Association of side effects of COVID-19 vaccines in postmenopausal women

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ABSTRACT

Objective: A reliable and safe vaccines is the only certain way to avert the COVID-19 outbreak. Acceptance of vaccines is impacted by a number of variables, including beliefs about the vaccine's safety and adverse effects. Vaccine side effects can vary based on the type, but they are typically mild, localized, transient, and self-limiting. Therefore, the purpose of this study was to ascertain the side effects of COVID-19 vaccination in postmenopausal women that had been reported.

Methodology: This multicenter, cross-sectional study was conducted in many hospitals, using a non-probability sampling technique. The duration of the study was about six months, from June 1, 2022, to November 30, 2022. A total of 300 postmenopausal women with ages above 50 years who received one of the COVID-19 vaccines, for example Pfizer, AstraZeneca, Sinopharm, Sinovac, and Cansino (double doses or booster doses), were included in the study. Different demographic parameters (gender, type of vaccine, number of doses, and local and systemic side effects) were documented as frequencies and percentages. Age and weight were documented as mean and standard deviation.

Results: The study findings showed that the mean age ofpost-menopausal womenwas 58.88 ± 7.15 years. Hypertension and diabetes mellitus were found to be present as associated comorbidities in 126(42.0%) and 66(22.0%) women, respectively. Around 84(28.0%) participants received the Pfizer vaccine, followed by the AstraZeneca vaccine in 72(24.0%) participants and the Sinovac vaccine in 72(24.0%) participants. The most commonly reported side effect after 1^{st} dose was fever, whichwas reported by 228(76.0%) participants, and out of them, 126(55.3%) reported it to be mild. Swelling of the glands was the most commonly reported side effect after

the second dose in 156 (52.0%) participants. Around 126 (80.8%) of the participants described it as mild.

Conclusion: This study concluded that the most commonly reported symptoms were fever, myalgia, pain, swelling, and redness at the injection site. These overall side effects were generally mild to moderate, non-life threatening and did not necessitate hospitalization. Most vaccine recipients reported that their subjective level of acceptance was satisfactory. **Keywords:** COVID-19 vaccines, post-menopausal women, myalgia, pain, fever

INTRODUCTION

Millions of people have been killed by epidemics and illnesses like the plague, smallpox, and influenza all over history. Numerous vaccines have been developed as a result of advancements in science and medicine, which have decreased the danger of many diseases and the mortality rates associated with them [1]. The coronavirus pandemic, which originated in China and spread throughout the globe in the year 2020, killed millions of people and left behind horrifying damage on different levels [2]. Since then, specific companies have started to compete, producing numerous vaccines with high potency, leading to a noticeable decline of the majority of the negative effects coming from this pandemic [3]. The Food and Drug Administration (FDA) stated, Pfizer-BioNTech's vaccine, which has an efficacy rate of up to 95%, was the first to be presented to the international market [4]. Additionally, a large number of immunizations have been made public and are now effective. They include the AstraZeneca, which has an efficacy of 76% [5], Sinopharm, which has an effectiveness of 79% [6]. Sputnik V vaccine, which has an efficacy of 80% [7]. There are currently three non-replicating viral vector vaccines in use worldwide: AZD1222, Oxford-AstraZeneca; BNT162b2, Pfizer-BioNTech; and mRNA-1273, Moderna [8]. These vaccines were extensively administered despite the existence of some anti-vaccination beliefs [9].

It is important to note that deleterious reactions to coronavirus vaccines can occur, just like with any other vaccine [10]. As vaccination programs across the globe got underway, a variety of side effects began exhibiting themselves. These ranged in severity from low impact, like a high body temperature, muscular pain, shivers, and nausea [11], to potentially fatal, like stroke [12]. There have been reports of a number of symptoms, such as dysgeusia, fatigue, and respiratory

problems, as well as mouth-specific conditions like stomatitis, petechiae, necrotizing gingivitis, oral ulcerations, candidiasis, and white oral mucosal lesions [13,14].

Additionally, numerous studies have documented a range of adverse reactions to vaccinations, from mild symptoms like chills, fever, fatigue, headaches, and arm pain to serious ones like thrombosis and anaphylaxis [15,16]. Additionally, a recent research found that receiving the COVID-19 vaccine caused a number of menstrual abnormalities, including lengthened cycles, pain, and bleeding [17]. Following vaccination, menstrual problems have been observed to be a frequent complaint [18,19]. Based on the similar outcomes of other vaccines, this finding is not surprising [20].

In addition, healthcare professionals work as a resource and reliable means of information for the general public regarding vaccinations. They can protect themselves from misleading and deceptive information. Therefore, their behavior will have an impact on both their own and other people's health [21]. Mild to moderate side effects were discovered in prior studies on the COVID-19 vaccine, with the severity of adverse effects varying based on the COVID-19 vaccine used [22]. Fever, headaches, localized pain at the injection site, and pain in the muscles were among the more common moderate side effects that were reported [23]. Governments around the globe have been aggressively working to implement successful mass vaccination programs since the invention and accessibility of COVID-19 vaccinations [24].

The frequency of side effects will undoubtedly rise as the worldwide vaccination campaign continues. Due to these factors, the current research covers a significant gap by analyzing the connection between coronavirus vaccines and negative effects in post-menopausal women. This will aid and direct vaccine producers to minimize the burden associated with vaccines as much as possible. Therefore, the goal of this study was to evaluate the frequency of side effects that have been documented in post-menopausal women after receiving the COVID-19 vaccines.

METHODOLOGY

This multicenter, cross-sectional study was conducted in many hospitals, after receiving ethical approval by the Ethical Review Committee. The non-probability sampling technique was

employed in this study. The duration of the study was about six months, from June 1, 2022, to November 30, 2022. A total of 300 postmenopausal women with ages above 50 yearswho received one of the COVID-19 vaccines, for examplePfizer, AstraZeneca, Sinopharm, Sinovac, and CanSino (double doses or booster doses), were included in the study. Those who had not received a vaccinationwere excluded from the study.

Participant's information was collected by a self-structured questionnaire. Demographic particulars of participants like age, gender, comorbidities, vaccination type and status and doses, prior exposure to COVID-19 infection, and the incidence of any general and local side effects following first-and second-dose vaccination were all recorded. Based on their severity, each side effect was classified as mild, moderate, or severe. Additionally, the level of participant satisfaction was noted.

Data was analyzed using SSPS version 20.0. Different demographic parameters (gender, type of vaccine, number of doses, and local and systemic side effects) were documented as frequencies and percentages. Age and weight were documented as mean and standard deviation.

RESULTS

The study included 300 postmenopausal women who met the inclusion criteria, with a mean age of 58.88 ± 7.15 years. The mean weight of the vaccinated postmenopausal women was 85.88 ± 15.35 kg. Hypertension and diabetes mellitus were found to be present as associated comorbidities in 126(42.0%) and 66(22.0%) women, respectively. Around 72(24.0%) women had COVID-19 infection. Among the participants, 18(6.0%) reported a previous infection with COVID-19, while 282(94.0%) did not contract the infection. Around 84(28.0%) participants received the Pfizer vaccine, followed by the AstraZeneca vaccine in 72(24.0%) participants and the Sinovac vaccine in 72(24.0%) participants. Furthermore, CanSino and Sinovac were received by 18(6.0%) and 54(18.0%) participants, respectively. Most of the participants 210(70.0%) received both doses of the vaccines whereas 90(30.0%) received booster doses, as shown in Table I.

The distribution of side effects of the vaccine after 1st dose revealed that a wide array of side

effects were reported by the participants, the severity of which is further categorized into mild, moderate, and severe. The most commonly reported side effect, fever, was reported by 228(76.0%) participants, and out of them, 126(55.3%) reported it to be mild. This was followed by pain210(70.0%), burning 156(52.0%) and swelling at the site of the injection 102(34.0%) in decreasing order of frequency, and wherein all these side effects were reported to be mild 144(68.6%), 138(88.5%) and 48(47.1%), respectively. Muscle pain was also a notable side effect reported by 120(40.0%) participants, although only 30(25.0%) reported it to be severe. Furthermore, 126(42.0%) participants reported joint pain, 120(40.0%) reported anxiety, 102(34.0%) reported rashes, 102(34.0%) reported swelling at the injection site, and 102(34.0%) reported cough. Most side effects were mild in intensity. Additionally, redness at the injection site, headache, lymphadenopathy, nausea, flu, fatigue, chills, swelling of glands, sore throat, shortness of breath, diarrhea, and chest pain were observed to be of low frequency and mild intensity, as shown in Table II.

The side effects after the 2nd dose of vaccination were found to be almost the same as those after the 1st dose; however, they slightly differed in frequency and severity. Swelling of glands was the most commonly reported side effect after the second dose in 156 (52.0%) participants. Around 126 (80.8%) of the participants described it as mild, while none described it as severe. Burning at the injection site was reported in 144(48.0%) participants, and in terms of severity, it was mild, as reported by the majority of participants 126 (87.5%). Feverand myalgia were reported by 84(28.0%) and 138(46.0%) participants, respectively, and in terms of severity this was the only symptom reported as severe by the most participants, that is, 66(78.6%) and 36(26.1%) respectively. Lymphadenopathy was reported by 138 (46.0%) participants, followed by mild pain at the injection in 126 (42.0%) participants. A headache was reported by 126 (42.0%) participants, rashes were reported by 120 (40.0%) participants, and mild shortness of breath was reported by 120 (40.0%) participants. Additionally, other milder side effects were observed in low frequency; swelling and redness at the injection site, flu, anxiety, fatigue, joint pain, chills, cough, sore throat, diarrhea, and chest pain. Interestingly, none of the participants reported nausea, as shown in Table III.

The overall subject level of satisfaction was found to be 198(66.0%) participants being satisfied, 30 (10.0%) being very satisfied, 72 (24.0%) feeling just Ok with their vaccination experience, as shown in Table IV.

V	Mean±SD n(%) 58.88±7.15		
Age (years)			
Weight (kg)	85.88±15.35		
Unortonsion	Yes	126(42.0%)	
Hypertension	No	174(58.0%)	
Diabetes Mellitus	Yes	66(22.0%)	
	No	234(78.0%)	
	Yes	72(24.0%)	
COVID-19 Infection	No	228(76.0%)	
Previous COVID-19 Exposure	Yes	18(6.0%)	
	No	282(94.0%)	
Type of Vaccine	Sinopharm	72(24.0%)	
	CanSino	18(6.0%)	
	Sinovac	54(18.0%)	
	AstraZeneca	72(24.0%)	
	Pfizer	84(28.0%)	
X 7	Vaccinated with 1 st and 2 nd dose	210(70.0%)	
Vaccination status	Vaccinated with Booster Dose	90(30.0%)	

Table I:Demographic characteristics of post-menopausal women (n=300).

 Table II: The distribution of side effects of COVID-19 vaccine after 1st dose of COVID-19 vaccine in post-menopausal women.

Variables	Yes n(%)	No n(%)	Mild n(%)	Moderate n(%)	Severe n(%)
Pain at the site of injection	210(70.0%)	90(30.0%)	144(68.6%)	48(22.9%)	18(8.6%)
Swelling at the site of injection	102(34.0%)	198(66.0%)	48(47.1%)	36(35.3%)	18(17.6%)
Redness at the site of injection	72(24.0%)	228(76.0%)	54(75.0%)	0(0.0%)	18(25.0%)
Lymphadenopathy	66(22.0%)	234(78.0%)	18(27.3%)	48(72.7%)	0(0.0%)
Fever (temperature >37.8 °C)	228(76.0%)	72(24.0%)	126(55.3%)	54(23.7%)	48(21.1%)
Headache	72(24.0%)	228(76.0%)	36(50.0%)	36(50.0%)	0(0.0%)
Nausea	66(22.0%)	234(78.0%)	48(72.7%)	18(27.3%)	0(0.0%)
Rashes	102(34.0%)	198(66.0%)	54(52.9%)	30(29.4%)	18(17.6%)
Burning at injection site	156(52.0%)	144(48.0%)	138(88.5%)	18(11.5%)	0(0.0%)
Flu	36(12.0%)	264(88.0%)	0(0.0%)	36(100.0%)	0(0.0%)
Anxiety	120(40.0%)	180(60.0%)	102(85.0%)	18(15.0%)	0(0.0%)
Muscle pain (Myalgia)	120(40.0%)	180(60.0%)	90(75.0%)	0(0.0%)	30(25.0%)
Fatigue	84(28.0%)	216(72.0%)	10.0(35.7%)	54(64.3%)	0(0.0%)
Joint pain	126(42.0%)	174(58.0%)	90(71.4%)	36(28.6%)	0(0.0%)
Chills	72(24.0%)	228(76.0%)	36(50.0%)	36(50.0%)	0(0.0%)
Cough	102(34.0%)	198(66.0%)	66(64.7%)	36(35.3%)	0(0.0%)
Swelling of glands	102(34.0%)	198(66.0%)	84(82.4%)	18(17.6%)	0(0.0%)
Sore throat	72(24.0%)	228(76.0%)	54(75.0%)	18(25.0%)	0(0.0%)
Shortness of breath	90(30.0%)	210(70.0%)	90(100.0%)	0(0.0%)	0(0.0%)
Diarrhea	54(18.0%)	246(82.0%)	18(33.3%)	36(66.7%)	0(0.0%)
Chest Pain	84(28.0%)	216(72.0%)	30(35.7%)	54(64.3%)	0(0.0%)

 Table III: The distribution of side effects of COVID-19 vaccine after 2nd dose of COVID-19 vaccine in post-menopausal women.

Variable	Yes n (%)	No n (%)	Mild n (%)	Moderate n (%)	Severe n (%)
Pain at the site of injection	126(42.0%)	174(58.0%)	108(85.7%)	18(14.3%)	0(0.0%)
Swelling at the site of injection	90(30.0%)	210(70.0%)	18(6.0%)	72(24.0%)	0(0.0%)
Redness at the site of injection	18(6.0%)	282(94.0%)	18(100.0%)	0(0.0%)	0(0.0%)
Lymphadenopathy	138(46.0%)	162(54.0%)	108(78.3%)	30(21.7%)	0(0.0%)
Fever (temperature >37.8 °C)	84(28.0%)	216(72.0%)	18(21.4%)	0(0.0%)	66(78.6%)
Headache	126(42.0%)	174(58.0%)	90(71.4%)	36(28.6%)	0(0.0%)
Nausea	0(0.0%)	300(100.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Rashes	120(40.0%)	180(60.0%)	120(100.0%)	0(0.0%)	0(0.0%)
Burning at injection site	144(48.0%)	156(52.0%)	126(87.5%)	18(12.5%)	0(0.0%)
Flu	30(10.0%)	270(90.0%)	0(0.0%)	30(100.0%)	0(0.0%)
Anxiety	90(30.0%)	210(70.0%)	72(80.0%)	18(20.0%)	0(0.0%)
Muscle pain (Myalgia)	138(46.0%)	162(54.0%)	66(47.8%)	36(26.1%)	36(26.1%)
Fatigue	72(24.0%)	228(76.0%)	18(25.0%)	54(75.0%)	0(0.0%)
Joint pain	102(34.0%)	198(66.0%)	72(70.6%)	30(29.4%)	0(0.0%)
Chills	108(36.0%)	192(64.0%)	36(33.3%)	72(66.7%)	0(0.0%)
Cough	12(4.0%)	288(96.0%)	12(100.0%)	0(0.0%)	0(0.0%)
Swelling of glands	156(52.0%)	144(48.0%)	126(80.8%)	30(19.2%)	0(0.0%)
Sore throat	36(12.0%)	264(88.0%)	36(100.0%)	0(0.0%)	0(0.0%)
Shortness of breath	120(40.0%)	180(60.0%)	66(55.0%)	54(45.0%)	0(0.0%)
Diarrhea	72(24.0%)	228(76.0%)	18(25.0%)	54(75.0%)	0(0.0%)
Chest Pain	90(30.0%)	210(70.0%)	54(60.0%)	36(40.0%)	0(0.0%)

Variable		n	%
Overall subject level of Satisfaction for vaccine	Very Satisfied	30	10.0
	Satisfied	198	66.0
	Unsatisfied	72	24.0

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Table IV: The	nrevalence of	level of s	safistaction i	for vaccine in	nost-menonau	isal women
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DISCUSSION

Studies have shown that the COVID-19 immunization may cause a number of side effects. Numerous recipients reported having local and/or systemic side effects after getting either dose of the vaccine, regardless of the vaccine's type (mRNA, Vector, etc.) [25,26]. Local side effects can include paresthesia, induration, itching, and joint or muscle pain at the injection site [27–29]. The systemic adverse effects include fever, shivers, tiredness, headache, nausea, muscle pain, and breathlessness [27-32]. Therefore, this study demonstrated the severity of side effects reported by postmenopausal women.

A cross-sectional study involved2269 female participants in analysis. The participants' mean age was 34.32 ± 8.53 years, with age ranging from 14 to 54 years. Pfizer-BioNTech, Sinopharm, and AstraZeneca were given to most participants (48.4%, 35.3%, and 13.4%, correspondingly), and most (85.4%) got two doses of each. About 22% of participants had COVID-19 infection that was confirmed, and 11.7% of participants described symptoms similar to COVID-19, but they were not verified by laboratory testing. Following the COVID-19 vaccination, 78.3% of people experienced side effects, which included fatigue, fever, nausea, headaches, and pain at injection site—14.4% of which were considered serious [19]. The present study was consistent with the above reported study and revealed that the most commonly received vaccines were Pfizer-BioNTech, Sinopharm, and AstraZeneca in 84(28.0%), 72(24.0%), and 72(24.0%), respectively. The majority of them received both doses of vaccines 210(70.0%). COVID-19 infection affected 72(24.0%) of the participants, while 18 (6.0%) had previously been exposed to COVID infection. After receiving COVID vaccinations, the most commonly observed side effects were fever, myalgia, swelling and burning at the injection site, and swelling of the glands.

Likewise, another study reported that the most commonly reported side effects were joint pain, fever, fatigue, headaches, and injection site swelling [33]. The most frequent post-vaccination side effects, according to a number of published studies, included pain, swelling at the injection site, fatigue, muscular and joint pain, drowsiness, feeling faint, a high body temperature and headache [34,35]. The present study corroborated the above findings and showed that fever, swelling, redness and pain at the injection site, fatigue and muscular pain were the most commonly observed side effects post vaccinations.

Similarly, another research showed that comparative to HCWs who received the Sinopharm and Sinovac vaccines, those participants who received the viral vector AstraZeneca vaccine were more probable to experience post-vaccination systemic and local side effects that affected the working performance of one-third of participants [33]. This was consistent with Zahid's research in Bahrain, which found that Sinopharm's vaccine had fewer adverse effects than AstraZeneca's [36]. Fever, injection site pain, and fatigue were the most frequently reported side effects among participants who got the Oxford-AstraZeneca vaccine, and these side effects were also noted among Saudi HCWs [37]. The present study was not in agreement with the above reported research and indicated that the most commonly injected vaccine was the Pfizer followed by AstraZeneca and Sinopharm. In terms of overall side effects, fever, injection site pain and swelling, and myalgia were observed.

Interestingly, one of the studies reported the most frequent local side effect of the Sinovac vaccine, was pain at the injection site as described by participants who received it [33] and these findings were similar to a Turkish study [38]. It is advised to lower the patient's limb being injected into to lessen pain in order to alleviate this very frequent adverse effect. Compared to an injection into a tense muscle, a relaxed muscle only slightly hurts. Without sufficient warming, injections may result in more pain at the injection site [37,23]. The present study was not in accordance with the above cited research and reported that fever was the most commonly found side effect after the first and second doses of vaccine.

According to one study, the majority of subjects experienced side effects that subsided after a few days to no more than two weeks [33]. The majority of the side effects following COVID-19 vaccination were self-resolving, and recipients recover quickly. No symptoms were severe

enough to require hospitalization. Numerous studies' vaccine users report that post-vaccination symptoms were typically mild. Their lives were not in danger because the symptoms were inconsequential and trivial [34,35,39]. These results were in line with those of the present study, which showed that the majority of side effects reported were mild to moderate in severity, self-limiting, and did not endanger the lives of post-menopausal women. Except for the mild cases of myalgia 36(26.1%) and fever 66(78.6%) that were recorded. Excluding fever 66 (78.6%) and myalgia 36 (26.1%), which were described as having a severe intensity after receiving the second dose of the vaccine.

Vaccine hesitancy, also referred to as a delay in or reluctance of vaccines despite their availability, can be brought on by the mere chance of adverse side effects. The immune system's response can be delayed by up to 69.6% of people who are reluctant to receive the COVID-19 immunization [40]. All patients, however, experienced substantial reduction in symptoms with medication within a relatively short period of time, demonstrating that the benefits of vaccination far exceed the risks [40]. The present study showed that most of the participants, 198(66.0%) were satisfied with their vaccinations because of the milder side effects reported post-vaccination, whereas 72 (24.0%) felt ok with their vaccinations.

However, rather than depending on the participants' subjective descriptions, the study's limitations could have been reduced by inquiring about the severity of the side effects on a rating scale. Inquiries have also been made regarding the booster dose's adverse effects. A thorough follow-up of the subjects after receiving both doses of the vaccine was also important to take into account.

CONCLUSION

This study concluded that the most commonly reported symptoms were fever, myalgia, pain, swelling, and redness at the injection site. These overall side effects were generally mild to moderate, non-life threatening and did not necessitate hospitalization. Most vaccine recipients reported that their subjective level of acceptance was satisfactory. Giving the people accurate information about vaccine side effects, likely adverse reactions, and the safety of the given vaccines is crucial. Numerous actions must be taken at the individual, organizational, and

population stages in order to lessen vaccine hesitancy. Future studies could examine how the vaccine affects people with different ages and illnesses.

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