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Review Article

Analysis of adverse event reporting patterns following COVID-19 vaccination: findings from VigiAccess, FAERS and EudraVigilance databases with comparative assessment of data representation and categorization across three databases

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ABSTRACT

The clinical presentation of COVID-19 varied from mild to severe or fatal illness, and vaccination played a pivotal role in preventing the spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Despite cumulative evidence suggesting that the benefits of COVID-19 vaccination outweighed the risks, evaluating its safety profile remained imperative. This study aimed to analyse adverse events following immunization (AEFI) after COVID-19 vaccination using three pharmacovigilance databases and to assess how these data were categorized and represented. A cross-sectional observational study was conducted in January 2024 using VigiAccess (WHO), FAERS (U.S. FDA), and EudraVigilance (EMA). The total number of reported AEFI cases for COVID-19 vaccines were 55,49,876 in VigiAccess, 11,640 in FAERS, and 23,16,918 in EudraVigilance. The most common reaction group in all three databases was general disorders and administration site conditions (VigiAccess 59.07%, FAERS 62.57%, EudraVigilance 62.67%). The most frequently reported reaction in VigiAccess was headache (22.73%), while fatigue (19.79%) was the most common reaction in FAERS. VigiAccess grouped AEFIs for different COVID-19 vaccines under the general term "COVID-19 vaccine," whereas FAERS and EudraVigilance categorized adverse events by specific vaccine types. All three databases categorized individual case safety reports (ICSRs) data, but only FAERS and EudraVigilance categorized the AEFI data. Overall, the comparative analysis revealed that the most commonly reported adverse reactions were consistent across the three databases, while also highlighting significant differences in how these databases represented and categorized the data.

Keywords: COVID-19 vaccine, VigiAccess, FAERS, EudraVigilance

INTRODUCTION

The global COVID-19 pandemic, caused by severe acute respiratory syndrome corona virus-2 (SARS-CoV-2), has had a catastrophic impact, posing a major threat to public health worldwide. Most patients typically presented with symptoms such as fever, cough (with or without sputum), and shortness of breath.[1,2]

During the early phases of the outbreak, various repurposed drugs such as hydroxychloroquine, chloroquine, remdesivir, favipiravir, azithromycin, and lopinavir, alongside convalescent plasma therapy, oxygen treatment and Immunoglobulins were used as emergency measures. In the absence of any definitive treatment, public health preventive measures were employed to reduce transmission, including isolation, contact tracing, wearing face masks, using personal protective equipment, and conducting environmental disinfection.[3]

To control the pandemic, achieving herd immunity through vaccination became crucial. Hence, vaccination of the entire population, beginning with vulnerable groups and subsequently extending to the wider community, was essential.[4,5] Effective and safe vaccines became essential for controlling the COVID-19 pandemic. However, due to the urgent need for a COVID-19 vaccine, its development was expedited, raising concerns regarding both safety and effectiveness. Despite this accelerated process, vaccines proved to be clinically effective.[6-8]

The World Health Organization (WHO) has approved a total of 13 vaccines for emergency use, highlighting the global effort to expand immunization coverage and control the pandemic.[9] These are the following vaccines.

Protein subunit vaccines

It includes Covovax (Serum Institute of India), Nuvaxovid (Novavax), SKYCovione (SK Bioscience Co. Ltd.), and Corbevax (Biological E. Limited).

mRNA vaccines

It includes Spikevax (Moderna), and Comirnaty (Pfizer/BioNTech).

Viral vector vaccines

It includes Convidecia (CanSino Biologics Inc.), Jcovden (Janssen), Vaxzevria (Oxford/AstraZeneca), and Covishield (Serum Institute of India).

Inactivated virus vaccines

It includes Covaxin (Bharat Biotech), Covilo/BIBP-CorV (Sinopharm), and CoronaVac (Sinovac Life Sciences Co.).

Marketing authorization for a new vaccine is granted based on a favourable risk-benefit balance for its intended population and its indications. However, not all risks may have been identified at the time of initial authorization, and many risks associated with vaccine use may only be identified or fully understood after authorization. Hence, post-authorization risk monitoring is crucial. The relevance of evidence concerning vaccine safety has increased, especially amid the COVID-19 pandemic, due to the accelerated clinical research process and reduced research time.[10,11]

In response to these challenges, vaccine pharmacovigilance programs have been established to ensure monitoring of vaccine safety and effectiveness.[12] Vaccine pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and communication of adverse events following immunization and other vaccine-related or immunization-related issues, and to the prevention of untoward effects of the vaccine or immunization.[13]

Post-authorization surveillance relies primarily on gathering reports from healthcare professionals, patients and pharmaceutical companies. The reports collected on suspected adverse reactions to vaccines, undergo progressive evaluation and are then used to assess potential safety signals.[10]

At the global level, the WHO Program for International Drug Monitoring facilitates a collaborative effort aimed at developing vigilance practices worldwide. VigiAccess serves as a web-based tool for accessing VigiBase, the WHO's global database of reported potential side effects of medicinal products. It presents summarized statistical representations of data on potential side effects reported to the WHO PIDM. This data is structured hierarchically based on the Medical Dictionary for Regulatory Activities (MedDRA), an internationally recognized classification system for medical terminology.[10,14-16]

In the United States of America, vaccine-related vigilance is overseen by the vaccine adverse event reporting system (VAERS), which is part of the post-licensure vaccine safety monitoring system jointly managed by the CDC and FDA. VAERS accepts and analyses reports of adverse events following vaccination from healthcare professionals, vaccine manufacturers, and the general public. The FDA adverse event reporting system (FAERS) is a database that contains adverse event reports that were submitted to the FDA via VAERS and MedWatch, the FDA’s medical product safety reporting program for health professionals, patients, and consumers. Adverse events and medication errors are coded using terms in the MedDRA terminology.[10,16-19]

The European Medicines Agency (EMA) oversees the EU pharmacovigilance system. It is responsible for the development, maintenance, and coordination of EudraVigilance, a system designed for reporting suspected adverse drug reactions (ADRs) from healthcare professionals, patients, and pharmaceutical companies. EudraVigilance offers public access to individual case safety reports (ICSRs) and line listings of ADRs for medicines authorized in the European economic area. MedDRA is used to classify clinical information in EudraVigilance.[10,16,20]

Even though the cumulative evidence suggests that the benefits of COVID-19 vaccination outweigh the potential risks, it was imperative to thoroughly evaluate the safety profiles associated with the available COVID-19 vaccines. With widespread global deployment of COVID-19 vaccines, understanding the adverse events following immunization (AEFI) associated with these vaccines becomes crucial. Therefore, we conducted an analysis of AEFI data from various pharmacovigilance databases, such as VigiAccess, FAERS, and EudraVigilance, to assess the safety profiles of various COVID-19 vaccines.

The objectives of the study were to analyse AEFI patterns following COVID-19 vaccination using data from three

pharmacovigilance databases and to assess the categorization and representation of AEFI data across the three databases.

METHODS

A cross-sectional observational study was conducted in January 2024, reviewing three pharmacovigilance databases- VigiAccess, FAERS, and EudraVigilance, to identify all the reported AEFIs associated with the COVID-19 vaccine.

The research was conducted at the Department of Pharmacology in a medical college located in the western suburbs of Mumbai.

Search strategy and analysis

VigiAccess

A search was conducted in the VigiAccess database using the term "COVID-19 vaccine," and the resulting AEFI data was analysed. The analysis focused on identifying the top ten most frequently reported adverse reactions and the top ten reaction groups. AEFI associated with various COVID-19 vaccines were grouped together under the umbrella term "COVID-19 vaccine" in VigiAccess.

FAERS

Likewise, a search was performed in the FAERS database using the term “COVID-19 vaccine”, resulting in data on seven distinct COVID-19 vaccines. The AEFI data for each vaccine was individually analysed, recording the top ten most frequently reported adverse reactions and the top ten reaction groups, and then the data was compiled accordingly for all seven vaccines. The proportion of reported cases attributed to each vaccine was also analysed. The resulting list includes the following seven vaccines-Astrazeneca, Janssen, Moderna, Novavax, Pfizer-Biontech, Pfizer-Biontech, Bivalent, and COVID-19 vaccine nos.

EudraVigilance

To search for data on COVID-19 vaccines in the EudraVigilance database, we accessed the section corresponding to the letter "C" and scrolled through the entries until we found the relevant information. We found records for 14 distinct COVID-19 vaccines. The AEFI data for each vaccine was analysed, with the top ten most commonly reported adverse reactions and top ten reaction groups recorded individually. Subsequently, the AEFI data for all 14 vaccines was compiled accordingly. The proportion of reported cases attributed to each vaccine was also analysed. The 14 different vaccines are as follows: Moderna, Moderna Omicron XBB.1.5, Moderna Original/Omicron BA.1, Moderna Original/Omicron BA.4-5, Pfizer-Biontech, Pfizer-Biontech Omicron XBB.1.5, Pfizer-Biontech Original/Omicron BA.1, Pfizer-Biontech Original/ Omicron BA.4-5, Astrazeneca, Janssen, Novavax, Novavax XBB.1.5, Valneva, and Vidprevtyn beta.

The assessment of how each database categorized and represented ICSRs, reaction groups and adverse reactions data was also conducted.

Statistical analysis

The collected data were entered into Microsoft Excel for analysis. Descriptive data were summarized using tables and graphs. Frequencies and percentages were used to present descriptive variables.

RESULTS

VigiAccess

The total number of reported AEFI cases for COVID-19 vaccines were 55,49,876 in VigiAccess. Among these cases, 59.07% had adverse reactions belonging to the General disorders and administration site condition reaction group, followed by the nervous system disorder reaction group accounting for 37.51%, and the musculoskeletal and connective tissue disorder reaction group representing 24.54%. Figure 1a illustrates the complete list of the top ten adverse reaction groups in VigiAccess. Headache was the most commonly reported adverse reaction, accounting for 22.73%, followed by pyrexia at 18.10% and fatigue at 15.07%. Figure 1b illustrates the complete list of the top ten reported adverse reactions in VigiAccess.

FAERS

The total number of reported AEFI cases for COVID-19 vaccines in FAERS were 11,640. Among these cases, 62.57% had adverse reactions belonging to the general disorders and administration site condition reaction group, followed by the nervous system disorder reaction group accounting for 39.36%, and the musculoskeletal and connective tissue disorder reaction group representing 32.44%. Figure 2a illustrates the complete list of the top ten adverse reaction groups in FAERS. The most commonly reported adverse reaction was fatigue, accounting for 19.79%, followed by headache at 16.77% and pyrexia at 14.13%. Figure 2b illustrates the complete list of the top ten reported adverse reactions in FAERS.

Notably, 39.13% of the reported cases were linked to the vaccine classified as generic (not named), with Pfizer-BioNTech accounting for 23.83%, followed by Moderna at 18.70%. Figure 2c illustrates the percentage of reported cases for each vaccine in FAERS.

EudraVigilance

The total number of reported AEFI cases for COVID-19 vaccines in EudraVigilance were 23,16,918. Among these

cases, 62.67% had adverse reactions belonging to the General disorders and administration site condition reaction group, followed by the nervous system disorder reaction group, accounting for 39.98%, and the musculoskeletal and connective tissue disorder reaction group, representing 29.40%. Figure 3a illustrates the complete list of the top ten adverse reaction groups in EudraVigilance.

Pfizer-BioNTech accounted for 54.56% of the reported cases, while AstraZeneca and Moderna vaccines contributed to 23.90% and 16.71% of the cases, respectively. Figure 3b illustrates the percentage of reported cases for each vaccine in EudraVigilance.

Comparative assessment of representation and categorization of data across three databases

All three databases categorize ICSRs based on the age group and sex of the individuals. Additionally, they categorize ICSRs based on the year reported; however, in EudraVigilance, the data is limited to the last 12 months from the current month. In FAERS, the categorization extends to the outcome of the cases, distinguishing between serious and non-serious outcomes, including the number of deaths. This categorization is not present in VigiAccess and EudraVigilance. Moreover, both FAERS and EudraVigilance categorize ICSRs based on the type of reporter group, distinguishing between healthcare professionals and non-healthcare professionals (consumers), a categorization absent in VigiAccess.

All three databases classify ICSRs based on the geographical region of occurrence or reporting. "VigiAccess categorizes ICSRs by continent from which the reports are received, FAERS by domestic or foreign (where "domestic" refers to the country where the event occurred or the reporter's country being the US, and "foreign" refers to the country where the event occurred or the reporter's country being outside the US). EudraVigilance categorizes geographical regions based on two criteria: the European economic area (EEA) countries and EEA and non-EEA countries. Additionally, FAERS and EudraVigilance provide line listings of ICSRs, while VigiAccess does not offer this feature.

VigiAccess grouped AEFIs associated with different COVID-19 vaccines under the collective term "COVID-19 Vaccine", while FAERS and EudraVigilance categorized AEFIs by specific vaccine types. Table 1 illustrates the overview of the categorization of ICSRs across three databases.

With respect to the representation of adverse event data across the three databases, FAERS and EudraVigilance categorize individual reaction groups based on the age group and sex of the case. FAERS additionally categorizes the reaction group based on the year it was reported, a detail not addressed by EudraVigilance. Both FAERS and EudraVigilance categorize reaction groups based on the outcome of the patient. In FAERS, outcomes include serious (life-threatening, hospitalized, disabled, died, other outcomes) and non-serious, while in EudraVigilance, outcomes range from recovering, recovered with sequelae, recovered, not recovered, to fatal. Both databases also categorize reaction groups based on the type of reporter group, distinguishing between healthcare professionals and non-healthcare professionals. Geographical regions of occurrence/reporting are categorized by both FAERS and EudraVigilance. FAERS categorizes regions as either domestic or foreign occurrences/reporting, while EudraVigilance categorizes regions into EEA and non-EEA countries. VigiAccess doesn't categorize reaction groups based on any of the above criteria.

Table 1: Categorization of ICSRs across three databases.

Variables	Categorization of individual case safety reports (ICSRs)						Line listing of ICSRs	Vaccine differen-tiation
	Based on age group	Based on sex	Based on year reported	Based on the outcome of the patient	Based on reporter type	Based on geographic region		
VigiAccess	Yes	Yes	Yes	No	No	Yes (by continents)	No	No
FAERS	Yes	Yes	Yes	Yes	Yes	Yes (by domestic [US] and foreign [outside the US])	Yes	Yes
EudraVigil-ance	Yes	Yes	Yes (data limited to the last 12 months from the current month)	No	Yes	Yes (by EEA and non-EEA and by EEA countries)	Yes	Yes

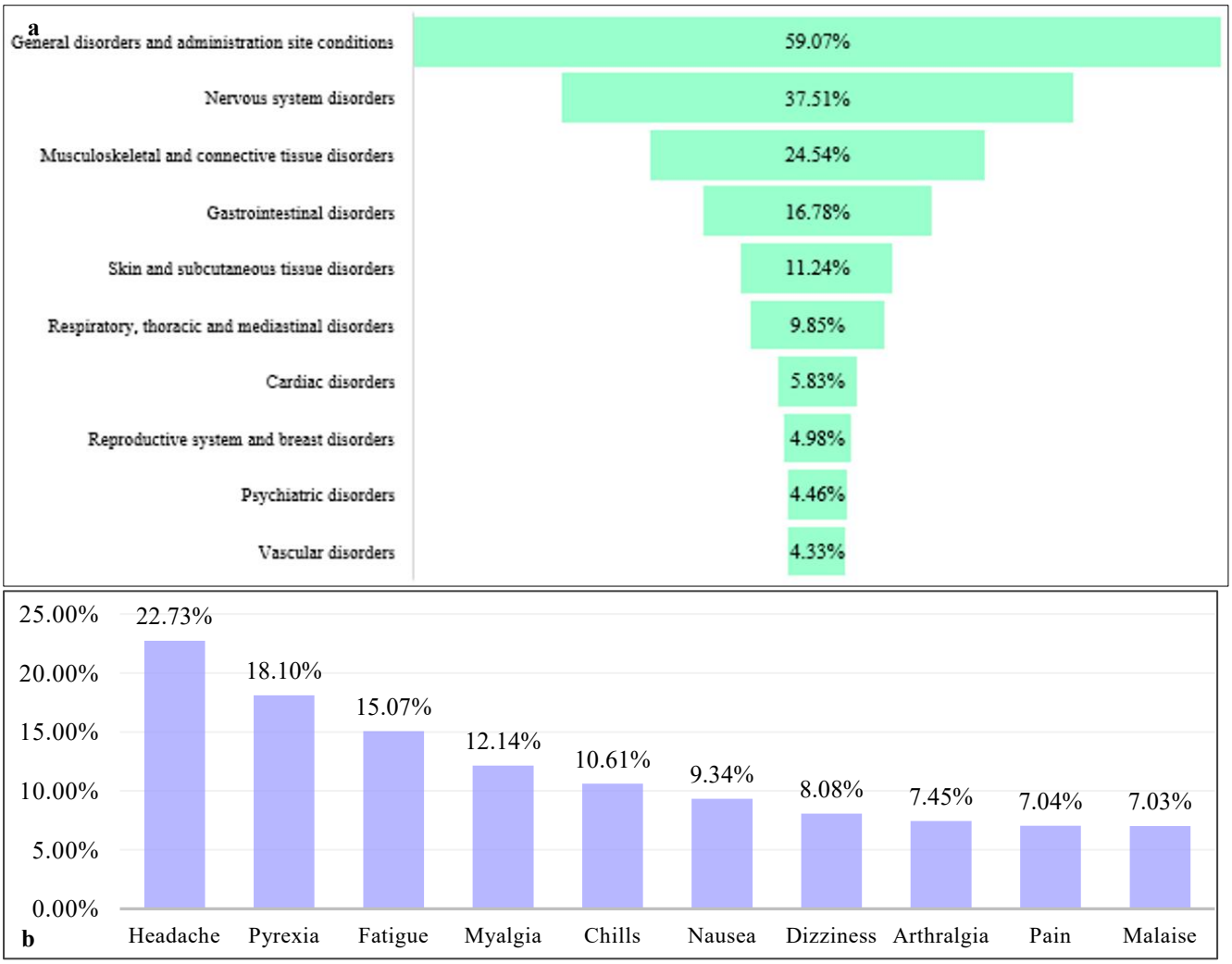

Figure 1: (a) Top 10 adverse reaction groups in VigiAccess, and (b) top 10 reported adverse reactions in VigiAccess.

Table 2: Representation of adverse events data across three databases.

Variables	Representation of adverse events data											
	Categorization of reaction groups						Categorization of adverse reactions					
	Based on age group	Based on sex	Based on year reported	Based on the outcome of the patient	Based on reporter type	Based on geographic region	Based on age group	Based on sex	Based on year reported	Based on the outcome of the patient	Based on reporter type	Based on geographic region
VigiAccess	No	No	No	No	No	No	No	No	No	No	No	No
FAERS	Yes	Yes	Yes	Yes	Yes	Yes (by domestic [US] and foreign [outside the US])	Yes	Yes	Yes	Yes	No	No
EudraVigilance	Yes	Yes	No	Yes	Yes	Yes (by EEA and non-EEA)	Yes	Yes	No	Yes	Yes	No

Table 3: Arrangement of adverse events data across three databases.

Variables	Arrangement of adverse events data		
	Reaction groups	**Adverse reactions (overall)**	**Adverse reactions within each corresponding reaction group**
VigiAccess	Alphabetical order	N/A	Decreasing order of their occurrence/reporting
FAERS	Decreasing order based on the frequency of adverse reactions within each reaction group	Decreasing order of their occurrence/ reporting	Decreasing order of their occurrence/reporting
EudraVigilance	Alphabetical order	N/A	Alphabetical order

Continued.

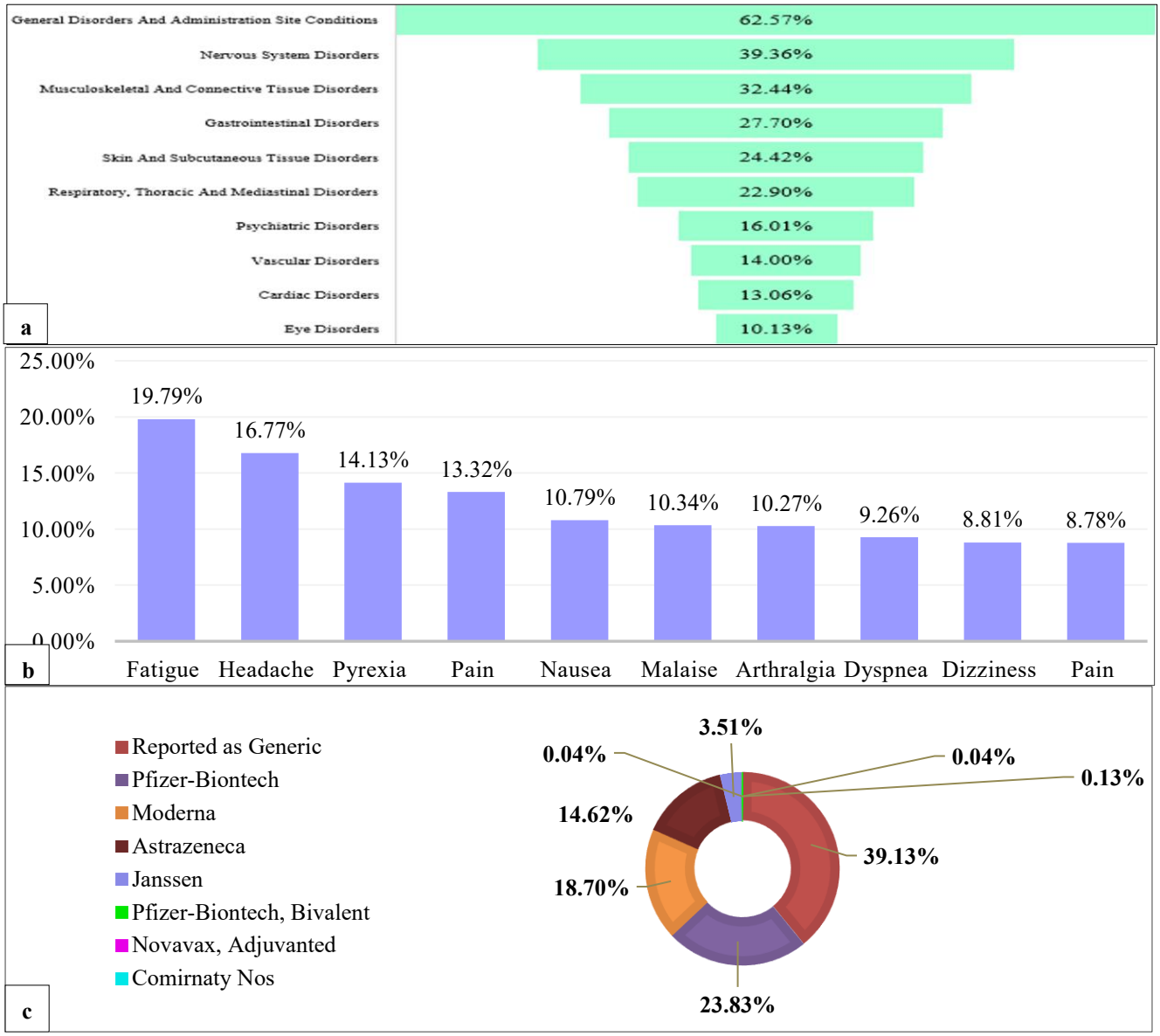

Figure 2: (a) Top 10 adverse reaction groups in FAERS, (b) top 10 reported adverse reactions in FAERS, and (c) percentage of reported cases for each vaccine in FAERS.

Continuing the analysis of adverse event data across databases, the categorization extends to individual adverse reactions in FAERS and EudraVigilance. FAERS and EudraVigilance categorize individual adverse reactions based on the age group and sex of the case. FAERS additionally categorizes adverse reactions based on the year of reporting, a detail not addressed by EudraVigilance. Both FAERS and EudraVigilance categorize adverse reactions based on the outcome of the patient. EudraVigilance also categorizes reactions based on the

type of reporter group, unlike FAERS. Geographical regions of occurrence/reporting of adverse reactions are not categorized by either FAERS or EudraVigilance.

VigiAccess doesn't categorize adverse reactions based on any of the mentioned criteria. Table 2 illustrates the overview of representation of adverse events data across three databases. VigiAccess and EudraVigilance arrange reaction groups alphabetically, while FAERS organizes them in decreasing order based on the frequency of adverse reactions within each group. In FAERS, aggregated adverse reactions are listed in decreasing order of their occurrence/reporting, but this aggregation is not present in VigiAccess and EudraVigilance. Within each corresponding reaction group, FAERS and VigiAccess arrange adverse reactions in decreasing order of occurrence/reporting, while EudraVigilance lists them alphabetically. Table 3 illustrates the overview of the arrangement of adverse events data across three databases.

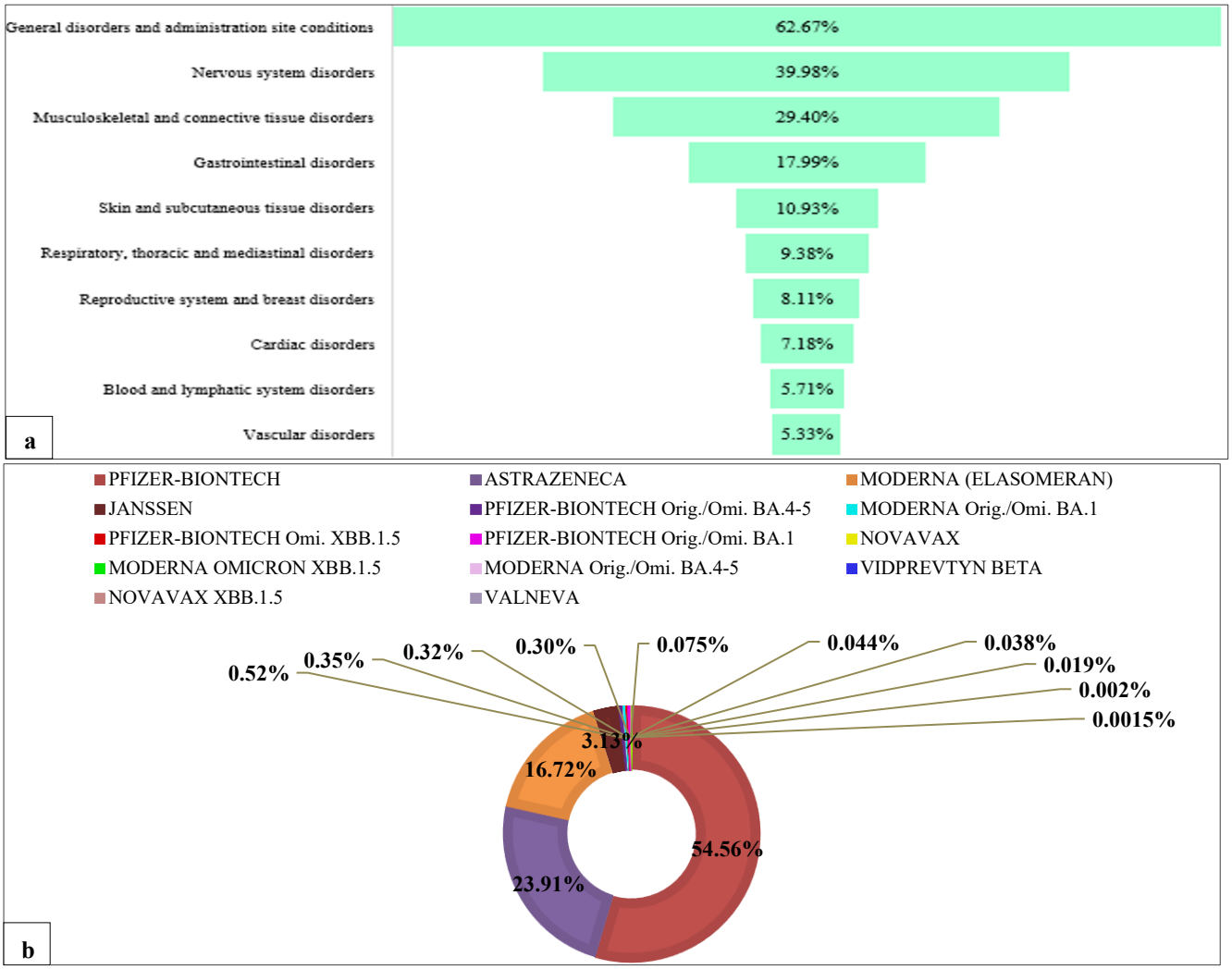

Figure 3: (a) Top 10 adverse reaction groups in EudraVigilance, and (b) percentage of reported cases for each vaccine in EudraVigilance.

DISCUSSION

The present study was conducted to assess the AEFIs associated with COVID-19 vaccines in VigiAccess, FAERS, EudraVigilance. Fatigue, headache, pyrexia are most common adverse events reported across all three databases. Generalized disorders, nervous system disorders, musculoskeletal and connective tissue disorder were the most common reaction groups across the three databases. Majority of adverse reactions reported in EudraVigilance were for Pfizer vaccine, whereas in FAERS, the majority of reports did not specify the vaccine name.

Yamoah et al conducted a similar study on AEFIs associated with COVID-19 vaccines, focusing solely on data from VigiAccess, without considering EudraVigilance and FAERS. Their analysis revealed that the ten most commonly reported AEFI manifestations were headache, pyrexia, fatigue, chills, myalgia, nausea, arthralgia, malaise, injection site pain, and pain in the extremities.[21]

Each ICSR corresponds to one or more “adverse reaction” or “reaction group.” “Adverse reaction” refers to the suspected reaction reported by the reporter. “Reaction group” is based on a classification of adverse reactions using the MedDRA dictionary of adverse event terms. As a result, the number of adverse events will not always be the same as the number of individual cases.

The AEFIs reported may or may not be directly linked to the administered vaccine. They may also be associated with underlying medical conditions of vaccine recipients, anxiety during vaccination, vaccine administration errors, and vaccine quality defects.[22] The data should not be interpreted as indicating causation. Establishing a causal link requires rigorous scientific evaluation and thorough assessment of all available data. Therefore, the suspected adverse events recorded in these databases should not be used to determine the likelihood of a particular adverse event occurring, nor do they confirm any potential link between a vaccine and observed effects; rather, they reflect suspected associations based on reporters' observations and opinions.

Furthermore, the AEFI reports in these databases do not encompass all safety-related data for a given vaccine, which may be due to potential submission of incomplete, inaccurate, untimely, or unverified information and hence should be interpreted alongside other available information when making vaccine-related decisions. Therefore, the information in these databases cannot be used to compare the safety profiles of different vaccines. Additionally, the databases alone cannot determine the incidence or prevalence of events due to potential under-reporting and lack of information on usage frequency.

VigiAccess grouped AEFIs related to different COVID-19 vaccines under the collective term "COVID-19 vaccine", which limits the categorization of ICSRs, reaction groups and adverse reactions by individual vaccine types.

The absence of outcome-based categorization of ICSRs in VigiAccess limits understanding of the proportion of severe cases among reported incidents. Additionally, the absence of categorization based on reporter type hampers insights into who is reporting which is crucial for understanding the reliability, accuracy, and context of the reported data.

The lack of categorization of AEFI data in VigiAccess hinders the identification of common adverse reactions among different age groups and genders. Additionally, the absence of outcome-based categorization limits understanding of the sequalae associated with AEFI. The absence of categorization based on geographical regions complicates the identification of prevalent reactions in specific regions.

FAERS organizes reaction groups in decreasing order based on the frequency of adverse reactions within each group, facilitating easier analysis. In contrast, VigiAccess and EudraVigilance arrange reaction groups alphabetically, which made organizing reaction groups in decreasing order based on the frequency of adverse reactions within each group a little cumbersome.

FAERS organizes adverse reactions in decreasing order of their occurrence/reporting within their corresponding reaction groups. Furthermore, it provides an aggregated list of adverse reactions, arranged in decreasing order of their occurrence/reporting, thereby facilitating easier analysis of adverse reaction patterns. Although VigiAccess lacks an aggregated adverse reaction list, it does present adverse reactions within each reaction group in decreasing order of their occurrence/reporting, thereby moderately facilitating analysis. EudraVigilance lacks both an aggregated adverse reaction list and the arrangement of adverse reactions within reaction groups in decreasing order of their occurrence/reporting, significantly complicating the analysis.

Analysing adverse reactions in EudraVigilance proved cumbersome due to the alphabetical listing of adverse reactions within their corresponding reaction groups, coupled with the absence of an aggregated adverse reactions list. The sheer volume of adverse reactions further complicates the task of arranging them based on their frequency of occurrence. In contrast to reaction groups, which are also alphabetically arranged, but the manageable number of just 27 facilitates analysis.

Limitations

This study analysed ADR reports from the pharmacovigilance databases VigiAccess, FAERS, and EudraVigilance, which may contain overlapping entries. No statistical disproportionality analysis (e.g., reporting odds ratio [ROR], proportional reporting ratio [PRR]) was performed; therefore, the identified signals cannot be definitively interpreted as true ADRs without statistical confirmation.

CONCLUSION

The comparative analysis of AEFI data from VigiAccess, EudraVigilance, and FAERS revealed that the most commonly reported adverse reactions are consistent across the three databases. However, it also highlights significant differences in how these databases represent and categorize the data.

Each system has unique strengths and limitations that impact their utility for analysing vaccine safety. The study underscores the importance of structured and detailed AEFI data presentation for effective pharmacovigilance. Clear categorization and easy accessibility of data are crucial for healthcare professionals and regulatory bodies to monitor vaccine safety.

It is essential to make India's existing pharmacovigilance database open access, similar to FAERS and

EudraVigilance. This would facilitate better monitoring of AEFIs within the Indian population. An open-access database would bridge current data transparency gaps, align India's vaccine safety protocols with international standards, and enhance overall healthcare practices.

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