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Research article

Surveillance of COVID-19 vaccines: A comprehensive analysis of the first immunization drive in Ecuador

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ABSTRACT

The initial phase of the COVID-19 vaccination in Ecuador occurred between April and November 2021. Initially, it focused on priority populations, including health professionals and other front-line workers. During this period, there was limited knowledge about the vaccine's adverse effects. A non-probability, observational study was conducted among university staff in Guayaquil, Ecuador, who received the AstraZeneca vaccine (n = 423) between April and November 2021. This study aimed to compare the acute adverse reactions by doses and to report the incidence of long-term adverse reactions within the AstraZeneca group. As a result, comparing acute adverse reactions between doses, the odds ratio for local pain, headache, muscle pain, fever, and chills are statistically higher after the first dose than the second dose. Survival curves indicated these symptoms appeared mainly within the first 6 h post-vaccination. This is the first pharmacovigilance study from Ecuador that analyzes survival probabilities for the AstraZeneca vaccine's adverse effects.

1. Introduction

Pharmacovigilance is the science of understanding, preventing, and detecting adverse effects and other problems caused by medicine and vaccines [1]. In contrast to clinical trials that provide information on medicine and vaccines obtained from a limited cohort, pharmacovigilance efforts are important to monitor adverse effects among a broader population [1]. Latin America, a region with over 650 million residents, faces challenges in terms of access to healthcare, limited resources, and high health inequalities, making it often difficult to identify and report adverse effects from medicine and vaccines [2]. During the pandemic global health

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Abbreviations

WHO	World Health Organization
PAHO	Pan American Health Organization
EMA	Agencia Europea de Medicamentos
ESPOL	Escuela Superior Politécnica del Litoral
UEES	Universidad Espíritu Santo
OR	odds ratios
PH	proportional hazards
HR	hazard ratios

crisis, mass vaccination initiatives have been the most effective solution to reduce the spread of viruses and minimize symptoms. However, the pandemic has also led to widespread fear of contracting and spreading the virus. This has emphasized the need for close monitoring and regulation of large-scale vaccine production while fueling skepticism about potential side effects [3]. Additionally, the proliferation of unverified information through various media channels has further complicated the situation [4].

The COVID-19 vaccination campaign was launched in Ecuador in March 2021 with the AstraZeneca vaccine [Vaxzevria, AstraZeneca, Cambridge, England] [5]. During this time, the Pan American Health Organization (PAHO) closely monitored the safety of COVID-19 vaccines in Latin America and the Caribbean, including the incidence of adverse events following immunization [6,7]. Other organizations were involved in the safety monitoring of the COVID-19 vaccine, such as the National Pharmacovigilance Centers and the WHO, which implemented the drug monitoring program database VigiBase [8]. These and other worldwide pharmacovigilance efforts showed that COVID-19 vaccines effectively reduced the incidence of symptomatic and severe disease [9,10]. On the other hand, adverse events that have been reported after Astra Zeneca vaccinations included fever (66%), headache (44%), myalgia (31%), injection site pain (13%), general malaise (15%), nausea (12%), chills (19%), joint pain (9%), fatigue (14%) and swelling of lymph nodes (7%) [11].

A document issued by the National Agency for Health Regulation, Control, and Surveillance (ARCSA) on April 9, 2021, reported 269 cases of adverse events related to thrombosis after using the AstraZeneca vaccine since the date of issue. Out of these cases, 102 patients were medically confirmed, and 39 were fatal. The most frequently reported adverse events were strokes (57 cases), followed by myocardial infarctions (34 cases) and pulmonary embolisms (22 cases) [12]. In addition, out of a population of 1.4 billion doses, 25 cases of transverse myelitis have been reported with the Pfizer vaccine and are currently under investigation. No new adverse reactions have been reported [13].

When considering Latin America, the data on the pharmacovigilance of vaccines for COVID-19 is lacking. A recent cross-sectional study was conducted in Colombia on 292 medical students who received the Pfizer-BiotNTec BNT162b2 vaccine against COVID-19, reported a high incidence of adverse events after vaccination (76.37%) [12], including pain at the injection site (73.6%), fatigue (56.8%), sleepiness (46.9%), and headache (38.6%). After the second dose, these symptoms recurred among participants [14]. Similarly, a cross-sectional study of healthcare workers in Guayaquil, Ecuador receiving the Pfizer-BioNTech COVID-19 vaccine found a high incidence (79%) of mild adverse effects after the first dose [15]. Another cross-sectional study in Ecuador comparing self-reported adverse effects of AstraZeneca, Pfizer-BiotNTec, and Sinovac vaccines showed that adverse effects are in the majority mild to moderate and occur more frequently for AstraZeneca vaccines [16]. Our study focusses in a long-term adverse reactions study following the AstraZeneca vaccine in Guayaquil, Ecuador.

2. Methods

2.1. Survey design and administration

We conducted a non-probability convenience sampling of 423 participants during the COVID-19 vaccination campaign in Guayaquil, Ecuador, who received the AstraZeneca vaccine. This survey adopted a descriptive non-experimental research design to investigate the symptoms and adverse events of the AstraZeneca vaccine. Acute pharmacovigilance includes the first 6 h post-vaccination, and long-term surveillance includes more than 72 h until 84 days.

The survey was designed based on the Pan American Health Organization (PAHO) “Manual for Surveillance of Events following Immunisation” and adapted for this study [6,7]. The classification of adverse reactions was obtained from the Agencia Europea de Medicamentos (EMA) [17]. Survey data was collected through online convenience sampling at Escuela Superior Politécnica del Litoral (ESPOL) in Guayaquil. Informed consent was acquired at the vaccination site, where participants were provided with a comprehensive study explanation before receiving the vaccination. The survey was electronically distributed to participants with informed consent, utilizing the user-friendly Google Forms platform to facilitate easy access and administration.

The study was approved by the COVID-19 expedited committee of the Ecuador Ministry of Public Health (No. 024-2020, dated February 12, 2021). The questionnaire briefly introduced the background, objective, and procedure, explained the voluntary nature of participation, declared the anonymity and confidentiality of responses, and provided instructions for completing the online questionnaire. The data were collected using the Google Forms platform, organised, and analyzed using the R studio program (R version 4.1.1).

The questionnaire was directed to participants in two phases according to the two-dose vaccination schedule (Fig. 1). Participants were promptly notified via email to complete the survey, ensuring their active engagement. Additionally, a reminder notification was sent via mail to ensure the timely administration of the subsequent vaccination dose. All the notifications were used manually using the information collected by the consent informed and Forms. The vaccination schedule was divided into two phases. Phase 1 survey was administered after the first dose of the vaccine and contained two parts. Part A: the initial questionnaire assessed acute adverse events immediately following the first dose (within the first 6 h). Part B: the follow-up questionnaire assessed longer-term (1 month after vaccination) adverse events after the dose. Participants received Part B at four different time points: 72 h post-vaccination (B1), seven days post-vaccination (B2), 15 days post-vaccination (B3), and 21 days post-vaccination (B4). The number of active respondents to questionnaires after each dose is reported in Table 1.

2.2. Participants

Inclusion criteria were ESPOL staff in Guayaquil, Ecuador, with internet access and >18 years of age, receiving a COVID-19 vaccination. We excluded participants who were not ESPOL employees, without internet, employees who did not want to participate, and participants under 18. To minimize bias during participant selection, the population that did not fit the study's objective was discarded from the questionnaire with the questions of age and confinement. Even though medication use was not an exclusion criterion due to the high medication rate in the population [18], information on whether the participant was currently under medication or took any medicine to mitigate the symptoms was collected in the questionnaire to be considered for statistical analysis. We screened 571 university employees, of which 423 were eligible and provided voluntary informed consent. Response rates for each questionnaire are shown in Table 1.

2.3. Statistical analysis

Demographic and clinical information of the sample is reported using descriptive measures such as percentages, mean, and standard deviation (SD). We employed logistic regression mixed models to gauge the likelihood of acute adverse effects manifesting

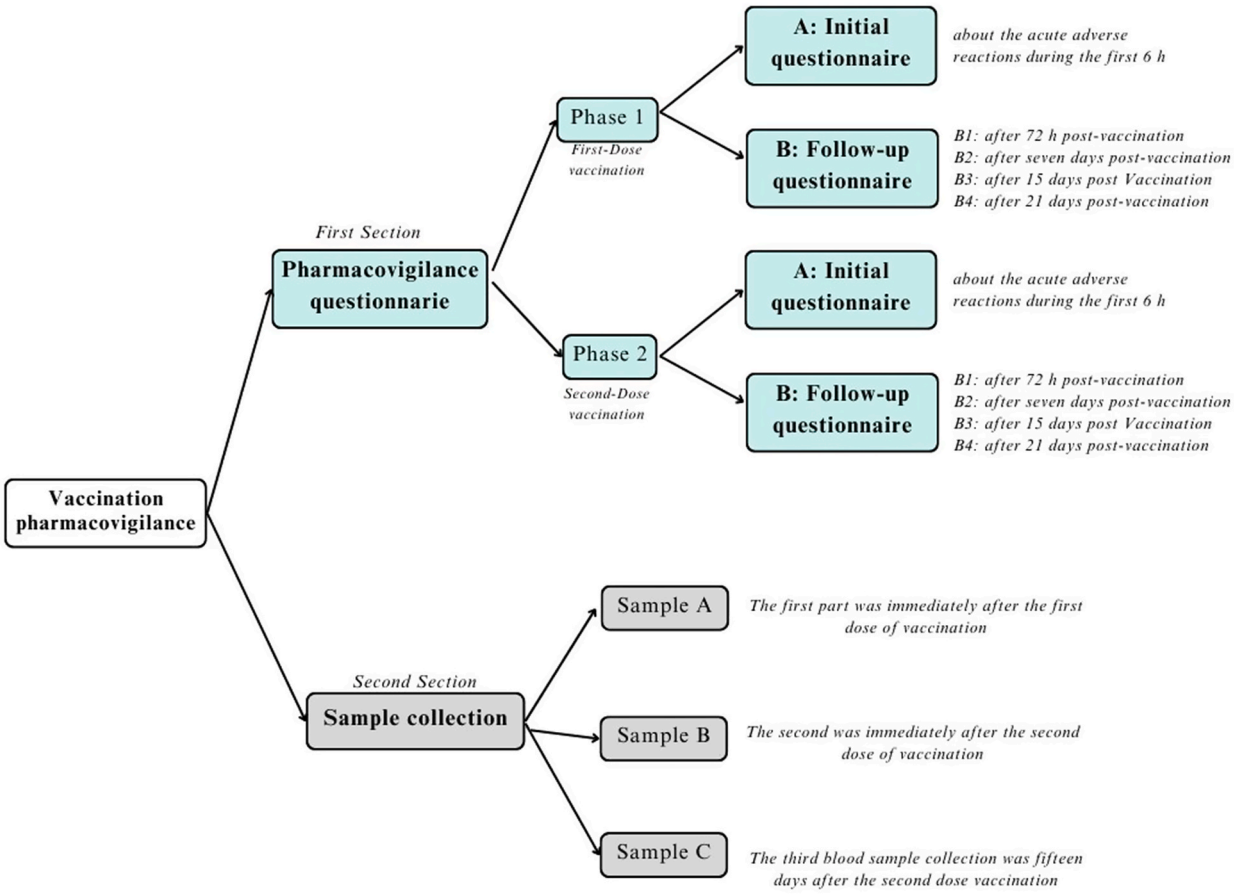

Fig. 1. Pharmacovigilance vaccination study design for AstraZeneca cohort.

Table 1
Active respondents of the follow-up questionnaires after first and second doses of AstraZeneca vaccine.

AstraZeneca	N = 423 (%)
Follow-up after the first dose	
Initial: 6 h after first dose	423 (100)
1st follow-up: Between 1 and 10 days after first dose	316 (74.7)
2nd follow up: Between 5 and 20 days after first dose	279 (66.0)
3rd follow up: Between 10 and 25 days after first dose	223 (52.7)
4th follow up: Between 15 and more than 25 days after first dose	140 (33.1)
Follow-up after second dose	
Initial: 6 h after second dose	173 (40.9)
5th follow-up: Between 1 and 10 days after second dose	125 (29.6)
6th follow up: Between 5 and 20 days after second dose	77 (18.2)
7th follow up: Between 10 and 25 days after second dose	54 (12.8)
8th follow up: Between 15 and more than 25 days after second dose	41 (9.7)

within 6 h following vaccination in both doses. The models were estimated via Penalized Quasi-Likelihood. We included demographic or clinical variables to account for confounding variables like medication, age, or comorbidities and avoid bias in the outcomes. We calculated the odds ratio and p-values for each adverse effect. Survival analysis was conducted to determine the probability of surviving an adverse effect after a given time and to assess whether this probability differs between the first and second doses. A Cox regression model was used to analyze the time-to-event data with a robust variance matrix that estimates covariances between observations of first and second doses of the same respondent. The medication indicator is also used as a predictor. A score test assessed the proportional hazards (PH) assumption. If the PH assumption was met, we estimated hazard ratios (HR) with 95% confidence intervals and tested whether the hazard ratio was equal to one. If the PH assumption was not met, we reported the difference in median survival time for adverse effects between the first and second doses if more than 50% of respondents reported the adverse effect.

Table 2
Characteristics of survey respondents.

	N = 423 (%)
Gender	
Male	193 (45.6)
Female	230 (54.4)
Age, years [a]	38.43 (9.68)
Ethnic group[b]	
Afro-ecuadorian	8 (1.9)
Indigenous	2 (0.5)
Blanco	14 (3.3)
Mestizo	369 (87.2)
Montubio	27 (6.4)
Unidentified	3 (0.7)
Are you currently breastfeeding? (Only woman)	
Yes	9 (4.0)
No	216 (96.0)
Comorbidity	
At least one pathology	156 (36.9)
Arterial hypertension	34 (8.0)
Diabetes	9 (2.1)
Asthma	25 (5.9)
Overweight/Obesity	93 (21.9)
Anemia	13 (3.1)
Heart disease	6 (1.4)
Pulmonary disease	3 (0.7)
Previous COVID infection	
Yes	91 (21.5)
No	332 (78.5)
Previous allergies vaccines related.	
Yes	96 (22.7)
No	327 (77.3)
Did you take any medicine?[b]	
Yes	360 (94.7)
No	20 (5.3)

Note: No pregnant women.
[a] Age reported as mean±SD.
[b] In the first or/and second dose.

3. Results

3.1. Demographic and clinical information

Table 2 provides the demographic and clinical information. The mean age of the sample was 38.43 years old (SD = 9.68), with a slightly higher representation of females. The most common comorbidity in the sample is obesity, and we determined that 27% were overweight, 26% were average weight, and 19% were obese. More than 94% of the sample have reported either being under medication or taking any medicine to mitigate the symptoms of one of the two doses.

3.2. Acute adverse effects for AstraZeneca

Most adverse reactions reported were significantly higher after the first dose than the second, including local pain, headache, fever, chills, muscle pain, joint pain, and generalized tiredness (Fig. 2, Table 3). Gender, age, and taking medicines affect the likelihood of most acute adverse effects reported. In contrast, previous COVID-19 infections correlate with the likelihood of some adverse effects such as muscle pain, chills, and cough.

3.3. Adverse effects survival analysis for AstraZeneca

Upon administration of the medication, it was noted that the typical duration for relief of localized pain falls within the initial 6-h window for both prescribed doses. Table 4 shows that the likelihood of encountering adverse effects in the subsequent period following the first dosage is more significant for individuals who have yet to experience a particular adverse effect than after the second dosage.

Both local pain and general tiredness were the most common adverse effects of the AstraZeneca vaccine, and these were selected to analyze the survival curves (Fig. 3). More than 50% of the cases experiencing local pain were within the first 6 h after both the first and second doses (Fig. 3A). More than 50% of the cases experience these symptoms for general tiredness and headache within the first five days and muscle pain within the first 11.6 days after the first dose (Fig. 3B–C). As for the second dose, it does not reach 50% of the cases. If one does not experience those effects within the first 30 days, one will not likely experience them for both doses. The survival probabilities for fever and chills are slightly above 50% in the first dose and above 75% for the second dose (Fig. 3F). These effects will likely appear within the first five days after the doses (Fig. 3).

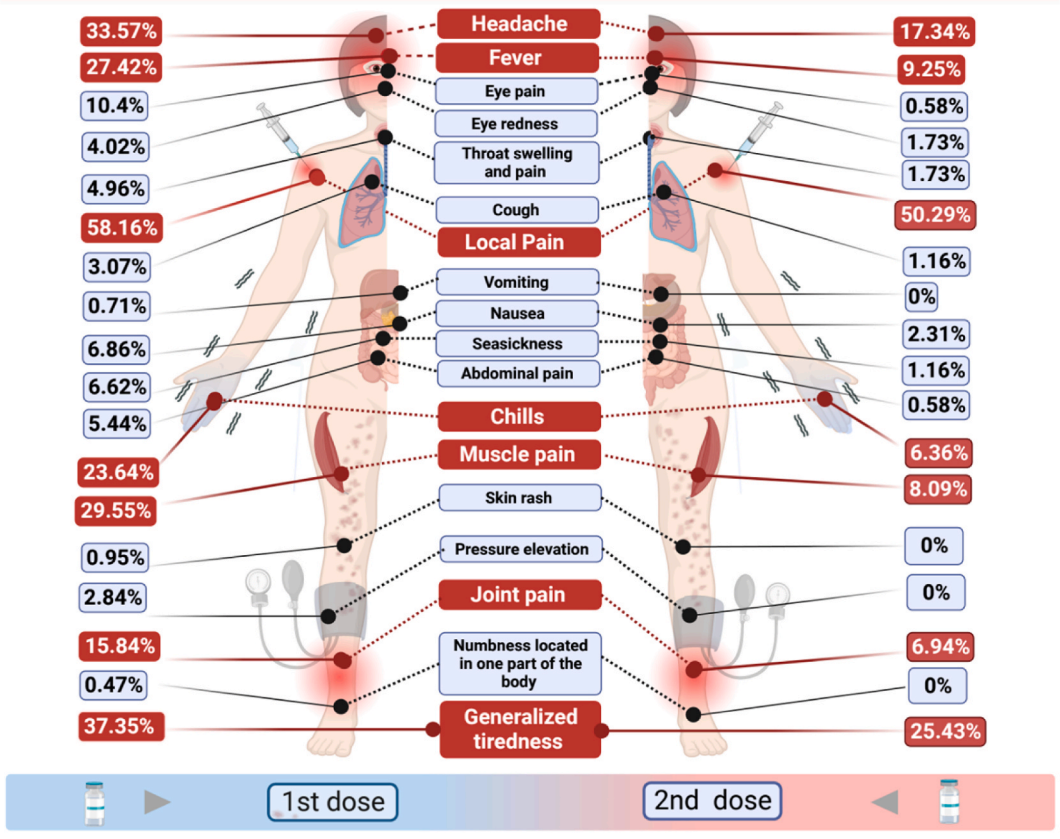

Fig. 2. Acute adverse effects reported after the first and second doses of the AstraZeneca vaccine.

Table 3
Odds ratio of acute adverse effects 6 h post first vs second dose accounting for covariables.

	First dose	Second dose	OR	Covariables (* = p-value <0.05)						
	N = 423	N = 173	(p-value)	Gender	Age	Ethnic	Comorbidity	Previous Covid	Allergy	Medicine
Local Adverse Effect										
Local Pain	246	87	1.49 (0.039)	*	*					*
Systematic Adverse Effect										
Generalized tiredness	158	44	1.94 (0.002)	*	*		*			*
Headache	142	30	2.65 (<0.001)	*	*					*
Muscle pain	125	14	5.22 (<0.001)	*	*			*		*
Fever	116	16	4.23 (<0.001)	*	*					*
Chills	100	11	5.26 (<0.001)	*	*			*		*
Joint pain	67	12	2.60 (0.004)		*					*
Eye pain	44	1	20.78 (0.001)		*					*
Nausea	29	4	3.99 (0.005)	*					*	
Seasickness	28	2	6.92 (0.003)						*	
Abdominal pain	23	1	9.93 (0.012)							
Throat swelling and pain	21	3	3.19 (0.044)	*						
Eye redness	17	3	2.68 (0.113)							
Cough	13	2	3.57 (0.072)	*				*		
Pressure elevation	12	0	Inf (0.999)	*			*			
Diarrhoea	12	1	5.81 (0.092)							
Skin rash	4	0	Inf (0.999)				*			
Vomiting	3	0	Inf (0.999)					*		
Numbness located in one part of the body	2	0	Inf (0.999)		*			*		*

Several demographic and nutritional variables, including sex, age, BMI, and cardiovascular risk, were analyzed in a survival model to determine their correlation with the probability of adverse reactions. However, after the analysis, only age and sex were found to have significant relations. In Table 5, you can find the proportional effects of a one-year increase in age on the hazard in the same dose. Younger patients have slightly higher odds of experiencing local and systemic adverse reactions (see p-values in Table 5). Moreover, male patients have lower odds of experiencing general tiredness, nausea, and muscle pain than female patients (see p-values in Table 5).

4. Discussion

The results present valuable insights into the pharmacovigilance of Ecuador's initial COVID-19 AstraZeneca vaccine campaign. Participants reported higher adverse reactions with the AstraZeneca group after the first dose 73% compared with the second 57% similarly reported by Desalegn et al., which found 91.3% of symptoms occurred after the first dose than after the second dose (67%) [19]. In our cohort, the most common adverse reactions reported for AstraZeneca were mild symptoms such as pain at the injection site and tenderness, 58% and 37%, respectively. These results are consistent with the Salomon group in Ethiopia, which also found higher local pain and tenderness in their vaccinated population with the AstraZeneca vaccine [20]. According to the Agencia Europea de medicamentos (EMA), the classification of adverse reactions of the AstraZeneca vaccine was very frequent, frequent, less frequent, and rare [17,21]. According to our results, the primary adverse reactions during the first 6 h post-vaccine were frequent: local pain, headache, muscle pain, chills, fever, nausea, articular pain, swelling at the injection site, and general discomfort.

Acute adverse reactions to the AstraZeneca vaccine are more common after the first dose than after the second. These reactions can include symptoms like local pain, general tiredness, headache, muscle pain, fever, and chills [21], which are the most common. We found that age and gender significantly affected most acute adverse reactions. Younger people and females reported a higher odds ratio for acute adverse reactions.

In the long-term surveillance, according to data in Table 5, the AstraZeneca vaccine is more likely to cause adverse effects after the first dose than the second. For 84 days, more than half of the participants experienced local pain, general tiredness, headache, and muscle pain, the most frequently reported adverse effects. However, there was a trend in the presentation of these effects, and it was observed that symptoms occurring within the first 6 h after the first dose or within the first ten days after the second dose were less likely to result in adverse effects, particularly with local pain. Tiredness and headache were typically experienced within the first five days, while muscle pain occurred around 11.6 days after the first dose. Fever and chills were less common, but if they did occur, they were more likely to appear after the first five days following vaccination. Babaee et al., 2022, differed in that the most common adverse effects were fatigue (28.37%), chill/fever (26.86%), and skeletal pain (22.38%) in the 72 h after the first and second doses [22].

Table 4
Estimated hazard ratio in the first vs second dose for adverse effects of AstraZeneca vaccine.

	N (%)		PH assumption test[a]	Estimated HR [b]			
	First Dose	Second Dose	$\chi 2$ (p-value)	(Diff in survival median)	p-value	[95% CI] HR	Medicine p-value
Local Adverse Effect							
Local Pain	312 (73.8)	100 (57.8)	4.13 (0.04)	(0)			0.001
Systematic Adverse Effect							
Generalized tiredness	243 (57.4)	64 (37.0)	0.17 (0.68)	0.631	0.001	[0.483, 0.825]	0.014
Headache	262 (61.9)	47 (27.2)	1.7 (0.19)	0.401	<0.001	[0.294, 0.546]	0.001
Muscle pain	212 (50.1)	34 (19.7)	2.98 (0.08)	0.355	<0.001	[0.250, 0.503]	0.001
Fever	197 (46.6)	26 (15.0)	0.05 (0.82)	0.316	<0.001	[0.213, 0.467]	<0.001
Chills	173 (40.9)	20 (11.6)	0.18 (0.67)	0.264	<0.001	[0.168, 0.415]	0.004
Joint pain	140 (33.1)	25 (14.5)	0.09 (0.76)	0.408	<0.001	[0.267, 0.624]	0.049
Eye pain	116 (27.4)	13 (7.5)	5.08 (0.02)				0.779
Nausea	75 (17.7)	6 (3.5)	0.52 (0.47)	0.224	<0.001	[0.102, 0.491]	0.063
Seasickness	84 (19.9)	13 (7.5)	4.45 (0.03)				0.026
Abdominal pain	75 (17.7)	8 (4.6)	1.49 (0.22)	0.271	0.001	[0.126, 0.586]	0.105
Throat swelling and pain	48 (11.3)	5(2.8)	0.89 (0.35)	0.313	0.011	[0.127, 0.889]	0.028
Eye redness	63 (14.9)	9 (5.4)	0.24 (0.62)	0.32	0.004	[0.148, 0.692]	0.779
Cough	66 (15.6)	6 (3.5)	0.10 (0.75)	0.286	0.002	[0.128, 0.637]	0.044
Pressure elevation	44 (10.4)	3 (1.7)	25.33 (<0.001)				0.071
Skin rash	35 (8.3)	1 (0.6)	31.23 (<0.001)				0.434
Vomiting	31 (7.3)	0 (0.0)	0 (1)				0.417
Numbness located in one part of the body	57 (13.5)	2 (1.2)	5.93 (0.01)				0.096

[a] Proportinal Hazard (PH).
[b] Hazard Ratio (HR).

Additionally, Tequare et al. (2021) observed higher rates of adverse reactions in AstraZeneca 72 h after the first and second doses [23].

After administering the first dose of AstraZeneca, unexpected adverse reactions were revealed during the follow-up period. Specifically, 13.5% of the participants reported experiencing numbness in a particular part of their body, while 10.4% reported elevated pressure. Unfortunately, a comparison between the adverse reactions after the first and second doses could not be made due to the limited number of participants who received the double dose.

Thus far, no evidence exists that the AstraZeneca SARS-CoV-2 vaccine leads to any lasting negative effects. Most vaccine-related symptoms tend to occur in the first few days or weeks following vaccination, making it likely that any adverse events would emerge. This research constitutes the first long-term monitoring of AstraZeneca COVID-19 vaccine symptoms after complete vaccination and provides valuable insights into the pattern of adverse reactions.

According to a recent study published in the "Obesity" journal in October 2021, individuals with a body mass index (BMI) of 30 or more, otherwise known as obesity, may be more susceptible to experiencing side effects following the administration of the AstraZeneca vaccine. While the study did not identify any comorbidities or anthropometric variables linked to survival outcomes, it did reveal that individuals with obesity were more prone to experiencing injection site pain and fever [24]. Our analysis has uncovered that two key factors, namely sex and age, significantly affect the likelihood of adverse reactions in the survival model. Specifically, we found that younger patients exhibit a higher odds ratio for specific local and systemic adverse reactions. Conversely, male patients display lower odds ratios for local pain, tiredness, headache, and muscle pain when compared to their female counterparts. Furthermore, a study conducted by Alemayehu et al. has highlighted that older patients, particularly those who fall within the age bracket of 50–60 years and have pre-existing comorbidities, face an elevated risk of adverse reactions [25].

A study published by The Lancet in 2021 discovered that young adults between 15 and 39 years old are at a higher risk of experiencing thrombotic episodes and thrombocytopenia within 4–13 days after vaccination. However, the study also revealed that individuals aged 65 and above did not experience any increased risk of these conditions post-vaccination. It is essential to understand the possible risks associated with vaccination and take necessary measures to address them, as highlighted by this study [26]. According to Duijster's research, women are more prone to adverse reactions than men, particularly after the initial dose. Our report

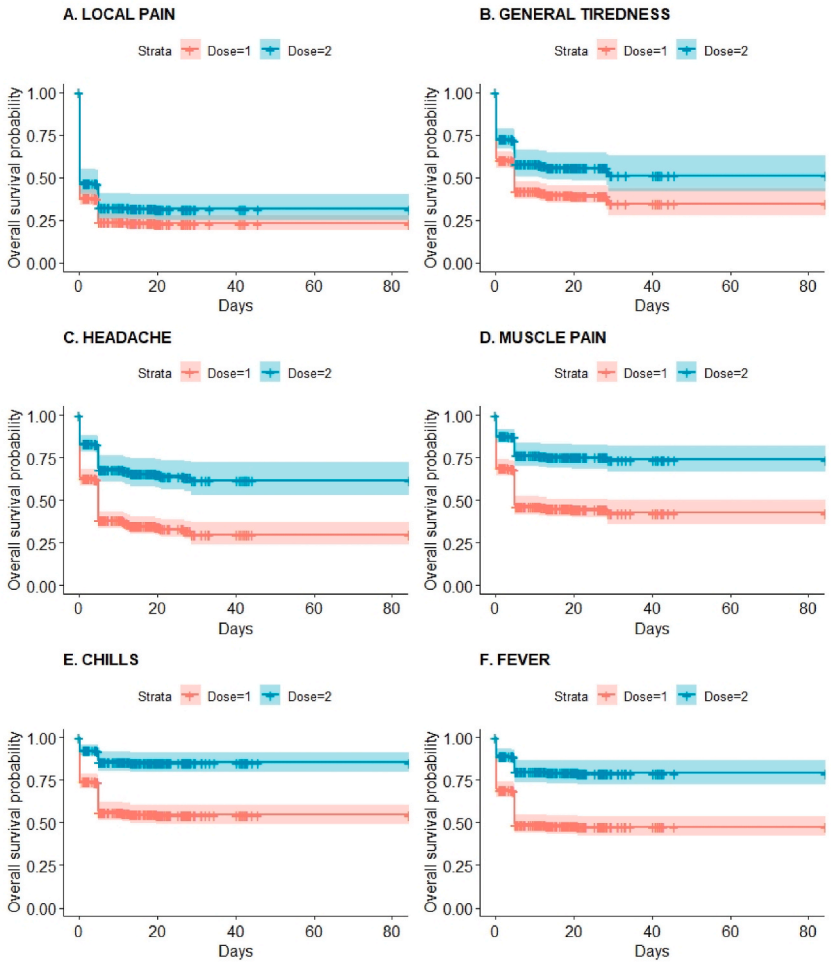

Fig. 3. Survival curves for most common adverse effects after the first and second dose of AstraZeneca Vaccine accounting for the effect of taking medicine. A. Local pain overall survival probability. B. General tiredness overall survival probability; C. Headache overall survival probability; D Muscle pain overall survival probability; E. Chills overall survival probability. F. Fever overall survival probability.

Table 5
Significant hazard ratio of a one-year increase in the patient's age and male vs female for adverse reactions of AstraZeneca vaccine.

	AGE			SEX (Male = 1, Female = 0)		
	PH assumption test	Estimated		PH assumption test	Estimated	
	$\chi 2$ (p-value)	HR	p-value	$\chi 2$ (p-value)	HR	p-value
Local Adverse Effect						
Local Pain	0.53 (0.47)	0.952	<0.001			
Systematic Adverse Effect						
Generalized tiredness	0.43 (0.51)	0.969	0.001	0.03 (0.86)	0.518	<0.001
Headache	0.23 (0.63)	0.959	<0.001			
Muscle pain	1.99 (0.16)	0.958	<0.001	0.10 (0.75)	0.584	0.011
Fever	0.01 (0.92)	0.947	<0.001			
Chills	0.13 (0.72)	0.946	<0.001			
Joint pain	1.03 (0.31)	0.971	0.018			
Eye pain	0.05 (0.83)	0.959	0.003			
Nausea	1.58 (0.21)	0.940	0.007	0.88 (0.35)	0.503	0.041
Throat swelling and pain	0.07 (0.79)	0.929	<0.001			
Seasickness	0.03 (0.85)	0.963	0.039			
Vomiting	2.21 (0.14)	0.908	0.001			
Skin rash	0.94 (0.33)	0.934	0.018			

confirms this trend, with age and gender being significant factors in the likelihood of adverse reactions occurring over time. Nevertheless, the variances observed were not statistically meaningful.

Our study on acute and long-term adverse effects of the AstraZeneca COVID-19 vaccine has significant implications for future research. One of the main limitations of our study was the incomplete response rates, which raised concerns about non-response bias and the sample's representativeness. The survey was conducted during the first large-scale vaccination campaign for academy professors, and there were several dropouts. Although the participants initially expressed interest during recruitment, the cohort needed to be more engaged in the long run. Despite regular email notifications and phone call reminders, better engagement was needed during this period. The matter remained unresolved despite multiple attempts to rectify the situation, such as sending reminder emails.

Furthermore, the limited number of participants could have underestimated infrequently reported adverse effects. In addition, small sample sizes pose a challenge in obtaining statistical evidence. This study had a long-term focus but stopped after just 21 days of administering the vaccine, which might limit our understanding of any delayed complications linked to the vaccines. It was decided to stop the study due to a high dropout rate among the academic professional cohort. The lengthy survey, which required participants to answer ten questions weekly, contributed to this trend. The increased dropout rate also emphasizes the need for innovative approaches to enhance participant engagement and retention, such as personalized follow-up reminders and proactive steps to reduce obstacles to ongoing participation. Considering the limitations identified in this study, it is vital to consider them when designing epidemiological investigations. By doing so, we can ensure that the evidence generated is robust, reliable, and applicable to a broader population. This, in turn, will help guide future public health policies and vaccination strategies, ultimately benefiting societies.

5. Conclusions

Our research has unveiled some crucial information regarding the adverse reactions that are commonly observed among individuals in Ecuador who have received the AstraZeneca vaccine for 84 days. Our findings suggest that the first dose of the AstraZeneca vaccine is linked to a higher frequency of adverse reactions than the second dose. The most commonly reported symptoms experienced by over 50% of participants were tiredness, headache, and muscle pain. However, it is essential to note that if these symptoms occur within 6 h after the first or ten days after the second dose, they will not be considered adverse effects.

Ethical standards disclosure

This study was conducted according to the guidelines laid down in the Declaration of Helsinki, and the study approved all procedures involving research study participants approved by the "Comité Nacional Expedito para Investigación sobre COVID-19" under protocol No. 024-2020. Written informed consent was obtained from all subjects/patients.

Data access statement

All the authors had complete access to the study data, allowing us to identify and analyze the information. All the patient information was previously anonymized and treated to be shared and analyzed.

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Data availability statement

The findings and supporting materials are available in this article. The author can only answer questions about the data information if it needs it.

CRediT authorship contribution statement

Andrea Orellana-Manzano: Writing – original draft, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. **Andrea C. Garcia-Angulo:** Writing – review & editing, Supervision, Software, Investigation, Formal analysis, Data curation. **Fernanda B. Cordeiro:** Writing – review & editing, Supervision, Project administration, Methodology, Investigation. **Diana Carvajal-Aldaz:** Writing – review & editing, Validation, Supervision, Resources, Methodology, Investigation. **Elizabeth Centeno:** Writing – review & editing, Visualization, Validation, Supervision, Resources. **María J. Vizcaíno:** Writing – review & editing, Validation, Methodology, Investigation. **Sebastián Poveda:** Writing – review & editing, Software, Methodology, Formal analysis. **Merly Garcia:** Writing – review & editing, Validation, Supervision, Methodology, Investigation, Data curation. **Carmen Matías-De la Cruz:** Writing – review & editing, Validation, Methodology, Investigation. **Derly Andrade-Molina:** Writing –

review & editing, Validation, Supervision, Methodology, Investigation, Funding acquisition. **Mariuxi Mirabá:** Writing – review & editing, Supervision, Resources, Methodology, Investigation. **Saurabh Mehta:** Writing – review & editing, Visualization, Validation, Supervision, Project administration, Funding acquisition, Conceptualization. **Washington B. Cárdenas:** Writing – review & editing, Validation, Supervision, Investigation, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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