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Adverse events reported from the COVID-19 vaccines: A descriptive study based on the WHO database (VigiBase®)

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ABSTRACT

The emergency approval of a few COVID-19 vaccines provided a ray of hope to fight the deadly pandemic. However, their approval was solely based on limited data from the clinical trials in a short period, thereby imposing a demand for post-marketing surveillance studies to monitor beneficial and adverse events (AEs). This study focuses on observing the serious adverse events (SAEs) data reported in the World Health Organization database. The data from VigiBase® was analyzed. The duplicates in the data were removed and analyzed based on age, gender, and SAEs at the system organ classification level and the individual preferred term level. A total of 103,954 AEs were reported. The majority of them were seen as females (80%), from Europe (83%), and were between 18 and 64 years (80.74%) of age. The most-reported AEs were of the nervous system (19.1%), musculoskeletal (11.2%), and elderly (>65 years) people. The reported SAEs from the COVID-19 vaccines were in line with the data published in the clinical trial reports. These SAEs to vaccines will need causality analysis and review of individual reports.

INTRODUCTION

The ongoing COVID-19 pandemic, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has enveloped the entire globe with severe impositions for almost every phase of human life (Nicola *et al*., 2020; The World Bank, 2020). Globally, 174,439,909 confirmed cases of COVID-19, including 3,768,987 deaths, as reported by World Health Organization (WHO). As of June 11, 2021, a total of 2,156,550,767 vaccine doses have already been administered (World Health Organization, 2021a). The rapid upsurge in active COVID-19 cases produced a significant health care crisis due to a lack of alertness to confront a sudden pandemic, especially in the developing nations (Blumenthal *et al*., 2020). At the onset of COVID-19, disease management faced several issues because of no availability of specific effective medication (Aygün *et al*., 2020; Elengoe, 2020). Hence, a hit and trial strategy of drug repositioning/repurposing with older medication invented for different indications was implanted to find an answer to this dreadful disease (Harrison, 2020; Li, 2019). However, several therapies were being tried and are still under clinical trials to prove their efficacy, yet infection control measures, sanitation, symptomatic, and supportive therapy has been the cornerstone of

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effective clinical management of the COVID-19 (Blumenthal *et al.* 2020; Bundgaard *et al*., 2021; Lio *et al*., 2021). Later, Food and Drug Administration (FDA) approved Remdesivir for the treatment of COVID-19 on October 22, 2020 (FDA, 2020a).

As there was no definitive therapy in conjunction with a tremendous rise in the number of cases, an effective vaccine vestiges the only answer in building immunity to halt the disease's further progression (Bundgaard *et al*., 2021; Chowdhury *et al*., 2020; Green, 2020; Haque, 2020; Kaur & Gupta, 2020; Tabish & Basch, 2020; World Health Organization, 2021b). Multiple institutes, including the Organization for Economic Co-operation and Development (OECD), WHO reported that vaccine development and vaccination of the majority population most probably the best remedy to achieve the ultimate, long-standing defensive action strategy against COVID-19 miseries (Organization for Economic Co-operation and Development, 2021; World Health Organization, 2020). Additionally, the SARS-CoV-2 (coronavirus), the principal offender of COVID-19 disease, the genetic sequence was publicly available on January 11th, 2020. This discovery instigated several robust research targeting vaccine development against COVID-19 (Thanh *et al*., 2020). Consequently, connoisseurs, statesmen, politicians, opinion leaders, and many professional groups believe and expect that in the current pandemic situation, the vaccine can only minimize morbidity, mortality, and transmission and offers the most remarkable optimism of coming back to everyday life (Shrotri *et al*., 2021). Later, WHO developed a new webpage named "COVID-19 vaccine tracker and landscape" reported a total of 287 vaccine candidates under development and of which 102 were in the clinical trial phase, and 185 were under preclinical development till June 11, 2021 (World Health Organization, 2021b).

The COVID-19 vaccines in clinical development are mostly protein subunit vaccines, viral vector (non-replicating), nano-particles, DNA, inactivated virus, and RNA vaccines (Kaur & Gupta, 2020; Kyriakidis *et al*., 2021; Shin *et al*., 2020; Yan *et al*., 2021). Most of the trials regarding COVID-19 vaccine underway and few clearing phase-3 studies, the pharmaceutical industries applied obtained for the emergency use authorization (EUA) of few vaccines (Oliver *et al*., 2020, 2021; Rizk *et al*., 2021). There was a total of nine vaccines that have been approved around the world, namely, Comirnaty (BNT162b2), Moderna COVID-19 Vaccine (mRNA-1273), CoronaVac, COVID-19 Vaccine AstraZeneca (AZD1222), a vaccine from Sinopharm, and the Wuhan Institute of Virology, Sputnik V, BBIBP-CorV, EpiVacCorona, and Covaxin, as of January 29, 2021 (Craven, 2021). On December 11, 2020, the FDA gave EUA the Pfizer-BioNTech vaccine for COVID-19 to be distributed in the United States of America for individuals aged 16 years and older (Oliver *et al*., 2020). Later, by December 18, 2020, FDA also approved the Moderna vaccine for COVID-19 for use in individuals 18 years of age and older (Oliver *et al*., 2021). However, FDA reported that emphasizing the EUA is only based on limited efficacy safety data, and it is not full approval of these COVID-19 vaccines (Angelis & Darrow; 2021; National Center for Immunization and Respiratory Diseases, 2021). In India, two vaccines, namely, Covishield from Serum Institute of India and Covaxin from Bharat Biotech, received Restricted Emergency Approval for prevention of COVID-19 (Press Information Bureau Government of India, 2021). Although these COVID-19 vaccines have been approved for emergency use, their long-term efficacy is yet to be established (Cyranoski, 2020; Singh and Upshur, 2021).

It is incredibly critical to monitor the vaccine safety and/or serious adverse events (SAEs) using Pharmacovigilance which is defined as "the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem" (World Health Organization, 2021c). WHO maintains a global database of adverse events (AEs) through VigiBase®, which maintains the global safety data of various therapeutic interventions as Individual Case Safety Reports (ICSRs) for implementation strict pharmacovigilance (Bergvall *et al*., 2014; Charan *et al*., 2021; Dutta, 2018; Kaur *et al*., 2020; Kuemmerle *et al*., 2011). The VigiBase, the WHO global ICSR database system, came into existence in 1968 and consists of over 20 million ICSR from over 130 countries (Lindquist, 2008). ICSRs are also known as spontaneous or voluntary reports generated in the post-marketing phase of the drug (Gliklich *et al*., 2014; Moore *et al*., 2020; Sharrar & Dieck, 2013). Each ICSR contains information regarding patients' demographics, drugs, AEs, and administrative information (Kröger *et al*., 2015; Upsala Monitoring Center, 2021; Wysowski & Swartz, 2005).

This descriptive analysis is an extension to the studies conducted using the same database on drugs used in COVID-19 therapeutics, including Favipiravir, Remdesivir, and Tocilizumad (Charan *et al*., 2021a, 2021b; Kaur *et al*., 2020), and primarily focuses on identifying and describing various SAEs reported for the COVID-19 vaccines through the WHO database, thereby facilitating identification of safer vaccines, preventing patients from unnecessary tribulations, and reducing the hospitalization and treatment costs in order to assure rational vaccination regimens and strategies.

METHODOLOGY

Data source

This study was conducted on data obtained from the VigiBase®, maintained by the WHO Uppsala monitoring center, Uppsala, Sweden. All vaccine safety data reported from December 15th, 2020 to January 24th, 2021 were analyzed. Data were cleaned from duplicates and irrelevant entries by the first and second authors (SD, RK), and any discrepancy for removal or retention of individual entries for the analysis was resolved by discussion and consensus in the presence of the first corresponding author (JC). This database has all the data reported in the form of adverse drug events associated with COVID-19 vaccines using ICSRs, the VigiBase– —the unique WHO global database, Uppsala Monitoring Centre, Uppsala, Sweden (https://www.who-umc.org/vigibase/vigibase/). In addition, the detailed information regarding patient's demographics (age, gender, country, and medical history); drugs (an indication of use, route of administration, start and end date); AEs (date of onset, seriousness, outcome, dechallenge and rechallenge outcomes, and causality) and administrative information (type and source of report) were recorded.

Data interpretation and analysis

Each report in VigiBase® represents an individual AEs, and there could be more than one report for a single individual; thus, the number of reported AEs were more than the number of individuals who had an adverse event. Hence, the data were cleaned manually to remove the duplicates in the same AEs reported for the same individual in different terminologies.

All the adverse drug reactions in the ICSR are automatically coded as per medical dictionary for regulatory activities (MedDRA) (https://www.who-umc.org/vigibase/vigibase/) and WHO-ART terminology (https://www.who-umc.org/vigibase/vigibase/know-more-about-vigibase/). MedDRA is the hierarchical terminology that is composed of five levels: lowest level terms, preferred term (PTs), high-level group terms, high–level terms, and system organ classification (SOCs) (ICH 2021a, 2021b).

In the present study, the SOC and PT categories of AEs were only employed for the analysis. Here, PT refers to a clinical condition in the form of symptom, sign, diagnosis, investigation, medical, social, family history, and characteristic surgical or medical procedures (ICH, 2021b). Each PT is linked to specific SOC, which is grouping by manifestation site (e.g. Cardiovascular disorder), etiology (infections and infestations), and purpose (surgical and medical procedures) (Bousquet *et al*., 2005). The age, gender, and severity of all the AEs were compared with the SOC and PT. The adverse event's seriousness was decided as per the ICH E2B criteria, which identifies SAEs as those leading to either life-threatening event, hospitalization, disability, congenital abnormality, or death (ICH, 2021c).

Ethical approval

This study had no direct interaction with human participants and was based on the WHO's database (VigiBase®); hence, ethical approval was not required.

Statistical analysis

Descriptive statistics were reported in the form of frequency and percentages. The cross-tabulation function of Statistical Package for Social Science (SPSS) version 23 (IBM Corp. Released 2015. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.) was used for the analysis.

RESULTS

A total of 103,954 AEs were reported till January 24th, 2021 from 32,044 subjects (Average 3.24 AEs per person). Out of the total subjects, 5,731 (17.9%) were males, and 25,652 (80%) were females. Thus, 28,799 (27.7%) AEs from 8,007 individuals were categorized as SAEs (Fig. 1). The majority of SAEs were reported in females and between the age group of 18 and 64 years. Around 83% of the SAEs were reported from European countries (n = 23,987), followed by Americas (n = 4,795) and Asia (n = 17) (Fig. 2)**.** In almost 74% of cases, the BNT162b2 (Pfizer) vaccine was used. Around 1% of SAEs were fatal (Table 1).

The majority of the SAEs were reported from the broad category "general disorders and administration site conditions" (30%), followed by "Nervous system disorders" (19.1%), "Musculoskeletal and connective tissue disorders" (11.2%), and "Gastrointestinal disorders" (10.7%) (Table 2)**.**

Upon analyzing the PTs in the broad categories, 28,799 SAEs were reported. Headache (8.11%) of various types were the most common SAEs, followed by pyrexia (7.09%), fatigue (5.18%), nausea (4.4%), chills (4.2%), and myalgia (3.9%). Pain (1.93%), pain in extremity (1.98%), and vaccination site /injection site/administration site pain (1.88) accounted for another major portion of SAEs (Table 3).

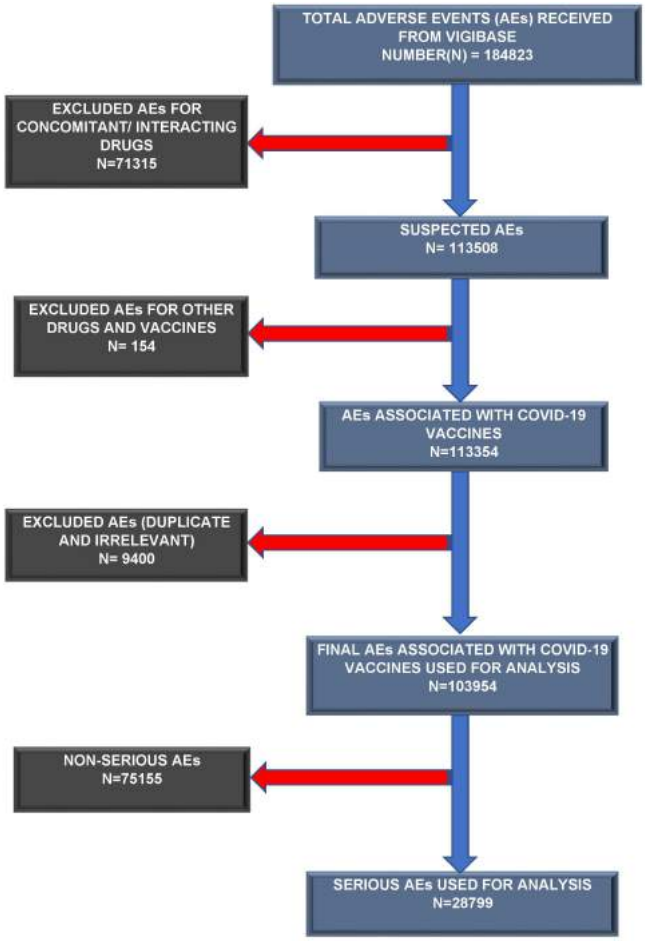

Figure 1. Schematic Diagram of assessment of Adverse Events associated with COVID-19 vaccines in VigiBase database.

Table 4 describes the distribution of serious and non-serious AEs between the type of vaccines, gender, and age groups. Comparing serious versus non-serious AEs with various vaccine candidates shows the probability of serious AEs is comparatively low compared to the non-serious AEs. The age group > 65 years had more serious AEs as compared to other age groups. There was an equal distribution of serious and non-serious AEs between males and females.

There was a total of 424 deaths. The distribution of these deaths per the vaccines, gender, and age group has been mentioned in Table 5**.**

DISCUSSION

The present study was conducted to assess the SAEs reported in the global pharmacovigilance database (VigiBase®) associated with various COVID-19 vaccines like BNT162b2 (Pfizer) AZD1222/ChAdOx1 nCoV-19(AstraZeneca), Moderna, etc. that are currently being used across the world for vaccination. Approximately, one-third of the total AEs reported were serious in nature. The majority of the AEs reported were from the female subjects and age group 18–64 years. In addition, a significant chunk of AEs was reported from Europe, and in the majority of the cases, the BNT162b2 (Pfizer) vaccine was used. The reason

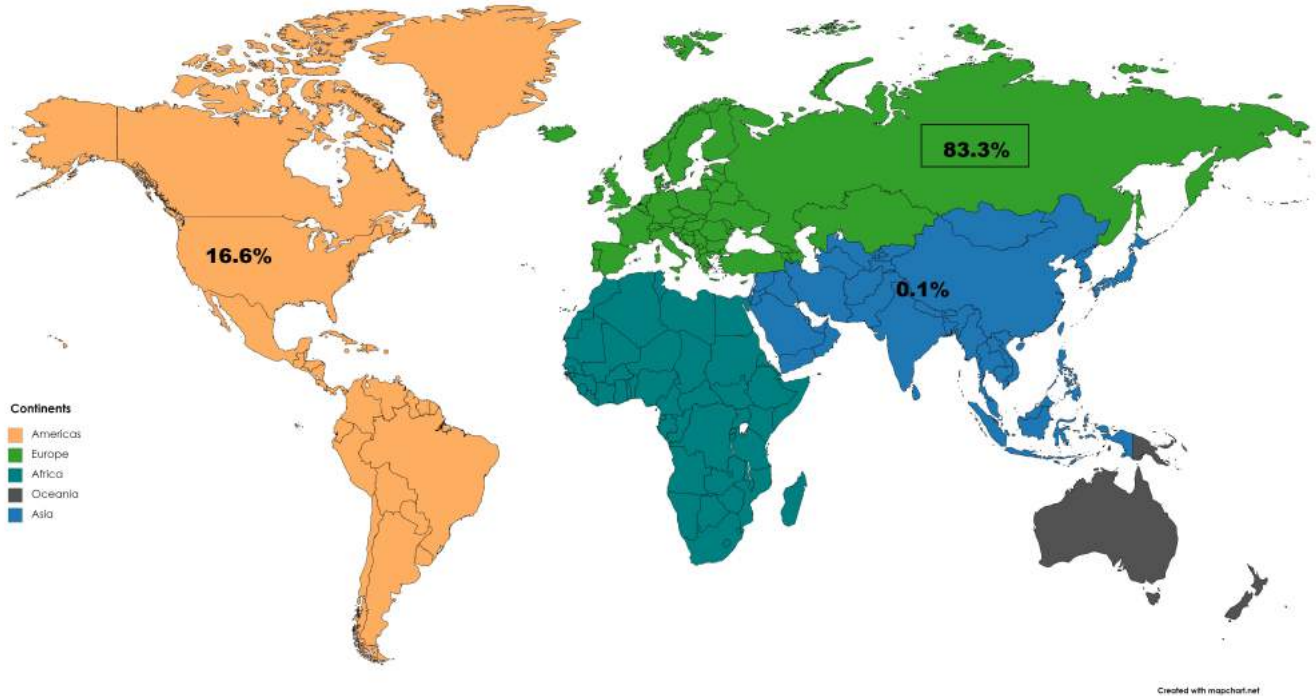

Figure 2. Distribution of Serious Adverse Events reported in VigiBase associated with COVID-19 vaccines across continents.

Table 1. Characteristics of SAEs (28,799 SAEs reported from 8,007 individuals) reported for COVID-19 vaccines in WHO database (n = 28799).

Parameter		Frequency (%)
Age	<18 years	265 (0.92)
	18–64 years	23,255 (80.74)
	≥ 65 years	4,077 (14.15)
	Not reported	1,202 (4.17)
Gender	Female	22,866 (79.4)
	Male	5,361 (18.6)
	Not reported	572 (2)
Outcome	Fatal	334 (1.2)
	Not recovered/not resolved	6,856 (23.8)
	Recovered/resolved	9,454 (32.8)
	Recovered/resolved with sequelae	269 (0.9)
	Recovering/resolving	5,363 (18.6)
	Unknown	3,336 (11.6)
	Not reported	3,187 (11.1)
Name of vaccine	BNT162b2	21,384 (74.3)
	AstraZeneca	5,649 (19.6)
	Moderna	1,697 (5.9)
	Not specified	69 (0.2)
Notified by	Consumer/non-health professional	13,061 (45.4)
	Other health professionals	6,250 (21.7)
	Physicians	4,102 (14.2)
	Pharmacists	804 (2.8)
	Lawyer	1 (0.003)
	Not reported	4,581 (15.9)

for More AE reporting for BNT162b2 is that during the study period, maximum vaccination was done with BNT162b2, whereas the number of individuals vaccinated with other vaccines was comparatively less; thus, it is imperative to observe maximum AE with BNT162b2. The AEs reported were commonly classified under general disorders and administration site conditions with headache, fever, and fatigue as the commonest AEs observed.

In the current analysis, the ratio of serious and non-serious AEs was similar amongst males and females, but more numbers were reported from females. Multiple US studies reported that after the first dose of Pfizer-BioNTech COVID-19 Vaccine, almost 90% of the anaphylactic reactions and non-anaphylactic allergic reactions were observed in females, among which 81% of them with anaphylaxis and 67% with non-anaphylactic allergic reactions had a history of allergic reactions (CDC COVID-19 Response Team; Food and Drug Administration, 2021; Shimabukuro & Nair, 2021a; Shimabukuro, 2021b). However, in the above report, about 62% of the Pfizer-BioNTech COVID-19 vaccines were received by females, which can be a reason for the preponderance of allergic reactions in females (CDC COVID-19 Response Team; Food and Drug Administration, 2021b). Similarly, CDC again reported that Moderna COVID-19 Vaccine females were principal (~61%) recipients of this vaccine. Virtually 100% of the anaphylactic reaction and 91% of non-anaphylactic allergic reactions were observed in females, amongst which 90% of them with anaphylaxis and 60% with non-anaphylactic allergic reactions had a history of allergic reactions (Centers for Disease Control and Prevention, 2021).

The proportion of the female population in the United States was 50.51% (The World Bank, 2019a). In Europe, it was 51.12% in 2019 (The World Bank, 2019b). WHO studied regarding difference among health care professionals (HCPs) in Europe and America in 2019. This study revealed that the percentage of female physicians in the USA and Europe was

Table 2. Distribution of SAEs reported from the COVID-19 vaccines as per the broad system-based classification (n = 28,779).

Adverse events broad heading categories	Frequency (%)
Blood and lymphatic system disorders	355 (1.23)
Cardiac disorders	710 (2.47)
Congenital, familial and genetic disorders	2 (0.01)
Ear and labyrinth disorders	191 (0.66)
Eye disorders	365 (1.27)
Gastrointestinal disorders	3,103 (10.77)
General disorders and administration site conditions	8,640 (30.0)
Hepatobiliary disorders	12 (0.04)
Immune system disorders	363 (1.26)
Infections and infestations	565 (1.96)
Injury, poisoning, and procedural complications	82 (0.28)
Investigations	1,006 (3.49)
Metabolism and nutrition disorders	234 (0.81)
Musculoskeletal and connective tissue disorders	3,225 (11.20)
Neoplasms benign, malignant, and unspecified (incl cysts and polyps)	3 (0.01)
Nervous system disorders	5,502 (19.10)
Pregnancy, puerperium, and perinatal conditions	17 (0.06)
Product issues	1 (0.003)
Psychiatric disorders	470 (1.63)
Renal and urinary disorders	83 (0.29)
Reproductive system and breast disorders	59 (0.20)
Respiratory, thoracic, and mediastinal disorders	1,709 (5.93)
Skin and subcutaneous tissue disorders	1,500 (5.21)
Social circumstances	22 (0.08)
Surgical and medical procedures	20 (0.07)
Vascular disorders	560 (1.94)

Table 3. Common individual Adverse Events reported from the COVID-19 vaccines.

Specific adverse events	Frequency (%)
Headache/tension headache/vascular headache/sinus headache	2,335 (8.11)
Hyperpyrexia/pyrexia/hyperthermia	2,042 (7.09)
Fatigue	1,492 (5.18)
Nausea	1,268 (4.40)
Chills	1,208 (4.19)
Myalgia/musculoskeletal pain	1,127 (3.91)
Dizziness/exertional/postural	832 (2.89)
Arthralgia/arthritis/arthropathy/osteoarthritis	731 (2.54)
Pain in extremity	570 (1.98)
Pain	555 (1.93)
Vaccination site/Injection site/administration site pain	542 (1.88)
Dyspnea/at rest/exertional	497 (1.73)
Vomiting/vomiting projectile	447 (1.55)
Malaise	444 (1.54)
Rash/rash erythematous/ macular/maculo-papular/ morbilliform/popular/pruritic/ vesicular/vasculitic rash	380 (1.32)

46% and 53%, respectively. In contrast, the nursing workforce explicitly percentage dominated by females was 86% and 53% in the USA and Europe, respectively (World Health Organization, 2019). Therefore, the more AEs reported in females could be attributed to many females as health workers. During the early rollout of the vaccine, it was preferably given to the HCPs, and the above data shows a female predominance in the HCPs hence more female HCPs might have received the vaccine as compared to the male ones, which could be a reason for the more number AEs reported by the females. However, the reporting difference is too skewed to be justified only based on this reason.

The study conducted on assessing the gender-specific differences in AEs reporting with various vaccines in Ontario during 2012–2015 emphasized that most of the AEs reported (66.2%) were associated with females (Harris *et al*. 2017). However, there was a more even distribution observed while analyzing the SAEs of either gender [57.5% female, and the relative risk reduction (RRR) 1.3] (Huang *et al*., 2014). Literature reveals that previous study (Huang *et al*. 2014), 63% on the MF59®-adjuvant H5N1 influenza vaccine. One more study (Halsey *et al*., 2013) on H1N1 vaccines reported female predominance in the AEs associated with the respective vaccinations. Multiple studies were conducted on the impact of gender and response to vaccines in elderly reported that the AEs with females as compared to males were consistently higher with the response to various vaccines like influenza, pneumococcal, herpes zoster, tetanus, and pertussis (Bayas *et al*., 2001; Beyer *et al*., 1996; Cook, 2007; Engler *et al*., 2008; Fink & Klein, 2015; Gergen, 1995; Hillebrand, 2015). The reactions observed by either gender were similar. However, female vaccine recipients reported more local reactions, like injection site pain, redness, and swelling, as well as some of the systemic reactions like joint pain, myalgia, headache, back pain, abdominal pain, fever, chills, and hypersensitivity reactions (Beyer *et al*., 1996; Fink & Klein, 2015). Few probable explanations in favor of females with higher AEs can be due to increased humoral and cell-mediated immune reactions to antigens, vaccines, and infections compared to males (Fish, 2008; Klein, 2012).

The SAEs with the Pfizer-BioNTech COVID-19 Vaccine from their clinical trial experience in the 16–55 years of age were reported by 0.4% of the recipients and 0.8% of the participants with more than 56 years of age and older (FDA, 2020b). In the present analysis, the SAEs constituted 25.23% of the total AEs reported in the VigiBase, and deaths were observed in 0.40% of total SAEs associated with the Pfizer-BioNTech vaccine. As per the data reported from clinical trials, death was reported in two (0.01%) vaccine recipients, and both were above 55 years of age (Centers for Disease Control and Prevention, 2021; FDA 2020a). The proportion of non-fatal SAEs was 0.6% with the vaccine, and the most common AEs reported were appendicitis (0.04%), acute myocardial infarction (0.02%), and cerebrovascular accident (0.02%) (FDA, 2020a).

As per the clinical trial experience of Moderna COVID-19 Vaccine, the proportion of vaccine recipients who developed at least one AEs was 1%. In our analysis, the SAEs constituted 26.73% of the total AEs reported in the VigiBase, and death was observed in 1.23% of total SAEs associated with the

Table 4. Distribution of serious and non-serious adverse events as per the vaccine, gender, and age groups.

		Serious	Non-Serious	Total
Vaccine name (*n* = 103,954)	BNT162b2(Pfizer)	21,384 (25.23)	63,357 (74.77)	84,741
	AstraZeneca	5,649 (45.15)	6,861 (54.84)	12,510
	Moderna	1,697 (26.73)	4,650 (73.27)	6,347
	COVID-19 vaccine (vero cell), inactivated	9 (28.12)	23 (71.87)	32
	Covaxin	0	2 (100)	2
	No vaccine name mentioned	60 (18.7)	261 (81.30)	321
Gender (*n* = 103,954)	Male	5,361 (29.30)	12,935 (70.70)	18,296
	Female	22,866 (27.41)	60,551 (72.59)	83,417
	Gender not reported	572 (25.52)	1,669 (74.48)	2,241
Age group (*n* = 103,954)	<18 years	265 (31.29)	582 (68.71)	847
	18–64 years	23,255 (25.98)	66,250 (74.02)	89,505
	>65 years	4,077 (53.32)	3,570 (46.68)	7,647
	Unknown	1,202 (20.18)	4,753 (79.82)	5,955

Values in parenthesis are percentages.
n = total adverse events.

Table 5. Distribution of death events per the vaccine, age, and gender (*n* = 103,954).

		Death (%)
Vaccine name	BNT162b2 (*n* = 84,741)	337 (0.40)
	AstraZeneca (*n* = 12,510)	9 (0.07)
	Moderna (*n* = 6,347)	78 (1.23)
Gender	Male (*n* = 18,296)	205 (1.12)
	Female (*n* = 83,417)	213 (0.25)
	Gender not reported (*n* = 2,241)	6 (0.27)
Age group	<18 years (*n* = 847)	3 (0.35)
	18–64 years (*n* = 89,505)	43 (0.05)
	>65 years (*n* = 7,647)	342 (4.47)
	Unknown (*n* = 5,955)	36 (0.6)

Moderna vaccine. As per the data reported to FDA, there were six deaths reported after vaccination, and most of them were above 70 years of age and associated co-morbid conditions. In the vaccine recipient group, the commonest SAEs reported were myocardial infarction (0.03%), cholecystitis (0.02%), and nephrolithiasis (0.02%). Three SAEs were also considered likely caused by the vaccines, one case of intractable nausea/vomiting, and two of facial swelling concerning the FDA's opinion (FDA, 2020a; CDC, 2020). This discrepancy in the proportion of SAEs between our study and the one reported to the FDA could be attributed to the fact that we had calculated the proportion of total AEs reported and not from the total patients vaccinated.

The AEs from the COVID-19 vaccine from AstraZeneca as reported to Medicines & Healthcare products Regulatory Agency (MHRA) were not classified as serious or non-serious but reported general disorders and administration site conditions like injection site reaction/pain, fatigue, headache, and nausea to be commonest SAEs (Medicines & Healthcare products Regulatory Agency, 2021). A recent study published based on an interim analysis of four clinical trials conducted in Brazil, South Africa, and the UK has also reported that 79 (0.7%) of whom received ChAdOx1 nCoV-19 suffered gastrointestinal disorders, injury, poisoning and procedural complications, infections/infestations, and nervous system disorders (Voysey *et al*., 2021). More serious AEs were reported in older age groups in our analysis than in the younger age groups. This warrants a cautious approach when administrating vaccines to the old age group people in the form of longer follow-up and watchful vigilance.

Limitations of the study

The data analyzed in this study have been adapted from VigiBase, a WHO global database for ICSRs. The data are collected from several sources, and the probability that the suspected adverse effect is drug-related is not the same in all cases. In the absence of proper reporting of other parameters and technical problems in causality assessment, it is not appropriate to attribute all of these events to the vaccine; hence in this paper, we used the term AEs and not the adverse drug reaction, which is more definitely linked to the drug. The data presented in this study does not represent the Uppsala Monitoring Centre or the WHO's opinion. Also, VigiBase do not give information about the total number of individuals vaccinated, and thus it was not possible to find out the ratio between the total individuals vaccinated and the individuals who had AE with vaccination. Besides this, the duration of the study is small, but the number of cases reported in this duration is sufficient to apply adequate statistical analysis and draw preliminary conclusions.

CONCLUSION

This study observed that the pattern of AEs reported in the database was in sync with the vaccines' reactogenicity. However, there is an urgent need for systematic analysis regarding different AEs reported in this study to measure causalities through proper review of reports and generating data in primary studies.

The present study is not directed toward accentuating the imperfections related to any specific vaccine and is only intended to spread awareness regarding the commonly reported AE with COVID-19 vaccines so that the recipients' possible follow-up may be done to avert any serious event. The victory or defeat

of the world's largest vaccination drive to successfully control the pandemic depends mainly upon the information regarding adversities associated with vaccination and awareness about their association with other co-morbidities.

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AUTHOR CONTRIBUTIONS

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis, and interpretation, or in all these areas; took part in drafting, revising, or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

CONSENT FOR PUBLICATION

All authors reviewed and approved the final version and have agreed to be accountable for all aspects of the work, including any issues related to accuracy or integrity.

DISCLOSURE

The authors declare that they do not have any financial involvement or affiliations with any organization, association, or entity directly or indirectly with the subject matter or materials presented in this article. This also includes honoraria, expert testimony, employment, ownership of stocks or options, patents or grants received or pending, or royalties.

DATA SHARING

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