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Factors associated with events allegedly attributable to SARS-CoV-2 vaccination among older adults: retrospective study in Teresina-PI, Brazil[a]

Fatores associados a eventos supostamente atribuíveis à vacinação para SARS-CoV-2 entre idosos: estudo retrospectivo em Teresina-PI, Brasil

Factores asociados a eventos presuntamente atribuibles a la vacunación contra el SARS-CoV-2en ancianos: estudio retrospectivo en Teresina-PI, Brasil

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Abstract

Objective: To analyze the factors associated with Events Supposedly Attributable to Vaccination or Immunization for SARS-CoV-2 among older adults. **Method:** Census, descriptive and retrospective study, carried out in Teresina, Piauí and approved by the Research Ethics Committee. A total of 51 elderly participated, who received at least one dose of the vaccine against COVID-19 and who presented or not a reported event between February and September 2021. **Results:** 76.5% of the older adults received the AstraZeneca vaccine in the 1st dose. The mean occurrence of events was 3.45. As for severity, 82.4% were classified as not severe; 17.6% were severe, of which 66.7% resulted in hospitalization, 22.2% in death and 11.1% in permanent disability. The most frequent events were related to the musculoskeletal system, followed by headache, related to the neurological and digestive system. There was a statistically significant association of the event related to the respiratory system with age group and of the immunization error with gender. **Conclusion and implications for practice:** Although events supposedly attributable to vaccination/immunization in older adults have been observed, it is noted that they are within the expected range, with their behavior being of a not severe, low-risk type for this group, in addition to being ensured the benefits when compared to the risks.

Keywords: COVID-19; Nursing; Adverse events; Older Adults; Vaccination.

Resumo

Objetivo: Analisar os fatores associados aos Eventos Supostamente Atribuíveis à Vacinação ou Imunização para SARS-CoV-2 entre idosos. **Método:** Estudo censitário, descritivo e retrospectivo, realizado em Teresina, Piauí e aprovado pelo Comitê de Ética em Pesquisa. Participaram 51 idosos que receberam, pelo menos, uma dose de vacina contra COVID-19 e que apresentaram ou não evento notificado entre fevereiro a setembro de 2021. **Resultados:** 76,5% dos idosos receberam a vacina AstraZeneca na 1ª dose. A média de ocorrência dos eventos foi de 3,45. Quanto à gravidade, 82,4% foram classificados como não graves; 17,6% graves, dos quais 66,7% resultaram em hospitalização, 22,2% em óbito e 11,1% em incapacidade permanente. Eventos mais frequentes estiveram relacionados ao sistema musculoesquelético, seguidos de cefaleia, relacionados ao sistema neurológico e digestivo. Observou-se associação estatisticamente significativa do evento relacionado ao sistema respiratório com faixa etária e do erro de imunização com o gênero. **Conclusão e implicações para a prática:** Apesar de ser observado eventos supostamente atribuíveis à vacinação/imunização em idosos, nota-se que estão dentro do esperado, sendo seu comportamento com tipologia não grave e de baixo risco para este grupo, além de assegurados os benefícios frente aos riscos.

Palavras-chave: COVID-19; Enfermagem; Eventos Adversos; Idoso; Vacinação.

Resumen

Objetivo: Analizar factores asociados a los Eventos Supuestamente Atribuibles a la Vacunación o Inmunización para el SARS-CoV-2 en adultos mayores. **Método:** Estudio censal, descriptivo y retrospectivo, realizado en Teresina, Piauí, y aprobado por el Comité de Ética en Investigación. Participaron 51 personas mayores, que recibieron al menos una dosis de vacuna contra la COVID-19 y que presentaron o no evento informado entre febrero y septiembre de 2021. **Resultados:** El 76,5% del grupo recibió la vacuna AstraZeneca, en la 1ª dosis. La media de ocurrencia de eventos fue de 3,45. En cuanto a la gravedad, el 82,4% se clasificó como no grave; el 17,6% fueron graves, de los cuales el 66,7% resultaron en hospitalización, 22,2% en muerte y 11,1% en invalidez permanente. Los eventos más frecuentes estuvieron relacionados con el sistema musculoesquelético, seguido de cefalea, relacionada con el sistema neurológico y digestivo. Hubo asociación estadísticamente significativa, relacionando el sistema respiratorio con el grupo etario y el error de inmunización al género. **Conclusión e implicaciones para la práctica:** Se observaron eventos supuestamente atribuibles a la vacunación/inmunización en mayores, que está dentro de lo esperado, con un comportamiento no grave y de bajo riesgo, además que los beneficios se superponen a los riesgos.

Palabras clave: COVID-19; Enfermería; Eventos adversos; Persona Mayor; Vacunación.

INTRODUCTION

The world is experiencing a period of disorder in the segments that support a country, which affects the economy, security, education and, above all, health, because of the COVID-19 pandemic. In view of this scenario, Brazil has sought to raise awareness among the population about preventive measures, as well as reorganize the health system with the main focus on reducing the mortality of those infected with the new coronavirus.[1]

It is noteworthy that the first cases of SARS-CoV-2 infection identified in humans occurred at the end of 2019, in the city of Wuhan, China. Subsequently, other countries also reported cases of the disease, namely: Italy, Spain, France, Germany and the United Kingdom.[2] In Brazil, the notification of the first case of COVID-19 occurred in February 2020.[3] In this perspective, the World Health Organization (WHO) issued a global alert about the emergence of a so far unknown disease, but which was spreading rapidly around the world, defining it as a global public health problem.[3]

Brazil has adopted and encouraged some individual and collective prevention measures against COVID-19, namely: hand washing with soap and water, use of a face mask and alcohol gel, in addition to social distancing, isolation and the not sharing of objects.[4] However, what was observed in practice was the increase in confirmed cases of COVID-19 and the non-compliance with such measures.

In the context of immunizations, the nursing team, made up of nurses, technicians and nursing assistants, plays a fundamental role in all the execution actions of the National Immunization Program (NIP), from its implementation in the Family Health Strategy (FHS) to the maintenance and safe administration of immunobiologicals in the vaccination rooms, minimizing the incidence of possible Events Supposedly Attributable to Vaccination or Immunization (ESAVI).[5,6] These are characterized by any unwanted medical occurrence after vaccination, which does not necessarily have a causal relationship with the administration of the vaccine or the receiving of an immunobiological agent, and may be expected, unexpected or due to immunization error (IE).[6]

As this virus continues to cause morbidity and mortality and catastrophe across the world, the pharmaceutical industry has started a race against time to manufacture immunobiologicals capable of preventing COVID-19. In Brazil, two immunobiologicals have been used in the vaccination campaign against this disease in the older adults, preferably: CoronaVac – developed by Sinovac in partnership with the Butantan Institute, which has approximately 78% preventive efficacy and 100% efficacy against severe forms of COVID-19 – and AstraZeneca/Oxford – developed by the University of Oxford with the Anglo-Swedish laboratory AstraZeneca, which uses a different technology for its elaboration, called "viral vector" and is 70.4% effective.[7]

Brazil instituted an operational plan for the vaccination strategy against COVID-19, which must be followed by all states and municipalities and which has the elderly as a priority group, as they are at greater risk of developing complications and deaths from the disease.[7] In this context, it is important to develop research that analyzes the possible factors associated with Events Supposedly Attributable to Vaccination or Immunization (ESAVI) for SARS-CoV-2 among the older adults.

The investigation of factors associated with Events Supposedly Attributable to Vaccination or Immunization for SARS-CoV-2 among older adults in Teresina, Piauí is important due to the pandemic scenario experienced as a result of the disease; because this population group is the one most likely to develop severe forms and progress to death, with vaccination being the only form of prevention so far; as well as the lack of scientific production on the subject.[8] Therefore, the objective of the present study is to analyze the factors associated with Events Supposedly Attributable to Vaccination or Immunization for SARS-CoV-2 among older adults in Teresina, Piauí.

METHOD

This is a census, retrospective study, inserted in a macro research project entitled: "Epidemiology, subjectivities and technologies: a Brazilian perspective in times of the COVID-19 pandemic". The research was carried out in the municipality of Teresina, capital of the state of Piauí, with data collected at the Municipal Health Foundation of this municipality, specifically, at the Directorate of Health Surveillance (DHS). The population of this study consisted of elderly people who received at least one dose of vaccine against COVID-19 and who may or may not have had a reported event. The information obtained covered the older adults vaccinated from February 2021 to September 2021.

For this study, an individual aged 60 (sixty) years or older was considered an older adult.[6] For the epidemiological determination of the prevalence of occurrence of events, the total number of older adults vaccinated with CoronaVac and AstraZeneca between February and September 2021 was collected from the DHS of the aforementioned municipality. Thus, the calculation was carried out in order to verify the vaccination behavior in the target public of the study.

As established inclusion criteria: older adults, of both genders, and who took one or two doses of immunobiologicals used in vaccination against COVID-19 in Teresina. As exclusion criteria: notifications with incomplete information, notifications classified as "immunization errors" and those that are not within the pre-established period.

Data collection took place from March to May 2022, through access to the spreadsheet generated from an electronic form (Google Forms), prepared according to Municipal Health Foundation guidelines. The instrument for data collection consisted of a form, prepared by the researchers themselves, based on the AEFI notification form, made available by the Ministry of Health[5] and the Municipal Health Foundation notification form. It is noteworthy that the form consists of two parts: sociodemographic, economic and clinical data, in addition to data related to immunization against COVID-19.

It is noteworthy that the events can be classified according to severity in: Severe Adverse Event (SAE), when it requires hospitalization, has risk of death that requires hospitalization, permanent disability, results in congenital anomaly, or causes death; in Not Severe Adverse Event (NSAE) are the common events and immunization error (IE) related to the vaccination technique.[6]

Data were collected through the application of a form, with the dependent variable being the presence of ESAVI for SARS-CoV-2, and the independent variables: sex, age, race/color, housing, pre-existing disease, use of medications, type of vaccine, number of doses, history of ESAVI, month of application of the material, vaccine that generated ESAVI, dose that generated ESAVI, intensity of ESAVI, type of ESAVI, classification of ESAVI, evolution of ESAVI and causality.

Initially, the data were organized and tabulated in a Microsoft Office Excel 2016® spreadsheet. To perform the descriptive and inferential statistical analysis, the database was processed using the Statistical Package for the Social Sciences (SPSS) software, version 26.

Regarding the qualitative descriptive variables, the relative and absolute frequency was used, this procedure aimed to verify the consistency between the variables, and for the variables with a possible association, the Fisher's exact test was performed, with significance of 5%. After verifying an association between some variables, the odds ratio was applied using binary logistic regression, with a significance of 5%.

With regard to quantitative variables, descriptive analysis was performed using mean and standard deviation. Finally, to measure the follow-up of the vaccination projection analysis, the technique of moving averages was applied, whose follow-up is carried out in an interval of no more than 15 days. Finally, data analysis was performed based on the scientific literature relevant to the topic.

The research project was approved by the Research Ethics Committee of the Universidade Federal do Piauí (UFPI), obtaining opinion number 5.1791222 and CAA: 53900121.9.0000.5214.

RESULTS

In the present study, 51 older adults who had registered some ESAVI in their notification forms participated in this study. The mean age was 73.33 years (Standard deviation=11.79), most were female (72.5%) and were not health professionals (86.3%). As for the distribution of those vaccinated according to the type of immunobiological administered, it was observed that most older adults (76.5%) received the immunobiological produced by AstraZeneca in the 1st dose. In the 2nd dose (11.8%) and 3rd dose (9.8%) vaccines produced by the Butantan Institute predominated.

There was an average of 3.45 ESAVI in the studied sample (Standard deviation=1.35). As for the classification of the severity of reported ESAVI, 17.6% (CI=9.1-29.7) were classified as severe, and of these 66.7% (CI=34.8-89.6) resulted in hospitalization, 22.2% (CI=4.9-54.4) in deaths and 11.1% (CI=1.2-41.4) in permanent disability. It is noteworthy that 58.0% of participants reported using medication before or during vaccination.

As for the characterization of ESAVI against COVID-19, it was observed that the most frequent was related to the musculoskeletal system (26.2%), followed by headache and related to the neurological system (25.4%), in addition to the digestive system (10.7%). It is noteworthy that 3.3% of immunization errors were reported.

Figure 1 shows the moving average evolution of vaccination during the studied period. Thus, it was observed that the largest vaccination records occurred in the period between April 26 and May 10.

It was observed that the adults aged <70 years had 49.0% (n=25) of events classified as not severe and, regarding the type of severity, 12.5% (n=1) resulted in permanent disability. In the adults aged ≥70 years, a higher number of ESAVI classified as severe can be observed, 11.8% (n=6), with 37.5% (n=3) of hospitalizations and 25.0% (n=2) of death (Table 1).

It is noteworthy that the severity of ESAVI occurred in the majority of adults aged 70 years or older, female and not health professionals. However, it was observed that there was no statistically significant association between the ESAVI severity classification and the type of severity with the sociodemographic variables (Table 1).

Table 2 shows that immunization errors were more common among elderly males. In addition, it showed its association with sex (p-value=0.026).

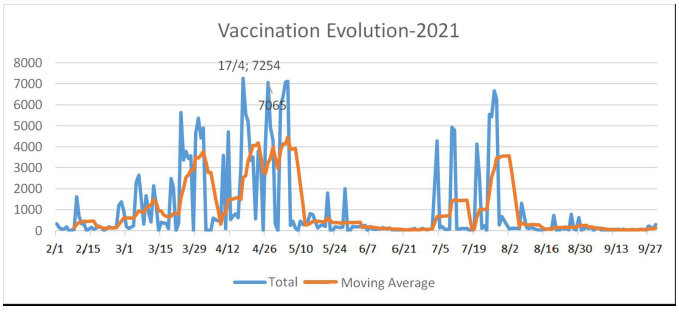

Figure 1. Evolution by moving average of the vaccination of older adults against COVID-19 notified in the Municipal Health Foundation (MHF) system, in the city of Teresina-PI-2022. (n=51)
Source: Research data, 2022.

Table 1. Association between the severity of the ESAVI (classification and type) and the social profile in older adults vaccinated against COVID-19 notified in the Municipal Health Foundation (MHF) system, in the city of Teresina-PI-2022. (n=51).

	Severity Rating			Severity Type			
	Not Severe	Severe	P-value	Hospitalization	Death	Permanent disability	P-value
	N(%)	N(%)		N(%)	N(%)	N(%)	
Age Range			0.152				0.237
<70 years	25(49.0)	3(5.9)		2(25.0)	0(0.0)	1(12.5)	
≥70 years	17(33.3)	6(11.8)		3(37.5)	2(25.0)	0(0.0)	
Race			0.883				
White	4(7.8)	1(2.0)		1(12.5)	0(0.0)	0(0.0)	0.074
Black	1(2.0)	0(0.0)		0(0.0)	0(0.0)	0(0.0)	
Brown	9(17.6)	1(2.0)		0(0.0)	0(0.0)	1(12.5)	
Yellow	2(3.9)	1(2.0)		0(0.0)	1(12.5)	0(0.0)	
Ignored	26(51.0)	6(11.8)		4(50.0)	1(12.5)	0(0.0)	
Sex			0.699				0.449
Feminine	30(58.8)	7(13.7)		3(37.5)	2(25.0)	1(12.5)	
Masculine	12(23.5)	2(3.9)		2(25.0)	0(0.0)	0(0.0)	
Healthcare professional			0.187				-
No	35(68.6)	9(17.6)		5(62.5)	2(25.0)	1(12.5)	
Yes	7(13.7)	0(0.0)		0(0.0)	0(0.0)	0(0.0)	

Source: Survey data, 2022.

Table 2. Association between ESAVI and immunization error and the social profile of older adults vaccinated against COVID-19 notified in the Municipal Health Foundation (MHF) system, in the municipality of Teresina-PI-2022.N:51.

	Immunization error			Headache and Neurological Sys.			Musculoskeletal Sys.		
	No	Yes	p-value	No	Yes	p- value	No	Yes	p- value
	N(%)	N(%)		N(%)	N(%)		N(%)	N(%)	
Age Range			0.837			0.254			0.741
<70 years	26(55.3)	2(50.0)		9(45.0)	19(61.3)		11(57.9)	17(53.1)	
≥70 years	21(44.7)	2(50.0)		11(55.0)	12(38.7)		8(42.1)	15(46.9)	
Race			0.631			0.558			0.368
White	5(10.6)	0(0.0)		1(5.0)	4(12.9)		1(5.3)	4(12.5)	
Black	1(2.1)	0(0.0)		0(0.0)	1(3.2)		1(5.3)	0(0.0)	
Brown	10(21.3)	0(0.0)		3(15.)	7(22.6)		4(21.1)	6(18.8)	
Yellow	3(6.4)	0(0.0)		2(10.0)	1(3.2)		0(0.0)	3(9.4)	
Ignored	28(59.6)	4(100.0)		14(70.0)	18(58.1)		13(68.4)	19(59.4)	
Sex			**0.026**			0.332			0.247
Feminine	36(76.6)	1(25.0)		13(65.0)	24(77.4)		12(63.2)	25(78.1)	
Masculine	11(23.4)	3(75.0)		7(35.0)	7(22.6)		7(36.8)	7(21.9)	
Healthcare professional			0.406			0.535			0.609
No	40(85.1)	4(100.0)		18(90.0)	26(83.9)		17(89.5)	27(84.4)	
Yes	7(14.9)	0(0.0)		2(10.0)	5(16.1)		2(10.5)	5(15.6)	

Fisher's exact test at 5% level.
Source: Research data, 2022.

In Table 3, it can be seen that being male increases the chances of suffering from an immunization error against COVID-19 by 9.818 times (CI=0.925-104.166) compared to being female. It can also be observed that older adults aged less than 70 years are 8.800 times more likely to suffer ESAVI related to the respiratory system when compared to elderly aged 70 years or older (CI=1.010-76.708).

When performing the crossing between events in the Respiratory and Digestive Systems and Fever in older adults vaccinated against COVID-19 with the categorical variables of the study, it was observed that the ESAVI with manifestation in the respiratory system were more frequent among adults aged <70 years. Furthermore, there was a statistically significant association between this type of ESAVI and age group (p=0.024) (Table 4).

Table 3. Chance analysis (OR) between sex, age group and immunization error in older adults vaccinated against COVID-19 notified in the Municipal Health Foundation (MHF) system, in the city of Teresina-PI-2022. (n=51).

	B	P-value	OR(CI-95%)
		Immunization Error	
Sex			
Feminine	B	-	-
Masculine	2.284	0.058	9.818(0.925-104.166)
		Respiratory System	
	B	P- value	OR(CI-95%)
Age Range			
<70 years	2.175	0.049	8.800(1.010-76.708)
≥70 years	B	-	-

Binary logistic regression, at 5% level.
Source: Research data, 2022.

Table 4. Association between Respiratory, Digestive, Fever ESAVI and the social profile of older adults vaccinated against COVID-19 notified in the Municipal Health Foundation (MHF) system, in the municipality of Teresina-PI-2022. (n=51).

	Respiratory System			Digestive System			Fever		
	No	Yes	p-value	No	Yes	p-value	No	Yes	p-value
	N(%)	N(%)		N(%)	N(%)		N(%)	N(%)	
Age Range			**0,024**			0.229			0.785
<70 years	20(47.6)	8(88.9)		19(50.0)	9(69.2)		1(53.8)	7(58.3)	
≥70 years	22(52.4)	1(11.1)		19(50.0)	4(30.8)		18(46.2)	5(41.7)	
Race			0,569			0.173			0.820
White	5(11.9)	0(0.0)		3(7.9)	2(15.4)		4(10.3)	1(8.3)	
Black	1(2.4)	0(0.0)		0(0.0)	1(7.7)		1(2.6)	0(0.0)	
Brown	10(16.7)	3(33.3)		6(15.8)	4(30.8)		7(17.9)	3(25.0)	
Yellow	3(4.8)	1(11.1)		3(7.9)	0(0.0)		1(7.7)	0(0.0)	
Ignored	28(64.3)	5(55.6)		26(68.4)	6(46.2)		18(61.5)	8(66.7)	
Sex			0,663			0.682			0.338
Feminine	36(73.8)	6(66.7)		27(71.1)	10(76.9)		24(69.2)	10(83.3)	
Masculine	11(26.2)	3(33.3)		11(28.9)	3(23.1)		7(30.8)	2(16.7)	
Healthcare professional			0,802			0.464			0.535
No	40(85.7)	8(88.9)		32(84.2)	12(92.3)		26(84.6)	11(91.7)	
Yes	7(14.3)	1(11.1)		6(15.8)	1(7.7)		5(15.4)	1(8.3)	

Fisher's exact test at 5% level.
Fonte: Research data, 2022.

DISCUSSION

Vaccination is considered one of the great achievements of humanity and despite being carried out with the aim of producing beneficial outcomes for the body, adverse events can occur. In the COVID-19 pandemic scenario, due to the approval of immunizers on an emergency basis, the Epidemiological and Sanitary Surveillance Protocol for Events Supposedly Attributable to Vaccination or Immunization (ESAVI) was established, which is intended for the detection, notification, investigation, and classification of such events.[9,10-11]

Considering this context, it should be emphasized that older adults are at greater risk of developing severe forms of COVID-19, due to the natural decline in the effectiveness of the immune system.[12,13] Thus, older adults, in general, are more vulnerable to the acquisition of infectious and contagious diseases, in addition to more commonly having unfavorable prognoses when compared to individuals of other age groups.[14,15]

In the present study, the factors associated with Events Supposedly Attributable to Vaccination or Immunization (ESAVI) for SARS-CoV-2 among older adults in Teresina-PI were analyzed. The participants' profile was: older adults, with a mean age of 73.33 years, mostly female and who not being health professionals. These data corroborate the profile identified in a study,[15] which brought the evaluation of adverse effects in patients who received up to two doses of the vaccine produced by AstraZeneca, whose profile of identified older adults was mostly made up of female participants, aged equal to or greater than 70 years.

It is important to reflect that this indicator of higher occurrence of ESAVI among women may be related to sociocultural issues, in which this group seeks more health services, whether for preventive or curative actions, compared to the male sex, not being different in the elderly population.[16,17]

As for the distribution of those vaccinated according to the type of immunobiological administered, it was observed that most of the older adults received, in the 1st dose, the immunobiological produced by AstraZeneca. This finding is justified because in Teresina, capital of Piauí, the vaccination campaign against COVID-19 in the older adults began with the administration of the immunobiological produced by AstraZeneca in drive-thrus.[18,19]

The participants in the present study had, approximately, the average of three ESAVI against COVID-19, most of which were classified as not severe. In line with the data from this research, studies indicate that most of the adverse effects related to vaccination against COVID-19 were of mild to moderate severity, being less prevalent after the booster dose of the vaccine.[16,20]

In a study developed[21] with the objective of understanding the adverse effects related to the immunobiological congener in Brazil, a higher prevalence of not severe events was also demonstrated (84.7%), among which 64.3% were local repercussions and 27.6%, systemic manifestations.

Important data evidenced in the literature refers to the inverse relationship between the age of the one vaccinated and the immunobiological reactogenicity, that is, the capacity of the immunizer to cause local or systemic side effects in the organism of the individual who received the vaccine is lower the greater their age. This information reaffirms the safety of administering immunizers in the elderly population.[16,22]

In the present study, serious events resulted in hospitalization, deaths, and permanent disability, but there was no statistically significant association between these outcomes and sociodemographic variables. Regarding this aspect, data that deserves to be highlighted concerns the use of medications before and/or after vaccination, a practice not recommended by the NIP, since, depending on the drug used, it can contribute to the reduction of the effectiveness of the immunobiological, as well as to the development of complications that may be confused and/or attributed to vaccines.[23]

Similar data were observed in research,[24] where 3.0% of the studied population had serious adverse reactions after vaccination with AstraZeneca or Coronavac immunizers, among which 4.71% evolved to death, being more frequent in people with 65 years of age and older, living in long-term care facilities and having comorbidities such as Diabetes Mellitus, cancer, heart disease, among others.

Regarding the characterization of ESAVI, in this study, those related to the musculoskeletal system were observed more frequently, followed by headache and neurological system, in addition to the digestive system. In another study,[16] local and systemic reactions were also described in the first 48 hours after vaccination, among which pain/sensitivity at the injection site, fatigue, headache, and myalgia stood out. Regarding these data, it should be noted that local events are expected repercussions for most immunological agents administered in the population, according to the NIP.[23]

In the present study, a significant association was observed between the manifestation of events in the respiratory system and age below 70 years, and these older adults are 8,800 times more likely to manifest events related to the respiratory system when compared to older adults aged equal to or greater than 70 years. However, the literature consulted has shown a directly proportional relationship between increasing age and the risk of developing complications or progression of respiratory tract diseases, and such manifestations are related to ESAVI.[24,25,26]

As for immunization errors (IE), data from the present study showed a prevalence of 3.3%. The study[24] showed that 1.11% of the adverse effects related to the vaccine corresponded to immunization errors, among which 27.2% occurred due to immunization extravasation during administration, followed by vaccination of pregnant women (18.5%), application of different products (13.6%), administration in public outside the priority group (11.1%), inadequate interval between doses (11.1%), administration in symptomatic patients (6.2%) and inadequate dosing (6.2%).

Immunization errors or vaccine errors are considered adverse events that occur as a result of inadequacies in production, handling, prescription and/or administration processes. It should be brought to this discussion that such failures are avoidable when there is the correct training of the professionals involved in immunization, as well as when adequate supplies and equipment are provided for the administration of vaccines, in addition to the correct supervision of the procedures.[13,20]

Still on this topic, the possible contribution of the emergency nature of immunization on the incidence of vaccine errors should be addressed. Especially at the beginning of the campaign to combat COVID-19, when there was a need for mass vaccination and which, associated with the atypical conditions of the workplace (often improvised), can justify the existence of failures in the process of immunization of the population. In this way, the responsibility of health management is reinforced to support the correct preparation of teams destined for routine vaccination campaigns and in emergency situations, as occurred in the COVID-19 pandemic.[13,20]

In this study, a statistically significant association was also observed between male gender and immunization error, and this population was 9.818 times more likely to suffer IE against COVID-19. Regarding this data, specifically, it is necessary to emphasize that the statistical analysis of association does not necessarily determine a cause-and-effect relationship, with the gender of the participants being a marker of low sensitivity to determine the occurrence of IE, as well as the prediction of these events.

Thus, the relevance of the present study becomes evident, as it demonstrates the safety of the vaccines studied in the elderly population, where, in most cases, mild and moderate repercussions related to vaccination were observed. In addition, the data obtained here can serve as a subsidy for the development of proposals to encourage and incentivize adherence to immunization.

CONCLUSION AND IMPLICATIONS FOR PRACTICE

Fifty-one older adults participated, with a mean age of 73.33 years, predominantly female, not being a health professional and who, for the most part, were vaccinated with the immunobiological produced by AstraZeneca in the 1st dose.

There was a prevalence of not severe ESAVI in older adults over 70 years. However, there were occurrences of severe events, mainly hospitalizations, permanent disability, and deaths. The most frequent ESAVI were related to the musculoskeletal system, followed by headache, and related to the neurological system, in addition to the digestive system.

Immunization errors were more common among elderly males. In addition, there was a statistically significant association between ESAVI related to the respiratory system and age group (under 70 years of age).

Despite ESAVI being evidenced in this study in the older adults, it is noteworthy that these are within the expected for their occurrence, with their behavior being not severe and of low risk for the elderly population, ensuring the overlap of benefits with risks.

This study presents as a limitation the obtaining of data from a secondary bank, given that the collection of information was restricted to those contained in the system, and there may be inconsistencies and non-standardization in the filling out due to the use by different professionals. Thus, the importance of correctly completing the ESAVI notification forms is evident, as well as monitoring these events associated with vaccination against COVID-19, especially regarding the older adults, with a view to better understanding the mechanisms of action of these immunizers and greater scientific clarification on the repercussions that these immunobiologicals can have on the body. Furthermore, the development of studies with a similar perspective is suggested, which will allow to continue investigating the existence of an association between the variables proposed in this analysis.

AUTHOR'S CONTRIBUTIONS

Study design. Samuel Lopes dos Santos.

Collection or production of data. Samuel Lopes dos Santos.

Data analysis. Samuel Lopes dos Santos.

Interpretation of results. Samuel Lopes dos Santos.

Writing and critical review of the manuscript. Samuel Lopes dos Santos.

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