

## Research Article

# A Survey on Adverse Events Induced by COVID-19 Vaccination and Assessment of the Psychosocial Consequences Generated by the Pandemic: An Observational Prospective Study in a Large Cohort in Southern Italy

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## Abstract

The COVID-19 pandemic caused by the novel coronavirus SARS-CoV-2 has rapidly spread globally since December 2019, resulting in a significant number of cases worldwide. This study aims to investigate suspected adverse reactions induced by COVID-19 vaccines and assess the psychosocial consequences associated with vaccination. Additionally, the study evaluates the potential of vaccination in protecting against severe symptoms of COVID-19. A prospective observational study was conducted, involving a survey administered to vaccine recipients recruited from the Special Community Care Units (USCA) of ASL Naples 2 North. The study population consisted of 10,000 subjects who received the COVID-19 vaccination and met the inclusion criteria. Statistical analysis was performed using descriptive statistics, univariate and multivariate logistic regression models. Overall, for all vaccines, the largest number of reports was of suspected non-serious adverse reactions (9.4%) vs. (2.22%) suspected serious adverse reactions. The highest rate of suspected adverse reactions was reported in patients receiving AstraZeneca<sup>®</sup> vaccination. The psychosocial consequences associated with vaccination showed increased stress and tension. The vaccination was significantly associated with a reduced risk of symptomatic COVID-19, emphasizing the protective effect of vaccination against severe disease symptoms. In conclusion, the reported data may contribute to the existing body of knowledge on vaccine safety and efficacy and emphasize the importance of addressing vaccine hesitancy to ensure widespread vaccine acceptance.

**Keywords:** COVID-19; Vaccines; Adverse reactions; Psychosocial consequences; SARS-CoV-2

## Introduction

The rapid global spread of the SARS-CoV-2 virus since December 2019 has resulted in the COVID-19 pandemic, presenting a significant challenge to public health worldwide [1-3]. As a response to this

crisis, the development and distribution of vaccines have played a crucial role in mitigating the severity of the disease [4-7]. However, it is essential to thoroughly investigate the potential adverse reactions associated with vaccination and consider the psychosocial aspects generated by the pandemic and the vaccination process [4,8-11]. Vaccine hesitancy, characterized by indecision, uncertainty, delay, or reluctance to receive the vaccine, has emerged as a concern among the target population due to fears of adverse events and perceived vaccine efficacy [12,13]. This study aims to address these concerns by examining suspected adverse reactions induced by COVID-19 vaccines and assessing the psychosocial consequences resulting from vaccination. Additionally, the study evaluates the effectiveness of vaccination in protecting against severe symptoms associated with COVID-19.

## Materials and Methods

A survey based prospective observational study was conducted between May 2021 and June 2022, enrolling patients undergoing

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COVID-19 vaccination. The study enrolled patients receiving COVID-19 vaccination from the Special Community Care Units (USCA) of ASL Naples 2 North. Different surveys, at different timepoints, evaluating patients' fear, doubts and reluctance about COVID-19 vaccination were administered to each enrolled patient. Each patient signed a written informed consent before starting any procedures of the study. The study enrolled patients living in one of the 32 municipalities of ASL Naples 2 North who received the COVID-19 vaccination and met the inclusion criteria. The study employed various questionnaires administered at different time points to gather data on suspected adverse reactions and psychosocial consequences. Descriptive statistics were used to analyze the baseline characteristics of the study participants, while univariate and multivariate logistic regression models were employed to evaluate the association between severe disease symptoms and vaccination. Statistical analysis was performed using SPSS v17.1.

## Results

A total of 10,000 patients were enrolled in the study. Of these, 54.3% were females. The analysis stratified by age groups showed that 73.6% were aged less than 40 years, while 26.4% were aged 41 years or older. All participants received at least one dose of the COVID-19 vaccine; with a majority (97.5%) receiving two doses and a significant rate (73.3%) receiving three doses (Table 1).

**Table 1:** General characteristics of patients received at least one COVID-19-vaccine dose.

	Overall 10000
<b>Gender N (%)</b>	
Male	4,568 (45.68)
Female	5,432 (54.32)
<b>Age groups N (%)</b>	
≤ 30 years	4,464 (44.64)
31-40 years	2,899 (28.99)
41-50 years	1,603 (16.03)
51-60 years	620 (6.20)
61-70 years	342 (3.42)
≥ 70 years	72 (0.72)
<b>Education N (%)</b>	
Junior high school/high school diploma	2,486 (24.86)
High school diploma/high school diploma	5,672 (56.72)
Bachelor's degree (humanities major)	749 (7.49)
Bachelor's degree (science major)	841 (8.41)
Postgraduate specialization/doctorate/master's degree	252 (2.52)
<b>Vaccination Status N (%)</b>	
1st dose	10,000 (100)
2nd dose	9,752 (97.52)
3rd dose	7,335 (73.35)

Overall, for all vaccines, the largest number of reports was of suspected non-serious adverse reactions of 2,558 (9.4) vs. 57 (2.22) suspected Serious adverse reactions (Table 2).

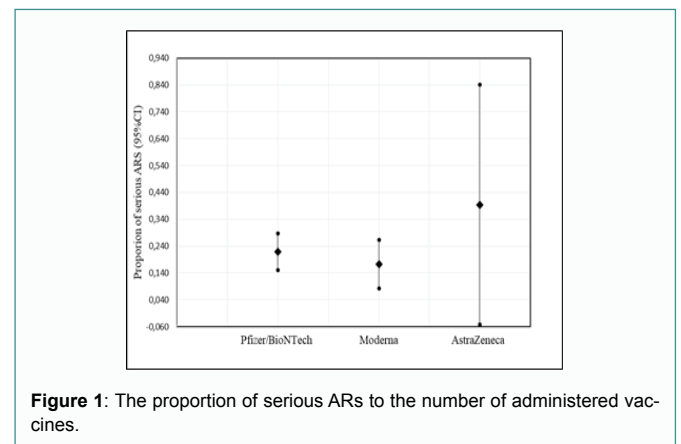
Analysis of suspected adverse reactions reported after vaccine administration revealed significant differences between different vaccine types. Particularly, the highest rate of suspected adverse reactions of 0.39 (-0.05-0.84) was reported in patients receiving AstraZeneca® vaccination (Figure 1).

Serious adverse reactions were identified and categorized, with thrombosis, facial paralysis, hypertension, pericarditis, and spontaneous abortion being among the most frequently reported (Figure 2).

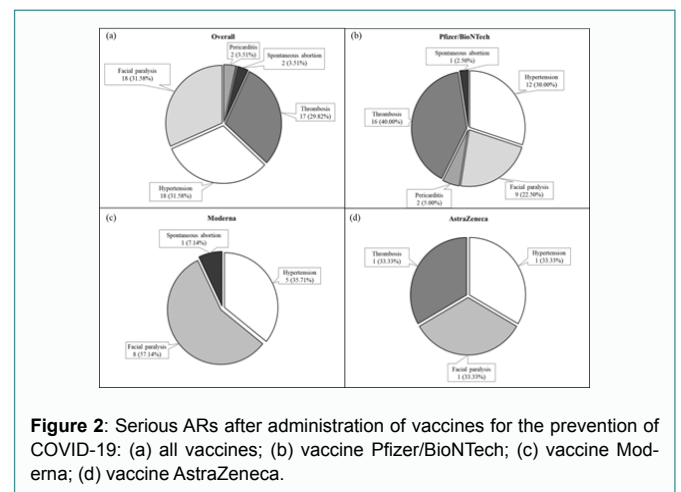
Additionally, the study assessed the psychosocial consequences resulting from vaccination, with a proportion of participants reporting increased stress, tension, and difficulty in relaxing (Table 3).

**Table 2:** Status report of suspected ARs after administration of all vaccines for the prevention of COVID-19.

	Administered doses	ARs	Non-serious ARs	Serious ARs
	N	N (%)	N (%)	N (%)
Pfizer/BioNTech	18224	1,768 (9.70)	1,761 (9.66)	40 (0.22)
Moderna	8099	695 (8.58)	648 (8.00)	14 (0.17)
AstraZeneca	761	94 (12.35)	91 (11.96)	3 (0.39)
Johnson & Johnson	3	1 (33.33)	1 (33.33)	-
All vaccines	27087	2,558 (9.44)	2,501 (9.23)	57 (2.21)



**Figure 1:** The proportion of serious ARs to the number of administered vaccines.



**Figure 2:** Serious ARs after administration of vaccines for the prevention of COVID-19: (a) all vaccines; (b) vaccine Pfizer/BioNTech; (c) vaccine Moderna; (d) vaccine AstraZeneca.

Finally, univariate and multivariate logistic regression analyses revealed that vaccination was a predictor of contracting symptomatic COVID-19. A significant association with the risk of symptomatic COVID-19 was the somministrazione of vaccine, in fact the proportion of subjects who not received vaccination were at almost five times higher risk of the onset of symptoms severity than those who received a vaccination (Adjusted Odds Ratio [OR]: 4.876; 95% CI: 2.981-6.339, p value <0.001) (Table 4).

## Discussion

COVID-19 represented one of the most difficult to manage emergencies for the global sanitary systems [14]. Therefore, the research investigated both the symptoms of the disease [15-17] and the populations most susceptible to severe or lethal COVID-19 [18-20] and the impact of COVID-19 vaccination [4,10]. The fast development of safe and effective vaccinations resulted the main strategy to resolve the lockdown period, avoiding as much as possible further increments of incidence rates, as well as the rate of severe

**Table 3:** Assessment of the psychosocial consequences generated by the vaccination.

What psychosocial consequences the vaccination induced (1:5 Scale)?	Mean ( $\pm$ SD)*
Anxiety and/or serenity	3.1 ( $\pm$ 2)
Insecurity and/or security	3.7 ( $\pm$ 4)
Concern and/or confidence	3.3 ( $\pm$ 2)
<b>Did you lose so much sleep that you worried?</b>	<b>N (%)*</b>
Less than usual	863 (8.63)
More than usual	315 (3.15)
<b>Have you felt unable to concentrate?</b>	<b>N (%)*</b>
Less than usual	799 (7.99)
More than usual	321 (3.21)
<b>Have you felt under pressure?</b>	<b>N (%)*</b>
Less than usual	529 (5.29)
More than usual	795 (7.95)
<b>Have you felt a lot of tension?</b>	<b>N (%)*</b>
Less than usual	539 (5.39)
More than usual	1,230 (12.30)
<b>Have you felt stressed?</b>	<b>N (%)*</b>
Less than usual	573 (5.73)
More than usual	1,196 (11.96)
<b>Did you have difficulty relaxing?</b>	<b>N (%)*</b>
Less than usual	609 (6.09)
More than usual	902 (9.02)

\*Results were calculated from survey answers submitted to the 10,000 vaccinated participants

infections, complications, and death linked to COVID-19 infection [1-3]. Although the role those vaccines had in the resolution of the emergency, several fears, doubts and concerns raised among population undergoing vaccination. Particularly, most of patients' concerns, resulted linked to the possible fear of acute and long-term onset of adverse events linked to vaccines considered "not enough known", due to the relatively rapid development and availability for human use [4,7]. However, it is important to understand how to manage these situations to reach larger population consent in case of further emergencies, avoiding patients' fear, reducing the psychological consequences on patients, and resulting in an even faster and most effective vaccination campaigns. The present study aimed to investigate suspected adverse reactions induced by COVID-19 vaccines and assess the psychosocial consequences associated with vaccination. Additionally, the study evaluated the effectiveness of vaccination in protecting against severe symptoms of COVID-19. The findings of this study shed light on important aspects related to vaccine safety, psychosocial impact, and vaccine efficacy [21-24]. The results of the study revealed variations in the rate of suspected adverse reactions among different COVID-19 vaccine types [25]. As has been shown in other studies, the serious adverse reactions were identified and categorized, with thrombosis [26-28], facial paralysis [29-31], hypertension [32-35], pericarditis [36,37], and spontaneous abortion [38,39] being among the most frequently reported. Thorough evaluation and reporting of adverse reactions are crucial in ensuring

the safety of vaccine recipients and optimizing public confidence in vaccination programs. Moreover, the study assessed the psychosocial consequences generated by vaccination. A proportion of participants reported increased stress, tension, and difficulty in relaxing [40,41]. These findings highlighted the need for comprehensive support and education during the vaccination process. Addressing and mitigating psychosocial concerns and providing accurate information about vaccine safety can contribute to enhancing vaccine acceptance and reducing vaccine hesitancy. Logistic regression analysis demonstrated a significant association between vaccination and a reduced risk of symptomatic COVID-19 [42,43]. This finding underscores the effectiveness of COVID-19 vaccines in protecting against severe disease symptoms. Vaccination has played a crucial role in mitigating the impact of the pandemic, preventing hospitalizations, and reducing the burden on healthcare systems [44,45]. Continued efforts to promote vaccination coverage and ensure equitable access to vaccines are of paramount importance in controlling the spread of COVID-19 and achieving population-level immunity. While this study provides valuable insights, there are some limitations to consider. Firstly, the study relied on self-reporting of adverse reactions, which may introduce reporting bias. Additionally, the study focused on a specific geographical area, limiting the generalizability of the findings to other populations. Future studies with larger sample sizes and diverse populations are warranted to further explore the safety, psychosocial impact, and effectiveness of COVID-19 vaccination. This study contributes to our understanding of suspected adverse reactions induced by COVID-19 vaccines, the psychosocial consequences associated with vaccination, and the effectiveness of vaccination in reducing the risk of symptomatic COVID-19. The findings emphasize the importance of ongoing monitoring of vaccine safety, addressing psychosocial concerns, and promoting vaccine acceptance to ensure the success of vaccination programs in controlling the COVID-19 pandemic.

## Conclusions

Our study provides valuable insights into suspected adverse reactions induced by COVID-19 vaccines, the psychosocial consequences generated by vaccination, and the effectiveness of vaccination in protecting against severe symptoms associated with COVID-19. The reported data may contribute to the existing body of knowledge on vaccine safety and efficacy and emphasize the importance of addressing vaccine hesitancy to ensure widespread vaccine acceptance. Further research and monitoring are needed to comprehensively assess the long-term safety and effectiveness of COVID-19 vaccines.

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**Table 4:** Univariate and multivariate logistics regression of the risk of symptom severity onset among COVID-19 positive.

	Unadjusted OR (95% CI)	p-value*	Adjusted OR (95% CI)	p-value*
<b>COVID-19 vaccination</b>				
Yes	ref	ref	ref	ref
No	3.231 (2.121 -5.129)	<0.01*	4.876 (2.981-6.339)	<0.001*
<b>Gender</b>				
Male	ref	ref	ref	ref
Female	0.99 (0.92-1.07)	0.981	1.311 (0.89-1.91)	0.16
<b>Age groups</b>				
Under 40 years	ref	ref	ref	ref
Over 40 years	2.923 (0.876-5.079)	0.887	3.005 (0.889-7.241)	0.964

\*p-value less than 0.05 were considered to be statistically significant.

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