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EVENTS SUPPOSEDLY ATTRIBUTABLE TO COVID-19 VACCINATION IN BRAZIL – SCOPING REVIEW

Eventos supostamente atribuíveis a vacinação ou imunização contra a covid-19 no brasil – revisão de escopo

Eventos supuestamente atribuibles a la vacunación o inmunización contra covid-19 en Brasil – revisión del alcance

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RESUMO

Objetivo: identificar na literatura científica, os tipos de eventos supostamente atribuíveis e seus fatores associados e relacionados à vacinação contra Covid-19 em adultos e idosos no Brasil. **Método**: revisão de escopo, realizada de junho a agosto de 2023; foram selecionados estudos primários, disponíveis na íntegra, publicados de janeiro de 2021 a agosto de 2023, em português, inglês ou espanhol, nas seguintes bases de dados: Embase, Pubmed, Scopus e BVS. **Resultados**: 14 artigos compuseram a amostra final; foi evidenciado que é frequente a ocorrência de eventos supostamente atribuíveis a vacinação ou imunização, majoritariamente, os eventos adversos não graves, todavia, eventos adversos graves também foram relatados, como trombose do sistema nervoso central, convulsões, dispnéia, paralisias faciais e óbitos. **Conclusões**: a predominância dos casos relatados nos estudos foram relacionados ao imunizante da Oxford-AstraZeneca e ocorreram principalmente em mulheres, na faixa etária de 30 a 50 anos.

DESCRITORES: Reação no local da injeção; Adulto; Idoso; Vacinas contra COVID-19.

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ABSTRACT

Objective: to identify in the scientific literature the types of events and their factors associated with and related to Covid-19 vaccination in adults and the elderly in Brazil. **Method:** scoping review carried out from June to August 2023; primary studies were selected, available in full, published from January 2021 to August 2023, in Portuguese, English or Spanish, in the following databases: Embase, PubMed, Scopus and VHL. **Results:** 14 articles made up the final sample; it was demonstrated that the occurrence of events attributed to vaccination or immunization is frequent, mostly non-serious adverse events, but serious adverse events were also reported, such as central nervous system thrombosis, convulsions, dyspnea, facial paralysis and death. **Conclusions:** Most cases reported in the studies were associated with the Oxford-AstraZeneca vaccine and occurred mainly in women aged 30 to 50 years.

DESCRIPTORS: Injection site reaction; Adult; Aged; COVID-19 vaccines.

RESUMEN

Objetivo: identificar en la literatura científica los tipos de eventos supuestamente atribuibles y sus factores asociados y relacionados con la vacunación contra Covid-19 en adultos y ancianos en Brasil. **Método:** revisión del alcance, realizada de junio a agosto de 2023; Se seleccionaron estudios primarios, disponibles íntegramente, publicados de enero de 2021 a agosto de 2023, en portugués, inglés o español, en las siguientes bases de datos: Embase, Pubmed, Scopus y VHL. **Resultados:** 14 artículos constituyeron la muestra final; Se demostró que la ocurrencia de eventos supuestamente atribuibles a la vacunación o inmunización es frecuente, en su mayoría eventos adversos no graves, sin embargo, también se han reportado eventos adversos graves, como trombosis del sistema nervioso central, convulsiones, disnea, parálisis facial y fallecidos. **Conclusiones:** el predominio de los casos reportados en los estudios estuvo relacionado con la vacuna Oxford-AstraZeneca y ocurrió principalmente en mujeres, con edades de 30 a 50 años.

DESCRIPTORES: Reacción en el punto de inyección; Adulto; Anciano; Vacunas contra la COVID-19.

INTRODUCTION

The new coronavirus identified at the end of 2019, called SARS-CoV-2, was the causative agent of a series of pneumonia cases in the city of Wuhan, located in the province of Hubei (China). With high transmissibility, it spread to several countries, where the number of cases increased; it is now recognized as a pandemic, considered one of the most impactful events in modern history.[1]

Faced with the public health emergency caused by SARS-CoV-2, many countries have joined in a global effort to prevent the transmission of the new coronavirus, among which we can highlight the guarantee of global access to vaccines against COVID-19.[2]

In Brazil, the vaccination campaign against COVID-19 started on January 18, 2021, however, the country has a very important history of vaccination adherence, but, in recent years this adherence has been negatively influenced by several factors, among the main ones we can highlight social, cultural, religious and economic issues.[3]

Vaccines are considered to be one of the safest medicines, capable of providing several benefits, but like any other medicine, they are not risk-free, even though they are subject to demanding processes.[4]

Events supposedly attributable to vaccination or immunization (ESAVI) are classified as any adverse clinical event in individuals who have taken an immunobiological, they can be systemic or local, they are also classified according to intensity: NSAE (not serious adverse events) and SAE (serious adverse events). Among the mild cases, it is possible to highlight fever, pain and local edema, or even events considered more serious, such as hypotensive episodes, febrile convulsions and anaphylaxis.[5]

In the context of vaccines against the SARS-CoV-2 virus, ESAVI surveillance is characterized by the novelty of the vaccines used, the public's fear of safety, and the commotion caused by the scale of the pandemic.[6]

In 2022, the terminology "Adverse Events Following Vaccination (AEFI)" was updated to "Events supposedly attributable to vaccination or immunization (ESAVI)" through Technical Note No. 255/2022.[7]

The present study aims to identify in the scientific literature the types of events supposedly attributable and their factors associated with and related to Covid-19 vaccination in adults and elderly in Brazil.

METHOD

This is a scoping review, the aim of which is to provide a broad overview of the most important scientific evidence on the topic and to identify the gaps in existing studies.[8] The review was based on the protocol proposed by the Joanna Briggs

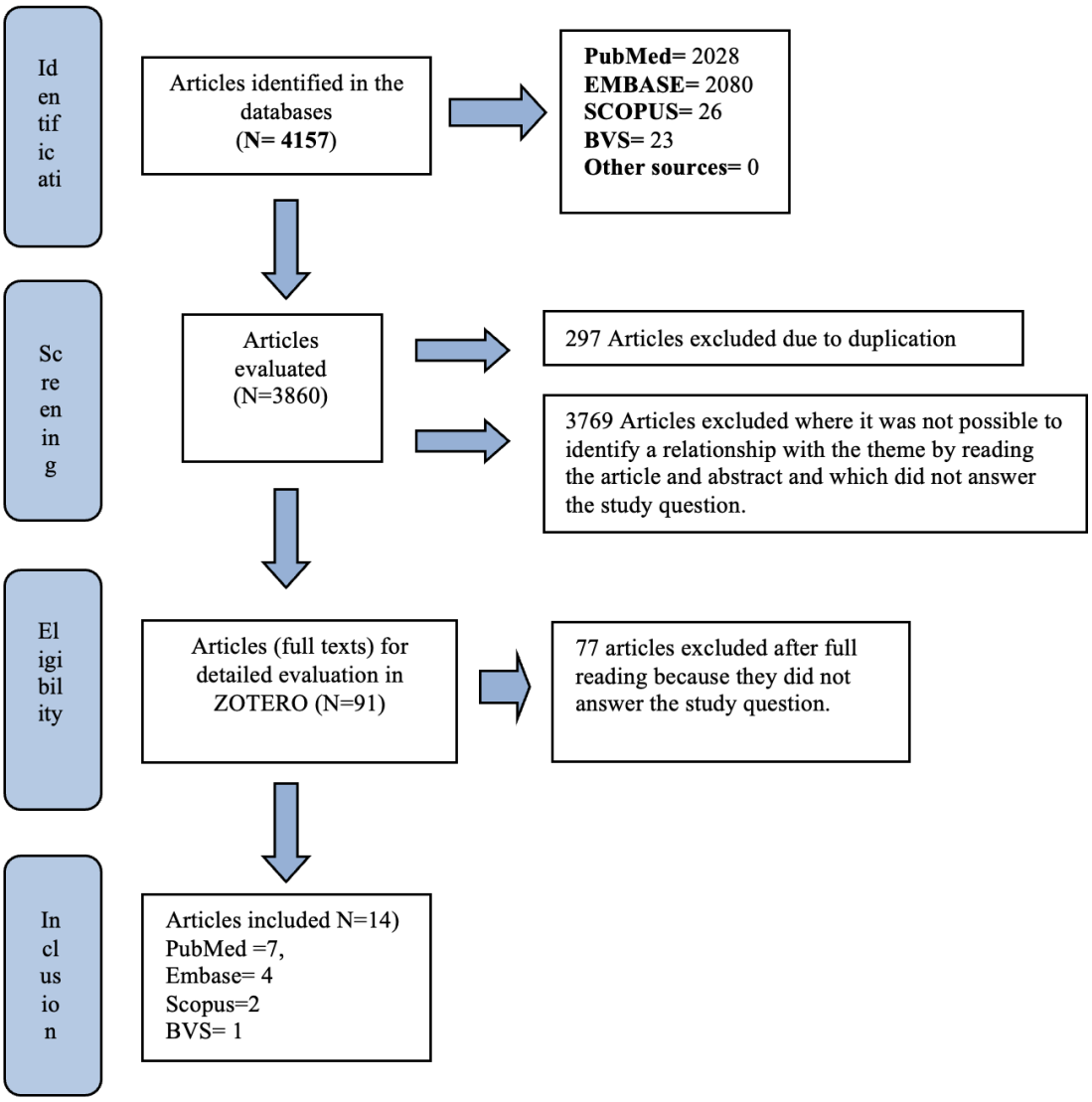
Institute[9] using the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR).[8] The study followed the following steps: 1) identification of the research question; 2) mapping of knowledge production; 3) selection of knowledge production; 4) data analysis; 5) data synthesis and presentation (JBI, 2020). The PCC strategy (P - population, C - concept and C - context) was used to prepare the research question; P (adults and elderly immunized with Covid-19 vaccines), C (adverse events AEFI/ESAVI), C (Brazil); Defined as: What is the literature evidence on adverse events after Covid-19 vaccination in adults and elderly in Brazil?

To search the databases, the controlled terms "Injection Site Reaction; Adult; Elderly; COVID-19 vaccine; Brazil" and its correlates, in Portuguese and English, from the Medical Subject Headings (MeSH) and Health Sciences Descriptors (DECS) were used, soon after the crosses were made with the selected terms using the Boolean operators "OR" and "AND".

The following databases were searched National Library of Medicine (PubMed), SCOPUS (Elsevier), VHL (Virtual Health Library) and Embase, from June to August 2023.

The inclusion criteria for the selection of articles were: a) articles published from January 2021 to August 2023, in line with the start of Covid-19 immunization in the Brazilian territory; b) articles available in full text, in Portuguese and English, that addressed the proposed topic; The exclusion criteria were: a) studies published outside the delimited period; b) publications that did not address the proposed topic; c) grey literature d) articles that addressed ESAVI in children, adolescents and pregnant women.

Figure 1 – Prism flowchart of the selection process of studies included in the scoping review, Recife (PE), Brazil, 2023[10]



The search strategy allowed the retrieval of 4157 articles in the databases, all titles/abstracts of the references retrieved during the search were read and analyzed individually, 3769 references were excluded after reading the title/abstract because they did not meet the proposed criteria; the studies selected for full-text reading were exported to ZOTERO 6.0 software, then duplicates were excluded (n=297) and after reading, articles that did not meet the established criteria were also removed.

In the end, 91 fully read articles remained, but 77 were excluded after full reading because they did not answer the study question. The final sample of this study consisted of 14 articles and data analysis was performed independently.

To analyze the studies found, four tables were prepared in which the key information of the studies was summarized, interpreted and compared to describe the information and evidence that answered the research question.

The protocol of this review has been registered in the Open Science Framework (OSF) under the DOI: 10.17605/OSF.IO/WN5X8

RESULTS

The results of the selected studies are presented in Chart 1, classified by author/year of publication, title, sample, method and results, published between the years 2021 (N=3), 2022 (N=10) and 2023 (N=1), all from Brazil. Of the 14 included studies, 9 were case reports, 3 were descriptive studies, and 1 was an ecological study.

Chart 1 – Articles found in the databases, Recife (PE), Brazil, 2023

Author/Year	Title	Sample	Method	Results
Cantarelli Rodrigues, T. *et al* 2021[11]	Bursite subacromial-subdeltoidea após vacinação contra COVID-19: um caso de lesão no ombro relacionada à administração de vacina (SIRVA) [Subacromial-subdeltoid bursitis after COVID-19 vaccination: a case of vaccine-induced shoulder radiculopathy (SIRVA)]	Woman presenting excruciating pain and tenderness at the right shoulder injection site 30 minutes after receiving her first dose of COVID-19 vaccine (AstraZeneca).	Case Report	Post-vaccination shoulder pain due to inadvertent administration of vaccine above the recommended dose, with no history of chronic pain or inflammatory disease in the affected shoulder, combined with consistent findings of local immune response.
Viana, J. A. *et al.* 2021[12]	Linfadenopatia após vacina para COVID-19: primeiro relato no Brasil [Lymphadenopathy after COVID-19 vaccination: first report in Brazil]	A 50-year-old man with a history of neurological deficit presented with fever, axillary discomfort in the right upper extremity, and convulsion 24 hours after receiving the Pfizer-BioNTech COVID-19 vaccine in the right arm.	Case Report	He underwent computed tomography of the chest, which showed densification of axillary fat associated with lymph node enlargement.

Author/Year	Title	Sample	Method	Results
Silva, R. B. da. *et al* 2021[13]	Eventos adversos pós-vacinação contra o SARS-CoV-2 (Covid-19) no estado de Minas Gerais. [Adverse events after SARS-CoV-2 (Covid-19) vaccination in the state of Minas Gerais]	All suspected cases of adverse events after COVID-19 vaccination in the state were analyzed, A total of 7,305 cases.	Descriptive study using data from e-SUS Notifica in the State of Minas Gerais during the period from January 20 to March 5, 2021.	Of the 7,305 adverse events reported after vaccination, 3% were considered serious, with an incidence rate of 20.85 per 100,000 doses administered, and 4.71% of serious adverse events resulted in death (incidence rate: 8.19 deaths per 100,000 doses administered). Of the deaths analyzed, most (84.4%) were classified as being caused by pre-existing conditions or other factors and not by the vaccines, demonstrating that none of the deaths have been causally related to the anti-Covid-19 vaccines to date. Regarding non-serious adverse events, 1.11% were due to immunization errors (IE), (TI: 8.62 IE per 100 thousand doses administered)
de Oliveira PMN. *et al.* 2022[14]	Trombocitopenia trombótica imune induzida por vacina (VITT) após vacinação contra COVID-19: Descrição de uma série de 39 casos no Brasil [Vaccine-induced immune thrombotic thrombocytopenia (VITT) after COVID-19 vaccination: Description of a Series of 39 Cases in Brazil]	39 suspected cases of VITT	Descriptive study using data from Bio-Manguinhos/ Fiocruz/ AstraZeneca and the National Immunization Program/ (PNI/MS) on AEFI surveillance of COVID-19.	Of the 39 cases included, most occurred after the first dose of vaccine (n = 34; 87.2%). 20 died; of the 39 patients, 17 (43.6%) had previous risk factors for thrombosis, 12 (30.8%) had no risk factors, and 10 (25.6%) had no information available.
Martins-Filho, Paulo Ricardo *et al.* 2022[15]	Vigilância de eventos adversos associados a 145 mil doses de vacinas contra a COVID-19 em um município brasileiro [Surveillance of adverse events associated with 145 thousand doses of COVID-19 vaccine in a Brazilian municipality]	Adverse events after vaccination (AEFI) associated with the first 145 thousand doses of COVID-19 vaccine administered in the municipality of Aracaju/SE	Observational, descriptive and retrospective study.	474 post-vaccination adverse events were reported and analyzed, all of which were considered non-serious. There was an association between Coronavac vaccine use and headache, injection site pain, lethargy, fatigue, diarrhea, and flu-like symptoms. However, the proportion of individuals reporting fever was higher among those who received the AstraZeneca vaccine.

Author/Year	Title	Sample	Method	Results
Tavares-Júnior JWL *et al. 2022* [16]	Mielorradiculoneuropatia aguda associada à vacina 2019 Responsiva à plasmaférese [Acute 2019 vaccine-associated myeloradiculoneuropathy responsive to plasmapheresis]	31-year-old patient	Case report	A 31-year-old male patient presented with acute tetraparesis and urinary retention one day after the first dose of the vaccine. Electromyography revealed motor-sensory asymmetry and axonal polyneuropathy. Cervical magnetic resonance imaging revealed longitudinally extensive transverse cervical myelitis. He returned to walk after 60 days with mild hypoesthesia of the left foot and mild urinary retention. The incidence of adverse events was 60%, the most common of which were local swelling/pain, fatigue/numbness, fever, headache, and arthralgia.
Ballestero M *et al.* 2022 [17]	Post-vaccination incidence and side effects of COVID-19 in a cohort of Brazilian healthcare professionals: an internet-based survey	6,115 Brazilian healthcare workers	Observational descriptive study.	The incidence of adverse events was 60%, the most common of which were local swelling/pain, fatigue/ numbness, fever, headache, and pain in the extremities.
Fritzen, M. *et al.* 2022[18]	Leukocytoclastic vasculitis after exposure to COVID-19 vaccine	A 60-year-old female patient with a history of chronic liver disease, portal hypertension, polycythemia vera, hypothyroidism and type 2 diabetes mellitus	Case Report	Painful purpuric lesions and palpable papules on the lower extremities for three days. She reported receiving the second dose of COVID-19 vaccine (AstraZeneca) approximately eleven days earlier.
Ortigosa LCM *et al.* 2022[19]	Hypersensitivity reaction to hyaluronic acid dermal filler after COVID-19 vaccination: A series of cases in São Paulo, Brazil	A series of 5 cases in which patients developed a delayed hypersensitivity reaction in the area of previous hyaluronic acid (HA) application shortly after Covid 19 vaccination	Case Report	All these case reports demonstrated a delayed hypersensitivity reaction to HA dermal filler more than 24 hours after COVID-19 vaccination.
Zamoner W *et al.* 2022 [20]	ANCA-associated vasculitis following Oxford-AstraZeneca COVID-19 vaccine in Brazil: Is there a causal relationship? A case report	58-year-old patient.	Case Report	Rapidly progressive glomerulonephritis 5 days after AstraZeneca vaccination.

Author/Year	Title	Sample	Method	Results
Eyer-Silva W de A *et al.* 2022 [21]	Facial Angioedema after the first dose of Covishield: follow-up after the second and third booster doses	63-year-old patient with no history of allergy or hypersensitivity to drugs or vaccines. She was on regular antihypertensive medication and had no other significant medical history.	Case Report	9 hours after vaccination, he first noticed the appearance of bilateral angioedema of the conjunctiva and face, accompanied by local pruritus and burning sensation.
Tomishige KS, *et al.* 2022 [22]	Multiple evanescent white dot syndrome (MEWDS) following inactivated COVID-19 vaccination (Sinovac-Coronavac)	38-year-old female patient	Case Report	Photopsias and painless loss of vision in her right eye 2 weeks after receiving the first dose of inactivated virus vaccine for COVID-19 (Sinovac).
Clemens, S.A.C, *et al.* 2022 [23]	Safety of the Fiocruz ChAdOx COVID-19 vaccine used in a mass vaccination campaign in Botucatu, Brazil	All citizens between the ages of 18 and 60 were eligible to participate in the campaign, regardless of underlying medical conditions.	Ecological study	A slight increase in emergency department visits was likely related to typical vaccine events such as local pain or myalgia.
Tavares-Júnior JWL, *et al.* 2023 [24]	Cogan's sign in a patient with suspected post-COVID-19 vaccine-associated myasthenia gravis	68-year-old patient	Case Report	Proximal limb weakness, left eyelid ptosis, and diplopia 1 month after receiving the fourth dose of COVID-19 vaccine.

DISCUSSION

In Chart 2, the case reports were classified according to the immunizer administered, the dose used, the adverse event, and the time of onset after vaccine administration; they were also classified according to risk factors, pre-existing conditions, and outcome.

Chart 2 - Characteristics of immunizers and events presented in case reports, Recife (PE), Brazil, 2023

Article	Immunizer	Dose	Time of symptom onset	Adverse event	Preexisting conditions/ risk factors	Outcome
Cantarelli Rodrigues, T. *et al* 2021 [11]	AstraZeneca	1st dose	30 minutes	- Sharp pain - Sensitivity - Edema	The injection was administered at the level of two fingers from the lateral border of the acromion, which was considered above the recommendation. Patient with chronic lymphocytic thyroiditis treated with levothyroxine sodium for 21 years.	Prednisone treatment, vitamin D supplementation, and physical therapy Active range of motion reduction and ongoing shoulder pain that has lasted for 8 weeks. Confirmed diagnosis of S.I.R.V. A (shoulder injury due to vaccination)
Viana, J. A. *et al.* 2021 [12]	Pfizer	Not informed	24 hours	- Fever - Axillary discomfort - Convulsion	Previous neurological deficit	Densification of axillary fat associated with lymph node enlargement.

Article	Immunizer	Dose	Time of symptom onset	Adverse event	Preexisting conditions/ risk factors	Outcome
Tavares-Júnior JWL *et al. 2022* [16]	Not Informed	Ist dose	24 hours	- Tetraparesis - Urinary retention	Not Informed	Electromyography revealed a motor-sensory asymmetry axonal polyneuropathy. Cervical magnetic resonance imaging revealed longitudinally extensive transverse cervical myelitis. He returned to walk without help after 60 days.
Fritzen, M. *et al.* 2022 [18]	AstraZeneca	2nd dose	72 hours	- Painful purpuric petechiae in the lower limbs (Leukocytoclastic Vasculitis)	Chronic liver disease Portal hypertension Polycythemia vera Hypothyroidism Diabetes mellitus 2	After three days of hospitalization, the lesions in the lower limbs and painful symptoms improved.
Ortigosa LCM *et al.* 2022 [19]	Case 1 - AstraZeneca Case 2 - Pfizer Case 3 - Pfizer Case 4 - Pfizer Case 5 - AstraZeneca	Case 1 - Ist dose Case 2 - 2nd dose Case 3 - 3rd dose Case 4 - Not informed Case 5 - 2nd dose	**Case 1** – 24 hours **Case 2** – 4 weeks **Case 3** – 24 hours **Case 4** – 1st event immediately/ 2nd event 48 hours **Case 5** – 1 week	Case 1 - Lip and chin edema Case 2 - Edema of the lower eyelids Case 3 - Pain and lip edema Case 4 - Herpes simplex virus lesions immediately after vaccination; jaw edema Case 5 - Edema, erythema, increased lip temperature, fever, malaise and purpuric petechiae on the extremities.	All 5 cases were after hyaluronic acid application Case 4 - carrier of herpes simplex virus.	**Case 1**: Lip edema, which remained for 4 months after vaccination **Case 2**: Edema in the lower eyelids with resolution within 7 days. **Case 3**: Lip edema with resolution after 72 h **Case 4**: Resolution after 5 days **Case 5**: Resolution in 3 weeks
Zamoner W *et al.* 2022 [20]	AstraZeneca	Ist dose	48 hours	- Myalgia - Pain at the site of application - Fatigue - Paleness - Arthralgia in hands, knees and ankles - Foamy urine (hematuria, proteinuria) - High blood pressure - Anemia	Hyperthyroidism	Crescent glomerulonephritis with glomerular sclerosis, fibrous crescents, interstitial fibrosis, and tubular atrophy.
Eyer-Silva W de A *et al.* 2022 [21]	AstraZeneca	Ist dose	9 hours	- Bilateral conjunctival and facial angioedema - Pruritus - Paresthesia	Hypertension	Complete remission within a few hours after medical attention
Tomishige KS, *et al.* 2022 [22]	Coronavac	Ist dose	7 days	Evanescent multiple white spot syndrome	Not informed	The patient was treated with corticosteroids and progressed with improvement in visual acuity and clinical condition. Visual acuity returned to normal standards
Tavares-Júnior JWL, *et al.* 2023 [24]	AstraZeneca	4th dose	1 month	- Asthenia - Left ptosis - Diplopia - Myasthenia gravis	Not informed	Neurological examination revealed Cogan's sign. After improvement, the patient was followed up on an outpatient basis

The AstraZeneca vaccine was present in 6 of the 9 reports, followed by Pfizer and Coronavac; the events occurred mostly after the 1st dose, but ESAVI was also reported after the 2nd and 4th doses, both related to the AstraZeneca vaccine, with an average onset of 48 hours after application and can last from 2 weeks to 1 month.

The prevalence of cases was in female patients (77.78%), with ages ranging from 34 to 68 years; no deaths were reported and most signs and symptoms resolved between 7 days and 2 weeks, (88.9%) refer to single cases of ESAVI and only one (11.1%) registers a series of 5 cases of the same event.[19]

The studies were conducted in the following states: São Paulo (n=5)[11-12,19-20,22], Ceará (n=2),[16,24] Rio de Janeiro (n=1)[21] and Santa Catarina (n=1);[18] published in 2021 (n=2),[11-12], 2022 (n=6),[16,18-19,20-22] and 2023 (n=1);[24] 6 came from the southeastern region of Brazil (66. 67%),[11-12,19-20-22], 2 from the Northeast region (22.22%)[16,24] and 1 from the South region (11.1%).[18]

The most common ESAVIs reported in the studies are classified as NSAE: Edema, application site pain, fever, fatigue, petechiae, pallor, myalgia, diplopia, asthenia, arthralgia, pruritus and paresthesia, hematuria, and proteinuria; Other ESAVIs have also been reported on a smaller scale, such as the appearance of herpes virus lesions of immediate onset after immunizer administration (n=1),[19] edema in various parts of the face after prior application of hyaluronic acid (n=5),[19] evanescent multiple white spot syndrome (n=1),[22] and myasthenia gravis (n=1).[24]

Pre-existing conditions that may be related to the occurrence of these events were observed, such as the presence of arterial hypertension, portal hypertension, diabetes mellitus, hyperthyroidism/hypothyroidism, chronic liver disease, polycythemia vera, and lymphocytic thyroiditis.[11,19-21]

Two studies were from the Southeast region,[13,23] one from the Northeast region[15] and the remaining two used data from patients from different regions of Brazil.[14,17] ESAVI reports were collected from the E-SUS Notifica databases, NIP/MS/Bio-Manguinhos/Fiocruz pharmacovigilance databases and were collected using a specific form. AstraZeneca was the vaccine manufacturer with the highest incidence of ESAVI reports, followed by Coronavac, Pfizer, Janssen, Sputnik and Moderna. In the five studies, most patients were female, aged between 18 and 86 years; symptoms mostly began after the first dose, but also occurred after subsequent doses, with averages of three, six and eight days after administration.

The data presented in Chart 3 were classified by sample, age, sex, state and region; the descriptive, observational and ecological studies on the subject were distinguished by a comprehensive analysis of the secondary data of the information systems available in Brazil, where it was possible to analyze the occurrence of ESAVI in large population samples.

The studies were carried out in the states of Minas Gerais,[13] Sergipe[15] and São Paulo,[23] and the locations of the other two studies were not specified.

Chart 3 – Distribution of sociodemographic characteristics of descriptive, observational, and ecological studies by sample, age, sex, state, and region, Recife (PE), Brazil, 2023

Article	Sample	Age	Sex	State	Region
Silva, R. B. da. *et al.* 2021[13]	7,305 cases for 940,013 doses administered	**13 to 17:** 4 **18 to 35:** 3.182 **36 to 49:** 2.736 **50 to 64:** 969 ≥ 65: 398 **N.I:** 16	**Male** 1.204 **Female** 6.101	Minas Gerais	Southeast
de Oliveira PMN. *et al.* 2022[14]	39 cases	23 – 86	**Male** 15 **Female** 24	No information	No information
Martins-Filho, Paulo Ricardo *et al.* 2022[15]	474 cases representing 145,133 doses administered	No information	No information	Sergipe	Northeast

Article	Sample	Age	Sex	State	Region
Ballestero M *et al.* 2022 [17]	6.115 Cases	**20-29** (1.371) **30-39** (1.916) **40-49** (1.300) **50-59** (892) **60-69** (514) **70-79** (115) **>80** (N: 7)	**Male** 1.992 **Female** 4.117 **Other** 378	Federal District/ No information on other states	**Midwest** 259 **Federal District** 255 **North** 204 **Northeast** 918
Clemens, S.A.C, *et al.* 2022[23]	20,769 cases out of 77,683 doses administered in the 1st and 74,051 doses administered in the 2nd year.	18-60	**Male** **Female** *No information on total number by sex	São Paulo	Southeast

Subtitle: N.I = Not Informed

In Chart 4, the descriptive, observational, and ecological studies are classified by immunizer, sample, onset and type of adverse event, presence of pre-existing conditions/risk factors, and occurrence of death; the majority of ESAVI reports were NSAE, but some occurrences of SAEs, including deaths, were reported; among the events considered non-serious, there was a predominance of symptoms: Headache, edema/pain at the site of application, myalgia, fever, fatigue, nausea/vomiting, diarrhea, and pain in the limbs; Other serious symptoms have also been reported, but in smaller numbers, including altered level of consciousness,[14] dyspnea,[14] convulsions,[14] visual changes,[14] facial paralysis,[17] anosmia,[17] herpes zoster,[17] myelitis/Guillain barre,[17] lymphadenopathy,[15] Bell's palsy,[23] deep vein thrombosis,[23] pericarditis[23] and demyelinating disorders.[23]

Chart 4 – Distribution of ESAVI cases in descriptive, observational, and ecological studies by immunizer, sample, onset of event after administration, type of event, pre-existing conditions/risk factors, and occurrence of death, Recife (PE), Brazil, 2023

Article	Immunizer	Sample	Time of symptom onset	Adverse event	Occurrence of death	Pre-existing conditions/ Risk factors
Silva, R. B. da. *et al* 2021[13]	**Coronavac** 2.250 **AstraZeneca** 5.055	**1st Dose:** 633.032 **2nd Dose:** 306.981 **Total:** 940.013	Average of 6 days	**1° - NSAE** 7.109 (97%) **AstraZeneca:** 5.005 (70%) **Coronavac:** 2.104 (30%) Of the 7.109 NSAE, 81 (1,11%) Were E.I **2° - SAE** 196 (3%) **AstraZeneca:** 50 (26%) **Coronavac:** 146 (74%)	Of the 77 reported deaths, 89.6% were in persons aged 65 years or older and 57.1% were female. The onset of symptoms occurred eight days after vaccine administration, and 84.4% were classified as pre-existing conditions caused by factors other than the vaccine.	Most of the deaths occurred in residents of long-term care facilities for the elderly and with comorbidities.

Article	Immunizer	Sample	Time of symptom onset	Adverse event	Occurrence of death	Pre-existing conditions/ Risk factors
de Oliveira PMN. *et al.* 2022 [14]	**AstraZeneca:**36 **Pfizer:**1 **Janssen:**2	Of the 39 VITT cases included: **1st Dose:** 34 (87,2%) **2nd Dose:** 4 (10,3%) **Absent:** 1 (2,5%)	Average of 8 days	**Symptoms reported in cases of VITT after Covid-19 vaccination:** Headache blurred vision Convulsions Changes in level of consciousness focal neurological signs abdominal pain Chest pain Dyspnea Edema Limb pallor	20 deaths (51%) The thrombotic site with the highest number of deaths was CNS thrombosis, with 18 deaths in 21 patients (85% mortality rate). Two deaths occurred after splanchnic vein thrombosis. CNS thrombosis was complicated by secondary intracranial hemorrhage in 16 patients, with 15 deaths (94%).	Of the 39 patients, 17 (43.6%) had risk factors for thrombosis, 12 (30.8%) had no risk factors, and 10 (25.6%) had information unavailable. The reported risk factors were Use of oral contraceptives (5) Smoking (4) Obesity (3) History of thrombosis (2) Pregnancy (1) Family History of Thrombophilia (1) Family History of Thrombosis (1) Cancer treatment (1) Lupus E. S. (1)
Martins-Filho, Paulo Ricardo *et al.* 2022 [15]	Coronavac AstraZeneca	145.133 doses **Coronavac** 85.587 doses **AstraZeneca:** 59.546	No Information	474 AEFI - All classified as NSAE. Headache: 112 Pain at injection site 74 Myalgia/arthralgia: 48 Nausea/vomiting: 38 Fever: 35 Drowsiness/Lethargy: 34 Fatigue: 31 Diarrhea: 29 Cold-like symptoms: 25 Stomach pain: 20 Local reaction (erythema, induration, swelling): 16 Dizziness: 9 Shortness of breath: 2 Lymphadenopathy: 1	No death reports	No Information

Article	Immunizer	Sample	Time of symptom onset	Adverse event	Occurrence of death	Pre-existing conditions/ Risk factors
Ballestero M *et al.* 2022 [17]	**Pfizer:** 68 **Moderna:** 1 **AstraZeneca** 2.091 **Sputnik V**: 7 **Coronavac**: 3.911 **Janssen:** 9 **Other:** 22	6.115 notifications from health professionals.	**1st dose** **Up to 3 days** **2.926** **4-7 days** **97** **>8+ days** **62** **None** **3.031** **2nd dose** **Up to 3 days** **1.744** **4-8 days** **87** **>8 days** **47** None 3.206	Local edema/pain 2.129 Tiredness/fatigue 1.316 Fever 854 Headache 1.380 Limb pain 1.007 Sickness 35 Coughing 111 Diarrhea 26 Shivering 23 Itching 11 Facial Paralysis 3 Myelitis/Guillain Barre 2 Anosmia 23 Herpes Zoster 8 No symptoms 2.503	No death reports	Hypertension 682 Diabetes mellitus 234 Lung Disease 188 Cardiovascular disease 113 Immunodeficiency 30 Allergies 290 other 512 None 4,569
Clemens, S.A.C, *et al.* 2022 [23]	AstraZeneca	74.051 Doses	1 week to 40 days	-Non-specific allergies -Bell's palsy -DVT -Pericarditis -Demyelinating diseases	The patient had several underlying risk factors for thrombotic events, including atrial fibrillation, mitral stenosis, and polyglobulia.	- Previous demyelinating disease - History of deep vein thrombosis - Atrial fibrillation - Mitral stenosis

The literature review allowed us to analyze data consistent with the Ministry of Health's ESAVI occurrence reports; the articles make clear that continued surveillance of ESAVI is critical to ensuring vaccine safety and maintaining public confidence in immunization programs.

CONCLUSION

Through the analysis of the articles, it is possible to observe that most of the research came from the south and southeast regions of Brazil, published in 2022, emphasizing the need to carry out new studies in other states and regions of the country; Most non-serious adverse events were described, but serious adverse events were also reported, among the deaths presented in the articles, the vast majority were of the elderly, with pre-existing conditions and associated risk factors.

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