ARAŞTIRMA / RESEARCH

Comparison of Adverse Effects of BioNTech mRNA and Sinovac Vaccines in Adults in Turkey

Türkiye'deki Yetişkinlerde BioNTech mRNA ve Sinovac Aşılarının Olumsuz Etkilerinin Karşılaştırılması

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Abstract

Objective: The aim of this study is to compare the side effects of Pfizer-BioNTech mRNA and Sinovac-CoronaVac vaccines administered in adults in Turkey.

Material and Method: This is a cross-sectional study. The study sample consisted of 187 adults, 95 in the Pfizer-BioNTech group and 92 in the Sinovac-CoronaVac group, who came for vaccination. A Visual Analogue Scale (VAS) and a questionnaire were applied to vaccinated individuals in a hospital. They were asked about any adverse effects at 6, 12 and 24 hours post-vaccination.

Results: The most common local adverse effect was pain at the injection site, but the most frequent systemic adverse effects were weakness and headache in both groups. Most (87.4%) of our participants who were vaccinated with the Pfizer-BioNTech vaccine and nearly half (48.9%) of those who received Sinovac-CoronaVac reported adverse effects. Pain felt at the injection site was 86.3% in the Pfizer-BioNTech group and 44.6% in the Sinovac-CoronaVac group. The least pain intensity in participants who were vaccinated with both Pfizer-BioNTech and Sinovac-CoronaVac vaccines was seen in the 24 hours.

Conclusion: The pain level at the injection site after Pfizer-BioNTech was higher than the Sinovac-CoronaVac vaccine. In our study the most systemic adverse effects with both vaccines were weakness and headache.

Keywords: Nursing, adverse effects, Pfizer-BioNTech, Sinovac-CoronaVac, vaccines, pain.

Öz

Amaç: Bu çalışmanın amacı, Türkiye'deki yetişkinlerde uygulanan Pfizer-BioNTech mRNA and Sinovac-CoronaVac -CoronaVac aşılarının yan etkilerini karşılaştırmaktır.

Gereç ve Yöntem: Bu araştırma kesitsel bir çalışmadır. Araştırmanın örneklemini Pfizer-BioNTech grubunda 95, Sinovac-CoronaVac grubunda 92 olmak üzere aşı için gelen 187 yetişkin oluşturdu. Bir hastanede aşılanan bireylere Görsel Analog Skala (VAS) ve kişisel bilgi anketi uygulandı. Aşıdan 6,12 ve 24 saat sonra herhangi bir yan etki olup olmadığı soruldu.

Bulgular: En yaygın lokal yan etki enjeksiyon bölgesinde ağrıydı, ancak en sık sistemik yan etkiler her iki grupta da halsizlik ve baş ağrısıydı. Pfizer-BioNTech aşısı ile aşılanan katılımcılarımızın çoğu (%87,4) ve Sinovac-CoronaVac alanların yaklaşık yarısı (%48,9) yan etki bildirdi. Enjeksiyon bölgesinde hissedilen ağrı Pfizer-BioNTech grubunda %86,3, Sinovac-CoronaVac grubunda %44,6'dır. Hem Pfizer-BioNTech hem de Sinovac-CoronaVac aşıları ile aşılanan katılımcılarda en az ağrı şiddeti 24. saat içinde görüldü.

Sonuç: Enjeksiyon bölgesindeki ağrı düzeyi Pfizer-BioNTech aşısında Sinovac-CoronaVac aşısına göre daha yüksektir. Çalışmamızda her iki aşıda da en fazla sistemik yan etki halsizlik ve baş ağrısı olmuştur.

Anahtar Kelimeler: Hemşire, yan etki, Pfizer-BioNTech, Sinovac-CoronaVac, aşı, ağrı.

1. Introduction

Severe Acute Respiratory Syndrome-Coronavirus-2 (SARS-CoV-2) pandemic has had a negative impact on the health systems (1), public health, and economies around the world (2), and continues to spread with new mutations (3,4). Vaccination is important in controlling the COVID-19 pandemic (5–7). It has been suggested that 60-70% population immunity is required to end the pandemic, and this can only be achieved with vaccines (1,5).

In December 2020, two mRNA vaccines (BNT162b2 and mRNA-1273) were manufacured to prevent COVID-19 (8,9), and started to be used on a global scale with emergency use approval (2,10). The first of these vaccines is the Pfizer-BioNTech (BNT162b2) vaccine, an mRNA vaccine that received Food and Drug Administration (FDA) approval for the first time (8,11). The mRNA vaccine developed by Moderna was the second vaccine that applied for FDA approval (1). Some of the vaccines against COVID-19 are inactive, such as Sinovac-CoronaVac (CoronaVac), while others, such as Pfizer-BioNTech , are mRNA vaccines (8). Inactivated vaccines activate the immune system, and contain some proteins or adjuvant substances. It is reported that the immune response they create is weaker and less effective than other vaccine groups (8). SARS-CoV-2 mRNA vaccines activate T cells and provide an immune response (11,12).

Three vaccines have been approved for emergency use in Turkey: Pfizer-BioNTech mRNA vaccine, Sinovac-CoronaVac inactivated vaccine, and Gamaleya (Sputnik V) non-replicative viral vector vaccines (10). The Turkish Medicines and Medical Devices Agency gave emergency use approval for the coronavirus vaccine CoronaVac developed by the Chinese company Sinovac-CoronaVac on January 14, 2021. Turkey began its first vaccination campaign against COVID-19 with this vaccine (1) and followed it with the administration the Pfizer-Pfizer-BioNTech vaccine on April 12, 2021. Both Pfizer-Pfizer-BioNTech and CoronaVac-Sinovac-CoronaVac vaccines are being administered currently in Turkey. COVID-19 vaccines can cause anxiety about possible adverse events (8,13), because they have been developed very quickly (8). Althought vaccination protects vulnerable groups, side-effects associated with vaccines were common (6). The adverse effects of COVID-19 vaccine included pain, fever, fatigue (8,13), muscle pain, malaise, chills (14–17), and joint pain (18). Also, researchers reported rarely seen adverse effects due to vaccine for COVID-19, such as cutaneous reactions (19), psychiatric pathologies (6), and intracerebral hemorrhage due to vasculitis (20).

Concerns about the adverse effects and efficacy of vaccines can have a negative influence on vaccination intention (21), and may cause vaccine hesitation. Instead, there has been vaccine hesitancy in several countries (22). To reduce vaccine hesitancy and increase vaccination rates, the efficacy and safety of vaccines must be established (17,23). Also, health professionals need to know about the common side-effects of these new vaccines (24).

Studies related to the adverse effects of the Pfizer-BioNTech and Sinovac-CoronaVac COVID-19 vaccines have been conducted with health care workers (7,9,16,18,21,25) and with adult citizens (17).

The aim of this study was to examine the early adverse effects of BNT162b2 vaccine (Pfizer-BioNTech) and an inactive vaccine (CoronaVac/Sinovac-CoronaVac) in a university hospital in Turkey.

2. Materials and Methods

The population for this study were adults who attended a university hospital as outpatients for COVID-19 vaccination between August 1, 2021 and September 30, 2021. Since it is not known that how many people would visit the hospital for vaccination between the dates of our research, the sample of the research was determined by the sample formula of which the universe is not certain. While calculating the sample size, the incidence of the event was accepted as 0.29 (26) and was calculated as 162 people at the 95% confidence interval. The study sample consisted of 187 adults, 100 females and 87 males, aged 18 and over, and who applied to a university hospital. There are 95 participants in the Pfizer-BioNTech group and 92 in the Sinovac-CoronaVac group. Inclusion criteria were being adults and participating voluntarily in the study. The exclusion criterion was not having a contact phone number.

A cross-sectional study was conducted through an anonymous questionnaire consisting of open and closed-ended questions. The questionnaire includes questions on COVID-19 infection, number of vaccinations, local and systemic side effects of vaccinations, presence of any chronic diseases, body mass index, gender, and age group, . Participants were interviewed face-to-face before vaccination and an explanation was given about how to evaluate it by giving Visual Analogue Scale (VAS). Evaluation of VAS and other side effects at 6 hours after vaccination was done through face-to-face interviews. Evaluation of VAS and other side effects at 12 and 24 hours after vaccination was done by telephone. There is a study in the literature that VAS evaluation is done by telephone (27). The main outcomes were local adverse effects (injection site pain) and systemic adverse effects (side effects other than injection site pain) due to vaccination.

2.1. Instruments

A patient information form was prepared by the researchers based on the literature. This questionnaire included questions on education, marital status, age, BMI, and previous COVID-19 infection. The form was filled in at the first evaluation meeting.

A Visual Analogue Scale (VAS) was used to collect the data. The pain intensity at the injection site, was assessed by using a 100mm VAS (0 mm, no pain, 100 mm, the worst possible pain). The VAS and the patient's complaints regarding vaccination were filled in by the researcher using face-to-face interview before the vaccination, and by telephone at 6, 12 and 24 hours after the vaccination.

2.2. Data Analysis

All data were analyzed using IBM-SPSS (Statistical Package for Social Science) version 26 (IBM Corp, Armonk, New York, USA). Descriptive statistics are given as frequencies, percentages, means and standard deviations. The chi-square test was used to analyze the significant difference between vaccine types with respect to the side effects.

Two-way analysis of covariance was performed in repeated measurements in order to determine whether there was a difference between injection pain levels due to two different vaccine types. Bonferroni correction was applied to compare the main effects. A p value of <0.05 was considered statistically significant.

2.3. Ethical Considerations

The study was approved by the non-invasive Izmir Katip Celebi University Non-Interventional Ethical Committee in Turkey (date 27.05.2021, approval number: 0256), and written permision was obtained for research from the hospital. Informed consent was obtained from all participants, and the purpose of the study was explained.

3. Results

The mean age of the participants was 43.95±15.56 years (min:17, max:84), and 56.8% for the Pfizer/Pfizer-BioNTech vaccine and 50.0% for the Sinovac-CoronaVac /CoronaVac vaccine were female. The proportion of those who had previously been infected with SARS-CoV-2 in our study was 21.1% for the Pfizer/Pfizer-BioNTech vaccine and 14.1% for the Sinovac-CoronaVac /CoronaVac vaccine. Nearly half of the partcipants in our study were vaccinated with the Pfizer-BioNTech vaccine. In the comparison of the two types of vaccines, the groups were homogeneous in terms of age and gender (Levene test, p>0.05) (Table 1).

Table 1. Study sample demographics according to vaccine type

	Vaccine type			
	Pfizer Pfizer-BioNTech (n=95) 50.8%		**CoronaVac/Sinovac-CoronaVac (n=92) 49.2%**	
Age groups	n	%	n	%
18-39	40	42.1	31	33.7
40-62	51	53.7	37	40.2
63-85	4	4.2	24	26.1
	(Levene test, p=0.056)			
Mean age	*40.35±12.33*		*43.95±15.56*	
	(min:18, max:74)		*(min:18, max:84)*	
Sex				
Female	54	56.8	46	50.0
Male	41	43.2	46	50.0
	(Levene test, p=0.189)			
Mean BMI	*25.38±4.16*		*26.87±5.11*	
	(min:15.57, max:39.06)		*(min:17.40, max:44.90)*	
History of COVID-19	20	21.1	13	14.1
	(Levene test, p=0.013)			
Chronic disease	24	25.3	37	40.2
	(Levene test, p=0.000)			
Total	95	100.0	92	100.0

The sample consisted of 187 adults who were vaccinated in Turkey with one of these vaccines. The distribution of participants' characteristics is shown in Table 1. The only local adverse effect was pain at the injection site, but the most frequent systemic adverse effects were weakness and headache in both groups (Table 2). The least pain intensity in participants who were vaccinated with either Pfizer-BioNTech or Sinovac-CoronaVac vaccine was seen at 24 hours after vaccination. A statistically significant difference was found between the pain intensity at the injection site according to the type of vaccine (p<0.001). There was a statistically significant difference between the pain intensity at 6 hours, 12 hours, and 24 hours in participants vaccinated with both vaccine types. The level of intensity of pain in participants vaccinated with the Sinovac-CoronaVac vaccine at six hours was similar to the level of pain intensity at 12 hours, and the least pain intensity was seen at 24 hours after vaccination (p<0,001).

Table 2. The frequency of reported adverse effects according to vaccine type

Adverse effects	Pfizer/Pfizer-BioNTech (N=95)		CoronaVac/Sinovac-CoronaVac (N=92)	
	n	%	n	%
None	12	12.6	47	51.1
Adverse effects present	83	87.4	45	48.9
	x^2=32.004, df=1, p=0.000			
Local Adverse effects				
Pain at injection site	82	86.3	41	44.6
Systemic adverse effects				
Weakness	18	18.9	8	8.7
Fever	11	11.6	2	2.2
Headache	9	9.5	4	4.3
Fatigue	7	7.4	3	3.3
Nausea	5	5.3	3	3.3
Diarrhea	3	3.2	-	-
Joint pain	2	2.1	-	-
Sore throat	2	2.1	-	-
Sleepiness	2	2.1	3	3.3
Itching	1	1.1	3	3.3
Excessive sweating	-	-	1	1.1
Total	95	100.0	92	100.0

The level of intensity of pain at six hours in participants vaccinated with the Pfizer-BioNTech vaccine was similar to the level of pain intensity at 24 hours, and the greatest pain intensity was seen at 24 hours after vaccination (p<0.001) (Table 3).

Table 3: The differentiation results of intensity of injection site pain according to the two different types of vaccine and different times

Hours	Pfizer Pfizer-BioNTech vaccine (N=95)	CoronaVac / Sinovac-CoronaVac (N=92)	**F**	**p**
	Mean ± SD	**Mean ± SD**		
VAS 6 hours	3.34±0.25^b	1.71±0.26^b	20.181	<0.001
VAS 12 hours	5.06±0.30^c	1.98±0.31^b	49.649	<0.001
VAS 24 hours	3.06±0.22^b	0.69±0.22^c	55.181	<0.001
Test Statistics‡	*F*=102.452; *p*<0.001	*F*=15.612; *p*<0.001		

Group Effect: *F*=51.735; *p*<0.001; Time Effect: *F*=16.388; *p*<0.001; Group*Time: *F*=28.666; *p*<0.001

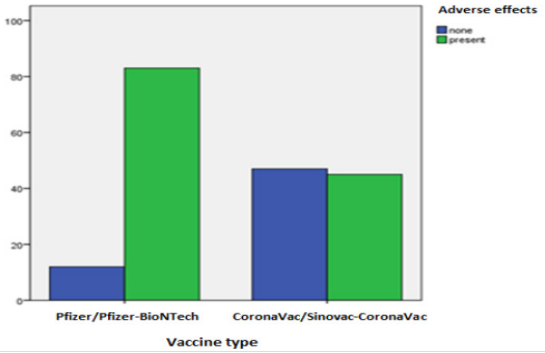
*Two-way analysis of covariance in repeated measures corrected for age, †: Comparisonsbetweengroupsateachmeasurementtime,‡:Comparisonsbetween measures in each group, superscripts a, b, and *c* indicate measures that differ in each group. Measurements with the same superscripts are statistically similar

4. Discussion

Due to concerns about side effects, many individuals hesitate to be vaccinated against COVID-19 (11,21,28,29). The most commonly used vaccines in Turkey for COVID-19 are the Pfizer/Pfizer-BioNTech and the Sinovac-CoronaVac vaccines. In this research, we compared the adverse effects of vaccination for COVID-19 with these vaccines in adult individuals. We also compared the pain levels at the injection site, which is one of the local adverse effects.

4.1. Adverse effects

Most (87.4%) of our participants who were vaccinated with the Pfizer-BioNTech vaccine and nearly half (48.9%) of those who received Sinovac-CoronaVac reported adverse effects. Different results have been found in the literature relating to adverse effects associated with vaccination for COVID-19, and researchers have reported that between 60% and 91.6% of participants had at least one side effect due to vaccination (12,15,16,19). Our results support these results in the literature. There was a difference between the percentages of adverse effects seen in the participants who were vaccinated with different vaccines ($p<0.001$). The percentage of adverse effects was higher in participants who had been vaccinated with Pfizer-BioNTech vaccine than in those vaccinated with Sinovac-CoronaVac vaccine (Table 2, Graphic 1).



Graphic 1. The distribution of adverse effects according to vaccine type

4.2. Local side effects

The percentage of participants who felt pain at the injection site seen in those vaccinated with Pfizer-BioNTech (86.3%) vaccine was also higher than in those vaccinated with Sinovac-CoronaVac (44.6%) vaccine, and this difference was statistically significant ($p<0.001$). Al Khames Aga et al. (2021) stated that 34.56% of participants had local adverse effects associated with three different types of vaccines. These were pain, redness, urticaria, and swelling at the site of the injection (11). A study examined the side-effects within eight days of vaccination in 627 383 individuals receiving the BNT162b2 vaccine or the ChAdOx1 nCoV-19 vaccine, and it was found that the rate of local side-effects was 71.9% after the first dose, and 68.5% after the second dose of BNT162b2 (30). In a trial with the Pfizer-BioNTech COVID-19 vaccination, it was determined that the most common local side effect experienced after the vaccination was pain (54.6%), while the most common systemic effects were fatigue (39.2%) and headache (34.1%) (19). The main local side effect in most studies was pain at the injection site, and between 75.6% and 89.8% of participants reported post-vaccination pain at the injection site (14–18,29). Another local side effect was redness at the injection site (12). In our study, the most common local side effect was injection site pain, and this support the literature.

4.3. Systemic side effects

Systemic side effects such as body pain, muscle pain, fever, and gastrointestinal side effects have also been seen in different studies (9,11,28). In our study, the most frequently seen systemic adverse effects with both vaccines were weakness and headache (Table 2). In studies with Pfizer-BioNTech vaccines, various results related to adverse effects were reported. Fewer was seen between 35% and 66% of the participants (14,19). Between 28.4% and 44% of the participants reported post-vaccination muscle pain (14–18) and also 21.2% of the participants had joint pain (18). Fatigue was seen in between 42% and 90% of participants in different studies (14–17,19). Between 34.3% and 42% of the participants reported post-vaccination headache (15,16). Also authors have reported the most common systemic side effects as headache/fatigue (53.6%), muscle pain (33.2%), malaise (25%), chills (23%), and joint pain (21.2%) (18). Our study supported these results. In a study on nurses vaccinated with the Sinovac-CoronaVac COVID-19 vaccine, it was determined that the most common local side effect was pain (54.6%), while the most common systemic effects were fatigue (39.2%) and headache (34.1%) (25). Riad (2021) found that the most common reported systemic side effects after Sinovac-CoronaVac vaccine were fatigue (62.2%), headache (45.6%), muscle pain (37.1%), and chills (33.9%) (16). In a study by Kadali et al. (2021), it was stated that some of the side effects of the BNT162b2 vaccine in healthcare workers were soreness, fatigue, headache, chills, fever, joint pain, nausea, sweating, itching and diarrhea (9). In our study, the participants reported similar adverse effects. Another study described the side effects of Pfizer-BioNTech COVID-19 vaccination experienced by healthcare workers (HCWs) in a tertiary hospital in Singapore. The most common symptom experienced by the HCWs was giddiness (32.7%) within 30 minutes (7). In a study with Egyptian participants in the first dose of Sinopharm vaccine, 50% of the participants had fatigue and lethargy, 7.5% had joint pain, 15% had headache, and 10% had fever (28). In another study with Sinovac-CoronaVac vaccine in healthcare workers in China, it was found that the most common systemic adverse reactions were fatigue, muscle pain, and headache (21).

4.4. Pain level

The level of intensity of pain in participants vaccinated with the Pfizer-BioNTech vaccine at six hours was similar to the level of pain intensity at 24 hours. Also, the greatest pain intensity was seen at 12 hours after vaccination ($p<0.001$). Pain level (VAS score) was reported to be higher in individuals who had received the Pfizer-BioNTech vaccination than in those who had received the Sinovac-CoronaVac vaccine. These results may be due to the different nature of the two vaccines: one of them is an mRNA vaccine and other is an inactivated vaccine. Sinovac-CoronaVac's is based on inactivated SARS CoV-2 virus (31). The ingredients of the mRNA Pfizer-Pfizer-BioNTech 's vaccine are largely mRNA, lipid bubbles, and

saline solution (13). The mRNA vaccines introduce mRNA into cells, usually via a lipid nanoparticle (31). The Pfizer-BioNTech vaccine was associated with a higher pain level at the injection site at 6, 12, and 24 hours after vaccination, while the Sinovac-CoronaVac, which is an inactivated coronavirus vaccine, was associated with a lower pain level. In the study of Alhazmi et al. (2021), the incidence of pain after Pfizer-BioNTech vaccination was found to be 85% (19). In addition, in the study of Dziedzic et al. (2021), when they investigated the side effects of mRNA and moderna vaccines for COVID-19, they determined that 81.3% of the pain was seen at the injection site 1 day after the vaccine (15). Our results are in line with these studies. According to this research, it can be said that the pain seen at the injection site after vaccinations for COVID-19 is an expected result.

5. Conclusion and Recommendations

This is the first research that examines the pain level at the injection site of two different types of COVID-19 vaccine. The pain level at the injection site due to Pfizer-BioNTech was higher than that of the Sinovac-CoronaVac vaccine. The adverse effects that are reported post Pfizer-BioNTech and Sinovac-CoronaVac vaccines among Turkish participants are similar to those that are reported in other research. Further studies should be conducted on the adverse effects of different types of vaccine for COVID-19.

Nurses, who are members of healthcare team, should undertake an important role in the fight against COVID-19 by educating and counselling people about the adverse effects of COVID-19 vaccine.

In Turkey, there are few studies on the adverse effects of vaccination for COVID-19. Therefore, there is a need for more research on the adverse effect of these vaccines.

6. Contribution to the Field

Knowing the side effects of COVID-19 vaccines administered to adults will raise awareness to reduce patients' admission to hospital.

Ethical Aspect of the Research

The study was approved by the non-invasive clinical research Izmir Katip Celebi University Non-Interventional Ethical Committee in Turkey (date 27.05.2021, approval number: 0256), and written permision was obtained for research from the hospital. Informed consent was obtained from all participants.

Conflict of Interest

This article did not receive any financial fund. There is no conflict of interest regarding any person and/or institution.

Authorship Contribution

Concept: SY, LK; **Design:** SY, LK, DB; **Supervision:** SY, LK, PÇ, DB; **Funding:** SY, LK, PÇ; **Materials:** SY, LK; **Data Collection/ Processing:** SY, LK, PÇ; **Analysis/Interpretation:** SY, LK, DB; **Literature Review:** SY, LK, PÇ; **Manuscript Writing:** SY, LK, PÇ, DB; **Critical Review:** SY, LK.

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