International Journal of Science and Research (IJSR)
ISSN: 2319-7064
SJIF (2022): 7.942

Apollo Telehealth's Comprehensive Analysis on the Impact of Telemedicine in the Management of COVID Vaccination Adverse Effects

Dr. Md. Mubasheer Ali[1], Prashant Janjal[2], Dr. Akhila Kosuru[3], Dr. Ayesha Nazneen[4]

[1]Senior Consultant Internal Medicine, Apollo Telehealth

[2]Public Health Specialist, Apollo Telehealth

[3]Senior Consultant, Apollo Telehealth

[4]HOD & Senior Consultant, Apollo Telehealth

Abstract: ***The COVID-19 pandemic has compelled scientists across the globe to introspect and accelerate research to search for solutions for treatments and vaccines to stop SARS-CoV-2 spread. Studies that have been published, primarily concerning SARS-CoV and to a lesser extent on MERS, have provided guidance on immunisation tactics for this novel coronavirus. (1) . This is based on the argument that severe acute respiratory syndrome virus 2 shares roughly 78 percent genetic similarity with SARS-COV and employs the same receptor namely human Angiotensin Converter Enzyme 2. WHO classified the illness to be pandemic and although research work on COVID vaccines began as soon as the novel coronavirus outbreak started out in China and subsequently to the rest of the world, a reliable and safe vaccine for COVID 19 could not be created until September 2020. In order to stimulate the generation of a cellular and humoral immune response intended to protect the recipient against a specific disease, vaccines primarily mimic a natural illness. The bulk of the known side effects, such as headaches, discomfort, swelling and redness at injection site, muscle aches, fever, and exhaustion, etc., are minimal in terms of severity., (2) . Another widespread concern is people's resistance to receiving safe and advised immunizations, commonly referred to as "vaccine hesitancy." This in-depth analytical review study sought to analyse and assess the benefits of telemedicine in controlling mild to moderate AEFI and describing their detrimental ramifications. These findings could give the general public a better grasp of how mild and moderate side effects from the COVID-19 immunization actually manifest in the real world and how easily they can be managed with telemedicine.***

Keywords: post COVID vaccination adverse effects, covaxin, covishield, telemedicine.

1. Introduction

India's national COVID vaccination program is built on scientific and epidemiological evidence, WHO guidelines and global best practices. On January 16, 2021, India rolled out the world's largest COVID-19 vaccination drive across 3006 vaccine centres in all its states and union territories (3).

Several COVID-19 vaccines have received restricted emergency use authorization from India's Central Drugs Standard Control Organization (CDSCO), such as the Oxford-AstraZeneca viral vector recombinant vaccine ChAdOx1 (Covishield), whole-virion inactivated corona virus vaccine BBV152 (Covaxin) in January 2021, recombinant adenovirus vectored Sputnik V vaccine in April 2021, Zydus Cadila's DNA based vaccine called ZyCov-D in august 2021 and Janssen's vaccine called Ad26. COV2. s. Apart from these CDSCO has also gave a green signal to Moderna's mRNA vaccine in June 2021. Most of these are not yet available for general public. All these vaccines were rolled out to be given in two doses for optimum efficacy except Janssen's Ad26. COV2. s and ZyCov-D that required one and three doses, respectively. In late December 2021, the CDSCO had approved two COVID-19 vaccines named Corbevax and Covovax. Corbevax is the vaccine made available to children aged 12 to 14 years from March 2022 (4). The two predominant vaccines used in India are Covaxin and Covishsield. Utilizing a technology platform derived from Whole-Virion Inactivated Vero Cells, Covaxin was created. Due to the fact that inactivated vaccines cannot reproduce, they are unlikely to reverse and result in pathological effects. They contain a dead virus that can no longer cause infection in humans but can still give instructions to the immune system to create a defence mechanism against an infection. (5) A solitary recombinant, replication-deficient chimpanzee adenovirus (ChAdOx1) vector expressing the S glycoprotein of SARS-CoV-2 makes up the monovalent vaccine Covishield. Following injection, the S glycoprotein of SARS-CoV-2 is synthesized locally, inducing immunological responses from the cells and neutralising antibodies (6).

The vaccines for SARS COV2 have demonstrated a high level of safety in global clinical studies, however more data is needed to formulate the exact pathway for the advent of the adverse effects post vaccination. Based on the kind of vaccination received, the parameters connected to the reported adverse effects such as earlier COVID infection, race, gender, age and presence of chronic diseases, are taken into account for analysis.

The term "adverse events after immunisation" (AEFI) refers to any unfavourable medical event that occurs after immunisation but does not automatically have a causal connection to the use of the vaccine. Any unfavourable or unanticipated sign, aberrant test finding, symptom, or illness may qualify as an adverse event. Adverse reactions that are reported can either be "True" (caused by the vaccination or

immunisation procedure) or "Coincidental" (not due to the vaccine or immunisation process but are temporally associated with immunization). According to WHO criteria, "serious" adverse events were those that required hospitalisation, prolonged hospitalisation, a life-threatening condition, or resulted in permanent impairment or death. Any adverse event that is not significant and does not represent a threat to the recipient's health is referred to as a "non-serious" adverse event. (7).

The adverse reactions to the COVID-19 vaccine, in particular Covishield and Covaxin, most frequently include fever, weariness, muscular discomfort, joint pain, and headache, according to data released from vaccination studies, but significant adverse events were seldom observed. In the Covaxin vaccination study, injection site discomfort, headache, tiredness, fever, body ache, stomach pain, nausea, and vomiting, as well as dizziness, giddiness, tremors, sweating, colds, and coughs, make up the bulk of the AEFIs that are recorded. There have not been any other major adverse reactions to vaccinations documented. Since they are self-limiting, no treatment is necessary.

The following adverse events or reactions (AEFIs) have been reported with Covishield by AstraZeneca. Tenderness, discomfort, tenderness, or itch where the shot is administered are very common side effects (may impact more than 1 in 10 persons), as well as overall malaise, weariness, chills, or fever, headache, nausea, and joint or muscle pain. Common side effects include inflammation or redness where the shot was given, fever, feeling unwell (vomiting or diarrhoea), discomfort in the arms or legs, and flu-like symptoms such a high body temperature, sore throat, a runny nose, a cough, and chills (which may impact more than 1 in 10 people). Uncommon side effects include tiredness or dizziness, stomach discomfort, swollen lymph nodes, increased perspiration, skin irritation, rash, or hives (which may occur up to 1 in 100 persons). Extreme hypersensitivity reaction (anaphylaxis), severe swelling of the lips, tongue, and throat which may cause difficulty in swallowing or breathing are unidentified side effects (the incidence cannot be established from the data supplied). Most rare side effects are venous and/or arterial thrombosis and thrombocytopenia and have very infrequently (less than 1 in 100, 000 vaccine recipients) been recorded. (5) (8).

The SARS-CoV-2 coronavirus genome is incorporated into the adenovirus DNA that serves as the foundation for the Sputnik vector vaccine. Adenovirus serves as a "container" to introduce a potential adversary to the immune system by delivering the coronavirus gene to cells and producing the SARS-CoV-2 virus's envelope proteins. The spike protein is then created by the cells using the gene. At the injection site, discomfort, redness, or swelling have been reported as minor adverse effects. Asthenia, Fatigue, muscle aches, a sore throat and a cough nasal obstruction, chills and a fever, vomiting and nauseous, Diarrhoea, Headache have also been reported (9) .

Precaution needs to be taken while vaccinating individuals having allergies, comorbidities, acute infection in the last 3 months, and individuals on chronic

Precaution needs to be taken while vaccinating individuals having allergies, comorbidities, acute infection in the last 3 months, and individuals on chronic

As of September 20, 2021, the adverse events following COVID-19 vaccination was 0.005%. However, these numbers may be grossly underestimated as the mechanism of adverse event following immunization (AEFI) reporting was not known to all.

As of 01 July 2022, the total number of COVID vaccinations done in India is 1, 97, 74, 71, 041 and as of March 20, 2022, the adverse events following COVID 19 vaccination was 0.006% (10). However, these numbers may be grossly underestimated as the mechanism of AEFI reporting was not known to all. As per the Government of India, anyone having any AEFI after receiving any COVID 19 vaccine can contact the helpline number: +91-11-23978046, technical helpline number: 0120-4473222, helpline email id: nvoc2019[at]gov. in, or can contact the vaccination centre where they took vaccination (10) .

Our study's major objective is to statistically assess and explain the usefulness of telemedicine in Apollo Telehealth (ATH) for providing care who have mild to moderate side effects after receiving the COVID 19 vaccination. Telemedicine is a significant advancement in the manner that healthcare is offered in the twenty-first century by utilizing information and communication technology (ICT). Doctor on call is a telehealth service devised and conceptualized by Apollo Telehealth in its endeavour to provide instant virtual access to the patients with expert doctors, specialists, and super specialists of ATH (11). Without waiting for long hours in hospitals for physical consultations and without spending large amounts on consultation fees this round-the-clock service is an exceptional tool for the patients for all their health queries and advises. The scope of this health care service extends from treating the symptoms of all illnesses to offering guidance on healthy lifestyles and managing chronic disorders. Patients of Doctor on Call receive personalized, high-quality healthcare in the comfort of their own homes. In the current COVID pandemic situation, it prevents unnecessary travels to hospitals and doctors in particular, while still giving the client the required care and much-needed mental peace. Through this facility, which is quick and easy to use, patients may access a wide range of current medical services utilizing technology and information.

2. Materials & Methods

This review was done at Apollo Telehealth (ATH), Hyderabad from January 2021 to May 2022. Before allowing access to the analysis, we made sure that the patients' and doctors' identities were safe. There was no identifying information from the patients or doctors in the voice or video call data that was analysed. We performed a descriptive analysis of COVID-19-post vaccination-related teleconsultations data, dating from the first received call

related to COVID-19 in Apollo Telehealth (ATH), (29th February 2020), to (27th November 2020). Figure 1 shows a flow chart of the process that we follow for teleconsultation call.

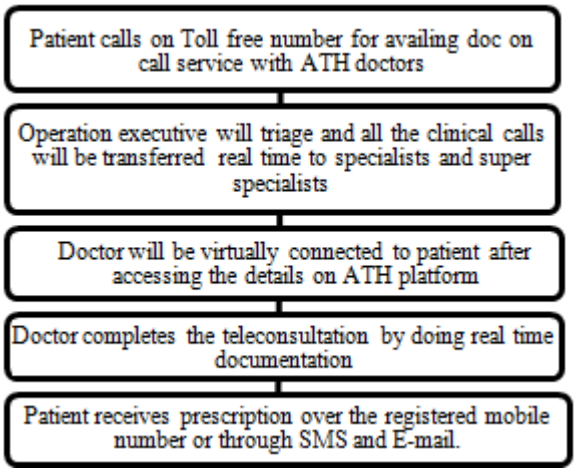

Figure 1: Process flow of teleconsultation call

Our data of EMR (electronic medical record) was retrieved from one primary source from the internal servers of ATH which included the patient demographical record, the raw data of transcripts of teleconsultations available in the dropdown sections provided for primary diagnosis, secondary diagnosis and chief complaints and also free text form of history of present illness that were typed by each attending physician during the teleconsultations with their corresponding clinical information (nature of adverse effects, vaccination history, type of vaccine etc) for each of the calls. To select the internal data from ATH we filtered the calls that corresponded to the COVID-19 post vaccination teleconsultations that were classified by the teleconsultant (physicians), during each of the calls. To ensure the robustness of the data, structure of the database and text formatting, we performed a visual inspection from a sample of cases chosen at random. From the structure of the EMR database, we identified duplicate data that we removed; excluded teleconsultations not pertaining to COVID 19 post vaccination, as some of the tele consultations (TC) were general vaccine queries. (Figure 2)

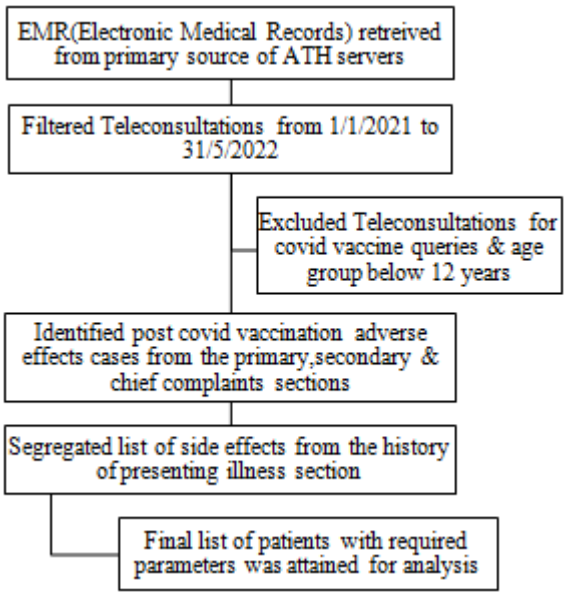

Figure 2: Analysis of patients' data for the study

As the nature of some of our data was in the form of text, we searched for alternatives to transform the qualitative information into a quantitative representation. We identified two strategies, the first one was to estimate the frequency of terms that provided the most common mentioned terms and the second one estimating clusters of topics. Collected data was primarily synthesized and presented as descriptive statistics (frequencies and proportions). We used Microsoft Excel to tabulate and analyze the data. The analyzed data is presented as tables in the Results section. (Table 1)

We acknowledge that this study has some limitations, including the single-centre setting which may hinder the generalizability of our findings. In addition, the causality association between COVID 19 vaccination and adverse effects cannot be confirmed here as the study was a single arm with no control group.

Statistical analysis

The statistical analysis was performed using Scipy module (ver.1.7.3) of Python. Descriptive analysis was performed in MS Excel for several demographic (Age, Gender and BMI) and clinical (side-effects and COVID vaccine type) aspects. In statistical analysis, several association tests were performed. For inferring association between a categorical feature with another categorical feature, Chi-square test was performed with 95% CI. For inferring association between a categorical feature with 2 unique entities against a numerical feature, Student's T test was performed with 95% CI. For inferring association between a categorical feature with >2 unique entities against a numerical feature, One-way F test was performed with 95% CI. To check multi-collinearity among side-effects, correlation of each was compared on a heatmap.

3. Results

Most of the tele consultations done included mild and moderate adverse effects post COVID vaccination. The treatment usually involves general instructions and remedies such as adequate rest, maintaining hydration and having a healthy nutritious diet along with symptomatic treatment as most of these adverse effects are self-limiting. These symptoms in a way indicate the vaccine is causing the desired immune response.

Since the vaccination drive in India started officially in January 2021 the study involves the time period of January 2021 to May 2022. The total number of COVID vaccine tele consultations during this time period were 70, 790 out of which finally 6373unique patient consultations were finally retrieved with the necessary parameters for this study

It is impossible to overstate the importance of timely and efficient communication during a large immunisation campaign against COVID-19. Hence there is a need for double and stronger effort to manage AEFI and to vaccinate against COVID-19. Worldwide, there already are reservations regarding the vaccine's efficacy, rate of development, and safety. The use of telemedicine in the shape of Tele Consultations on the dissemination of information of COVID-19 vaccination adverse side effects has indeed been playing a pivotal role towards attempting to

address the management of mild to moderate adverse effects virtually, as has been in use by the World Health Organization and many countries worldwide.

The final list of patients with required parameters attained were 6373. Out of these patients females were 2741 (43.02%), males were 3631 (56.98%). Among all the patients, 239 (3.75%) were from 12-17 years age group, 3549 (55.69%) were from 18-40 years age group, 1821 (28.57%) from 41-60 years age group and 764 (11.99%) above 60 years age group. The BMI of the patients below 25 were 4897 (76.85%) and 1475 (23.15%) were greater than or equal to 25. Among all the subjects the distribution of vaccine types was covaxin 3505 (55%), Covishield 2549 (40%), Sputnik 319 (5%).

All the study participants experienced all the adverse events post vaccination. Gender-wise comparison of adverse symptoms occurring post-vaccination were 2741 (43.02%) in female and 3631 (56.98%) in males. The overall incidence of Respiratory tract symptoms (42.22%), Fever (32.77%), Malaise (8.24%), Headache (5.97%), Giddiness (2.55%), Diarrhoea (1.58%), Dyspnoea (1.64%), Abdominal pain (1.22%), chest discomfort (1.18%), vomiting (1.54%), Arthralgia (0.55%), Injection arm pain (0.62%), Nausea (0.45%), Myalgia (0.35%), Chills (0.11%) (Table 1).

Table 1: Prevalence of the COVID-19 vaccine adverse effects based on gender

Side effect	*Female*	*Male*	*Total*	*p-Value**
Respiratory Tract Symptoms	1120 (40.87%)	1570 (43.25%)	2691 (42.22%)	4.65E-13
Fever	882 (32.17%)	1207 (33.23%)	2088 (32.77%)	7.47E-04
Malaise	236 (8.62%)	289 (7.96%)	525 (8.24%)	3.38E-04
Headache	187 (6.82%)	193 (5.33%)	380 (5.97%)	3.70E-21
Giddiness	74 (2.68%)	89 (2.45%)	163 (2.55%)	2.66E-02
Diarrhoea	44 (1.61%)	56 (1.56%)	101 (1.58%)	5.46E-01
Dyspnoea	42 (1.54%)	62 (1.71%)	104 (1.64%)	5.43E-02
Abdominal Pain	41 (1.51%)	36 (0.99%)	77 (1.22%)	1.66E-12
Chest Discomfort	27 (0.98%)	49 (1.34%)	75 (1.18%)	4.57E-07
Vomiting	20 (0.72%)	15 (0.40%)	34 (1.54%)	7.32E-11
Arthralgia	20 (0.72%)	15 (0.42%)	35 (0.55%)	1.77E-09
Injection Arm Pain	20 (0.72%)	20 (0.55%)	40 (0.62%)	1.24E-03
Nausea	16 (0.60%)	12 (0.34%)	29 (0.45%)	1.11E-08
Myalgia	9 (0.33%)	13 (0.36%)	22 (0.35%)	5.09E-01
Chills	3 (0.11%)	4 (0.12%)	7 (0.11%)	8.95E-01

*Chi-squared test was used with a significance level of < 0.05

Test for Association – Side Effects with Gender

H_0: Side Effects don't vary among different Genders.

The p-value of chi-square tests with 95% CI was observed to be 1.2e-104, thus failed to accept null hypothesis. Hence, side effects vary among different gender. When tested for each side effect for their association with gender, the p-values observed as shown in table 1, infer every side effect affects different genders distinctively, except Chills, Dyspnoea, Diarrhoea and Myalgia. The distribution among of side effects among different gender (along with p-values observed) Table 1

Test for Association – Side Effects with BMI

H_0: Side Effects don't change with varying BMI

The distribution of BMI was observed to be normal with mean=22.69 and median=22.354, validated with skewness of distribution (coeff. of skewness = 0.57). The distribution of BMI in all the side effects are observed to be normal which can be witnessed in their corresponding distribution plots Figure 2 and coeff. of skewness mentioned below each's. The p-value of Anova test with 95% CI was observed to be 5.69e-68, thus, failing to accept null hypothesis we can conclude side effects change with varying BMI.

Test for Association – Each Side Effects with BMI

When tested for each side effect, individually, for their association with BMI, the side effects-Malaise, Chills, Giddiness, Diarrhoea and Nausea were found to have association with BMI. The p-values of individual Anova tests (95% CI) are as follows –

Table 2: Individual side effects Anova tests

Side Effect	*p-value*
Respiratory Tract Symptoms	4.32E-52
Fever	1.17E-156
Malaise	1.19E-01
Abdominal Pain	1.62E-05
Headache	2.55E-14
Chills	2.86E-01
Giddiness	8.93E-01
Diarrhoea	5.07E-01
Nausea	1.80E-01
Arthralgia	3.88E-07
Vomiting	1.73E-10
Chest Discomfort	6.49E-04
Injection Arm Pain	2.10E-02
Dyspnoea	1.30E-10
Myalgia	5.08E-04

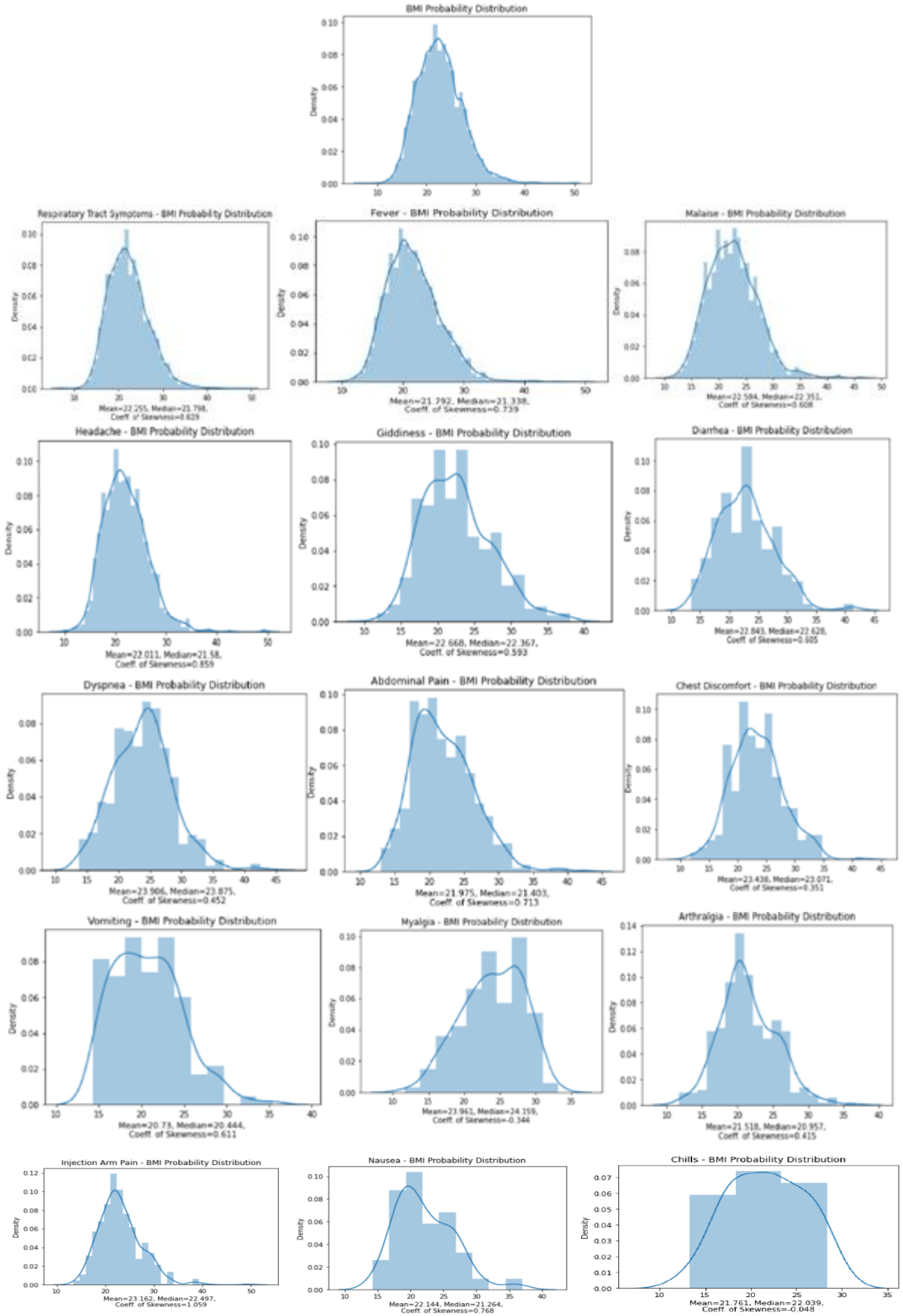

Figure 2: Distribution plots of side effects with BMI.

Side-Effects' Correlation for Multi-collinearity

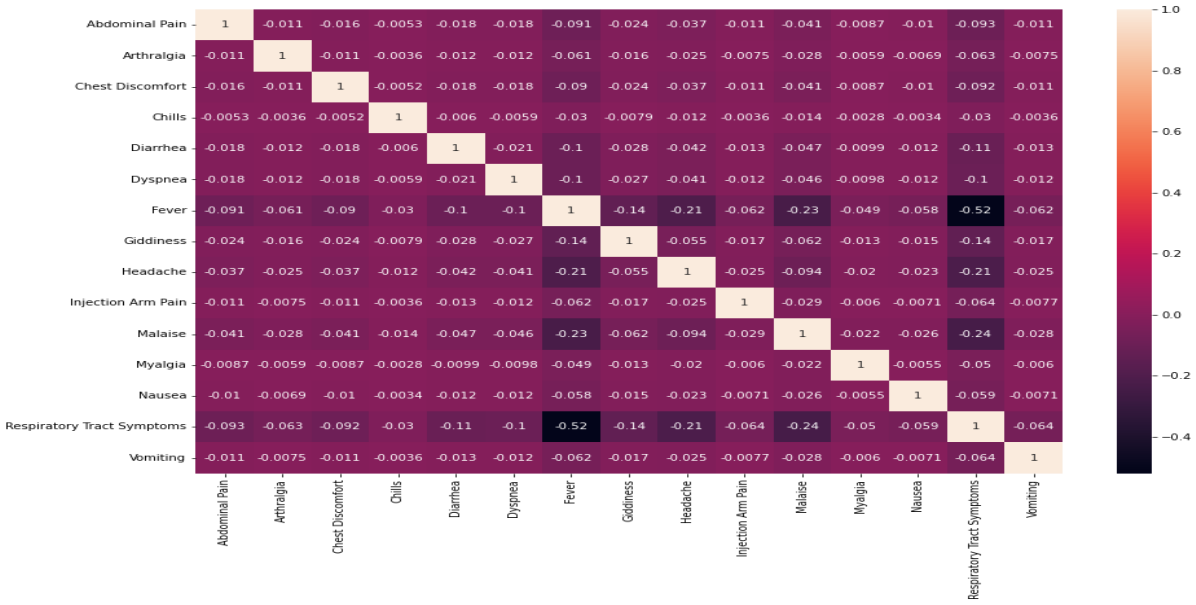

Figure 3: Heatmap of the correlation matrix of side effects

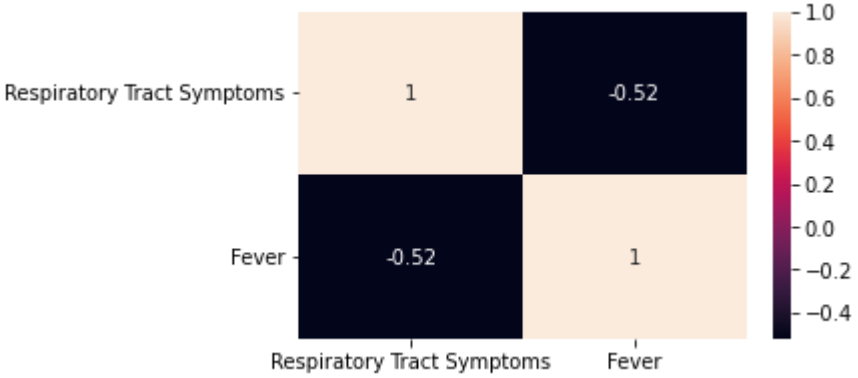

Figure 4: Observed Multi-collinearity

In the heatmap of correlation matrix, we can witness the correlation of side-effects of fever cases (2088) & Respiratory tract symptoms (2691) with each other. Among all, Fever and Respiratory Tract Symptoms are observed to be multi-collinear, i. e, having significant correlation and are inversely associated.

4. Discussion

The present study was aimed to evaluate the telemedicine intervention in controlling mild to moderate AEFIof COVID vaccination, along with assessing the prevalence of adverse effects occurring among the patients. In our study out of the 6373 total unique patients, males constituted higher percentage 56.98% than female patients 43.02%. Among these patients the majority were from 18-40 years age group 55.69%followed by 41-60 years age group 28.57%, above 60 years age group constituted 11.99% and patients constituting 12-17 years age group were 3.75%. The BMI of the group included 76.85% below 25 and 23.15% from greater than or equal to 25. The vaccine types were significant with 55% in covaxin group, followed by covishield group 40% and lesser in sputnik 5%.

In our study, most of the patients reported respiratory tract symptoms 42.22%, followed by Fever 32.77% and Malaise 8.24%. This incidence was greater in males 56.98% than females 43.02%.

The association test for side effects with gender inferred that every side effect impacted different genders distinctively, except Chills, Dyspnoea, Diarrhoea and Myalgia. The test for association between BMI and Side effects resulted that side effects change with varying BMI values. When tested for individual side effects multi collinearity tests fever and respiratory tract symptoms showed significant correlation.

After reviewing the published articles in India on Post COVID vaccine adverse effects the majority studies were focused on qualitative aspects such as COVID vaccine hesitancy, safety, efficacy, and isolated side effects of the particular vaccine types. Our study tries to address the various side effects experienced by the patients among the different vaccine types, extent of side effects, influence on gender, BMI and statistical significance of the each adverse effects and thus has helped in depicting how telemedicine has very conveniently helped to deal with these patients recover from mild to moderate adverse effects post COVID vaccination.

The Indian government has recently allowed vaccinations for children older than 12 years and booster doses of the COVID vaccine. Therefore, a long-term study that includes

the paediatric population along with booster doses and different sociodemographic characteristics of the community would shed more light on any potential long-term adverse effects of the COVID-19 vaccine and would also reiterate the fact as to how telemedicine would play that much needed missing link in the present healthcare infrastructure of India.

5. Conclusion

The easiest, safest and effective platform to evaluate and manage COVID 19 cases is telemedicine, which in turn has been successful in drastically reducing the transmission of disease. In the event of a pandemic, telemedicine also makes it possible for many of the essential clinical activities to continue to run normally and without interruption. The delivery of health care is enhanced through the use of telehealth. Therefore, telemedicine should be an important tool for medical care services while ensuring the safety of patients as well as healthcare providers in the event of COVID-19. This study provides a comprehensive analytical review that investigates the potential of telemedicine during the COVID-19 pandemic. As the COVID-19 pandemic spreads exponentially around the world, increasing the use of telemedicine as an innovative solution underscores the unmet needs of the global healthcare system. In the wake of such pandemics, only telemedicine has the ability to lessen many of the major logistical issues in the present healthcare delivery system of India. In addition to reduction in the disease transmission by avoiding unnecessary direct physical contact, telemedicine has also been helping the community to seek the best healthcare and support in continuum. This study demonstrates unequivocally how important telemedicine is for treating mild to moderate side effects following COVID immunisation. Without telemedicine, these patients who experienced adverse effects would have attended a hospital, further draining India's already overworked healthcare system. Physicians and patients are highly recommended to use telehealth technologies as a suitable choice to avoid and limit COVID-19 infection in light of the outcomes of this review research.

6. Future Scope

The study focused on the patients' self-reported side effects which were short-term in nature. Moreover, at the time of the study participants received first and second doses of COVID vaccination, examining long-term side effects with larger participants along with booster dosages might be recommended for future studies.

Conflicts of Interest: The authors declare that there was no conflict of interest.

References

[1] Kaur SP, Gupta V. COVID-19 Vaccine: A comprehensive status report. Virus Res.2020 Oct 15; 288: 198114.
[2] Alghamdi AA, Alkazemi A, Alissa A, Alghamdi I, Alwarafi G, Waggas HA. Adverse Events following AstraZeneca COVID-19 Vaccine in Saudi Arabia: A Cross-Sectional Study among Healthcare and Nonhealthcare Workers. Intervirology.2022; 65 (2): 104–9.
[3] India rolls out the world's largest COVID-19 vaccination drive [Internet]. [cited 2022 Aug 5]. Available from: https://www.who.int/india/news/feature-stories/detail/india-rolls-out-the-world-s-largest-COVID-19-vaccination-drive
[4] Information Regarding COVID-19 Vaccine [Internet]. [cited 2022 Aug 5]. Available from: https://www.mohfw.gov.in/COVID_vaccination/vaccination/index.html
[5] COVAXIN-India's First Indigenous COVID-19 Vaccine | Bharat Biotech [Internet]. [cited 2022 Aug 5]. Available from: https://www.bharatbiotech.com/covaxin.html
[6] Serum Institute Of India-ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)-COVISHIELD [Internet]. [cited 2022 Aug 5]. Available from: https://www.seruminstitute.com/product_covishield.php
[7] Global manual on surveillance of adverse events following immunization [Internet]. [cited 2022 Aug 5]. Available from: https://www.who.int/publications-detail-redirect/10665206144
[8] Kamal D, Thakur V, Nath N, Malhotra T, Gupta A, Batlish R. Adverse events following ChAdOx1 nCoV-19 Vaccine (COVISHIELD) amongst health care workers: A prospective observational study. Med J Armed Forces India.2021 Jul; 77: S283–8.
[9] Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial-The Lancet [Internet]. [cited 2022 Aug 5]. Available from: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736 (20) 31604-4/fulltext
[10] Information Regarding COVID-19 Vaccine [Internet]. [cited 2022 Aug 8]. Available from: https://www.mohfw.gov.in/COVID_vaccination/vaccination/index. html
[11] Apollo Telehealth | Telehealth Services in India | Telemedicine | TeleConsultation Services [Internet]. [cited 2022 Aug 5]. Available from: https://www.apollotelehealth.com/