular drugs			0,0000	0,53
yes	15 (65,22)	176 (99,44)		
no	8 (34,78)	1 (0,56)		
Antidiabetic drugs			0,3650	0,08
yes	4 (17,39)	51 (28,81)		
no	19 (82,61)	126 (71,19)		
Neurological and psychiatric drugs			0,0008	0,25
yes	4 (17,39)	101 (57,06)		
no	19 (82,61)	76 (42,94)		
Analgesics			0,0070	0,21
yes	1 (4,35)	61 (34,46)		
no	22 (95,65)	116 (65,54)		
Gastrointestinal drugs			0,0007	-0,26
yes	0 (0,00)	67 (37,85)		
no	23 (100,00)	110 (62,15)		
Ocular medications			0,9239	-0,04
yes	1 (4,35)	13 (7,34)		
no	22 (95,65)	164 (92,66)		
Respiratory system drugs			0,3261	-0,09

yes	1 (4,35)	25 (14,12)		
no	22 (95,65)	152 (85,88)		
Supplements and vitamins			0,0000	-0,31
yes	4 (17,39)	115 (64,97)		
no	19 (82,61)	62 (35,03)		

Discussion

According to WHO data, 15% of patients with COVID-19 develop severe disease, and 5% requires intensive care [9]. The risk of severe COVID-19 increases with age. Therefore, adults aged 65 and higher were among the first groups of people who received the vaccination. Pfizer-BioNTech mRNA vaccine was the first COVID-19 vaccine registered for use in individuals 16 years of age and older [10]. Currently, in Poland, the number of people fully vaccinated exceeded 19 million. 70% were people aged 60+ years [11]. According to the data from clinical trials, the effectiveness of Pfizer-BioNTech mRNA vaccines in patients aged 65 years and older is over 95% [12]. Another important aspect is the vaccine's safety, as many adverse effects (such as increased BP, pain, gastrointestinal disturbances) may be falsely interpreted as a symptom of a new disease of the patient and therefore cause the addition of new unnecessary pharmacotherapy.

Our results confirmed that adverse effects after vaccination affect a relatively small number of patients and are mild. It is consistent with results obtained in other studies [13–15]. Moreover, older people tend to have less frequent adverse effects than the younger population [13–15]. Our data indicated that such diversity could be observed even within the group of older patients: the group with no adverse effects was older than the group who developed adverse effects after the vaccine. It is known that biological ageing has a negative impact on the functioning of the immune system (immunosenescence) [16]. Inflammation state, associated with immunosenescence, is a pathomechanism responsible for many age-related disorders (e.g. cardiovascular diseases, rheumatologic diseases, chronic pain) [17–19]. It can be characterized by redness, swelling, heat, pain, and loss of tissue function resulting from local immune, vascular and inflammatory cell response.[20] Moreover, inflammation plays a significant role in severe COVID-19 course [21]. Immunosenescence also leads to a significant reduction in naïve T cells that can respond to a vaccine, therefore decreasing the effectiveness of vaccination in older people [2].

Data from clinical trials indicated that adverse effects most commonly observed after the BoNTech mRNA COVID-19 vaccine are typical for acute and chronic inflammation [13]. The results of our study confirm this observation. The elderly usually take a lot of drugs (for chronic disorders typical for this population: pain, cardiovascular diseases, CNS (central nervous system) disorders, diabetes), some of which have an anti-inflammatory effect [22–26]. Such ongoing pharmacotherapy may influence the risk of most common adverse effects associated with inflammation (pain, fever). Indeed, our data indicated that the use of drugs with anti-inflammatory effect was higher in the group of participants who did not

report adverse effects after vaccination. Chronic anti-inflammatory therapy may affect the immune response to the vaccine [27]. However, no recommendations suggest withholding NSAIDs (non-steroidal anti-inflammatory drugs) or other anti-inflammatories prior to receiving the COVID-19 vaccine [28].

Our study has some limitations concerning a relatively small number of participants and high disproportion between studied groups. Moreover, it would be worth considering the assessment of SARS-Cov-2 antibodies to estimate the immune response of the participants. Therefore, the research has been continued to provide more valuable data.

Conclusions

Older people constitute an important target group for COVID-19 vaccination. Therefore it seems crucial to study the potential effect of ongoing pharmacotherapy on the safety and effectiveness of vaccination. As some drugs commonly taken by this group of patients may influence the immune system (which is already altered by age-related physiology), consider the assessment of SARS-Cov-2 antibodies after vaccination seems rational.

Abbreviations

BP – blood pressure

CNS – central nervous system

COVID-19 – coronavirus disease 2019

NSAIDs – nonsteroidal anti-inflammatory drugs

WHO – World Health Organization

Declarations

Acknowledgment

Not Applicable.

Ethics approval and consent to participate

Presented study is a retrospective analysis of data from medical documentation. According to the regulations of Poznan Medical University Bioethics Committee, no ethics-committee approval is necessary in such situation

(http://www.bioetyka.amp.edu.pl/BADANIA_NAUKOWE_NIESPONSOROWANE.html). All of the participants agreed to take part in the study.

All methods were performed in accordance with relevant guidelines and regulations.

Consent for publication

Not applicable.

Availability of data and materials

The datasets are available from the corresponding author on reasonable request.

Competing interests

The authors declare no competing interests.

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The study received no funding.

Authors' contributions

KK – literature search, analysis of the results, preparation of manuscript, collection of data

AC – statistical analysis of the data, preparation of manuscript, language correction

KGM – collection of data, revision of manuscript

AJ – revision of manuscript

All authors read and approved the final manuscript.

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Figures

Figure 1

Box & whisper plot for age (a) and categorized histograms for categorical variables with statistically significant differences (b – f).