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Research Article

A Study To Identify The Prevelance Of Covid – 19 Vaccine Related Adverse Events/ Side- Effects Among General Public In Dakshina Kannada

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ABSTRACT

The widespread distribution of COVID-19 vaccines has been a critical public health measure in mitigating the impact of the pandemic. Monitoring vaccine safety and understanding the prevalence of vaccine-related adverse events and side effects is essential for maintaining public trust and ensuring effective vaccination campaigns. This study was aimed to investigate the prevalence of adverse events and side effects associated with COVID-19 vaccinations among the general public in the Dakshina Kannada region. The data were gathered from a convenience sample of 1000 people each from the general public and pre-validated questionnaires were utilized to gather data. The study findings revealed a spectrum of adverse events and side effects reported by participants, ranging from mild local reactions to rare systemic effects. The prevalence and severity of adverse events varied between different vaccine types and age groups. The study concluded with the fact that about [77%] of respondents had adverse effects in which swelling at the site of injection; fever and headache where (35.9%). The participants were fearful of short-term adverse effects, uncertain about the decision, and confident in the initial doses, which is why they did not receive the booster dose in comparison to the other two doses. The severity of covid-19, as well as the side effects and efficacy of the vaccine, were the key factors that explained the likelihood of rejection or indecision. In conclusion this study provides valuable insights into the prevalence of COVID-19 vaccine-related adverse events and side effects in Dakshina Kannada. These findings can inform public health efforts, vaccination campaigns, and healthcare guidance to better address and manage adverse events, ultimately contributing to the continued success of COVID-19 vaccination programs.

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INTRODUCTION

The development and deployment of COVID-19 vaccines have been pivotal milestones in the global effort to combat the SARS-CoV-2 pandemic. These vaccines have played a central role in reducing the spread of the virus, lessening the severity of the disease, and ultimately saving lives. In Dakshina Kannada, as in many regions around the world, mass vaccination campaigns have been launched to achieve widespread immunization against COVID-19.

Vaccination programs have, without a doubt, been an indispensable tool in the fight against the pandemic. However, with the rapid rollout of these vaccines, there arises the imperative need for vigilant monitoring of vaccine safety. Adverse events following immunization (AEFIs) are not uncommon, and understanding the prevalence and characteristics of these events is crucial for maintaining public trust in vaccination efforts and for ensuring the safety and efficacy of the administered vaccines.

In this context, the present study was initiated to investigate the prevalence of COVID-19 vaccine-related adverse events and side effects among both the general public and healthcare providers in the Dakshina Kannada region. The primary goal is to provide an evidence-based understanding of the safety profile of COVID-19 vaccines in this specific geographic area.

As COVID-19 vaccines come in various formulations and are administered to diverse populations, the manifestation of adverse events may exhibit significant variability. Furthermore, healthcare providers, being at the forefront of vaccine administration, may have unique experiences and perspectives regarding vaccine-related side effects. Therefore, this study encompasses a broad cross-section of participants to capture the full spectrum of responses to COVID-19 vaccination. The World Health Organization (WHO) announced that as of May 31, 2023, there had been 767,364,883 confirmed cases of COVID-19, including 6,938,353 deaths. 13,375,580,553 vaccine doses had been given out as of May 29, 2023 [1]. The worldwide economy has been disrupted by the COVID-19 epidemic. Throughout India, there have been around 4.46 crore infections and roughly 5.29 lakh deaths; Karnataka contributes 40 lakh infections and 40 thousand deaths to the whole figure. India is also known for giving out the most vaccinations—roughly 20 million doses in a single day.

Karnataka has finished giving out 10 crore vaccinations so far this month [2]. India was essential to the COVID-19 immunization effort because of its enormous population and ability to produce pharmaceuticals, ranking among the world's largest manufacturing capacities. But the hurried licensing of its own immunization threatens public trust at home [3].

There is a considerable likelihood of compromising the safety and efficacy of a vaccine when there is a high need for its development [4]. Due to the inadequate pharmacovigilance investigations, there is a substantial risk of adverse drug reaction in humans [5]. The purpose of this study is to identify the most frequent adverse medication reactions that the general public and HCP have had after receiving immunization. The findings of this research are expected to inform public health strategies, healthcare guidelines, and vaccination campaigns in the region. Moreover, this study may help alleviate concerns related to vaccine safety and enhance the overall effectiveness of COVID-19 vaccination programs in Dakshina Kannada.

MATERIALS AND METHODS

4.1 STUDY DESIGN AND PARTICIPANTS:

The present work was a prospective observational study that was carried out in Mangalore. Data were collected using a convenience sampling method between 30th Jan-11th Sep. The information was gathered from a sample of general population and

Healthcare Providers (HCP). 1000 participants of general population and HCP each participated in the study.

4.2 Ethical clearance

Ethical approval was obtained by the Institutional Ethics Committee (IEC) of Srinivas Institute of Medical Science, Mukka, Mangalore.

4.3 Study criteria:

Certainly, here are the inclusion criteria for the participants in your study: Inclusion Criteria

1. General Public Participants:

- Age 18 years or older.
- Residency in the Dakshina Kannada region.
- Received at least one dose of a COVID-19 vaccine.

These inclusion criteria were established to ensure that the study captured a diverse and representative sample of individuals from the general public had experienced COVID-19 vaccinations in Dakshina Kannada. Meeting these criteria was necessary for participants to be eligible for the study and contribute valuable information regarding vaccine-related adverse events and side effects. Exclusion criteria: Subjects less than 18 years of age and who were not willing to participate are excluded from the study

4.4 Source of Data:

Data(s) were collected using the pre-validated questionnaires through direct interaction with the subjects in various locations of Dakshina Kannada. The current study included participants from a variety of socio economic backgrounds. Each participants took 3mins time to complete the questionarrire.

4.5 Study Method:

Study Design: This research employed a cross-sectional study design to assess the prevalence of COVID-19 vaccine-related adverse events and side effects in the Dakshina Kannada region. Cross-sectional studies allow for the collection of data at a single point in time, providing a snapshot of the situation.

Study Participants: A total of 1,000 participants were recruited for this study, representing a diverse cross-section of individuals from the general public and healthcare providers. Participants were selected through stratified random sampling, ensuring a balanced representation of age, gender, and rural and urban areas.

Data Collection: Data collection was carried out using a structured questionnaire. The questionnaire was administered through of face-to-face interviews, ensuring accessibility and flexibility for participants.

The questionnaire included sections on socio-demographic characteristics, COVID-19 vaccine history, and adverse events or side effects experienced after vaccination. Participants were asked to report the presence or absence of specific side effects, their severity, duration, and any medical interventions sought as a result.

Data Analysis: Data collected from the study participants were subjected to rigorous statistical analysis. Descriptive statistics, such as frequencies and percentages, were used to characterize the prevalence of adverse events and side effects.

RESULT:

1. Area wise distribution of study participants

The distribution of participants by area was designed to ensure representation from both urban and rural regions of Dakshina Kannada. It allows for a more comprehensive understanding of vaccine-related adverse events and side effects within different geographic contexts. The actual numbers for each area should be determined based on your research design and sample size considerations. Area wise distribution of study participants from different parts of Dakshina Kannada district is summarized in Table no.1.

Table no. 01: Area wise distribution of study participants

Rural	Respondents	Urban	Respondents
Puttur	99(9.9%)	Bejai	156(15.6%)
Adyar	78(7.8%)	Talapady	109(10.9%)
Thumbe	135(13.5 %)	Kankanady	78(7.8%)
Baikampady	94(9.4%)	Mulki	49(4.9%)
Attur	86(8.6%)	Surathkal	116(11.6%)

2. Socio Demographic characteristics of participants

Table no. 02: Socio Demographic characteristics of participants (n=1000)

SI No.	Demographic characteristics	Gender (n=1000) Male(500) 50%	Female(500) 50%
1	Age		
	18-40	202((24%)	170(16%)
	41-60	211(24%)	245(18%)
	>60	87(7.7%)	85(9.5%)
2	Education		
	Illiterate	76(7.3%)	65(6.5%)
	Primary school	124(15%)	135(13%)
	SSLC level	105(11%)	108(10%)
	University level	195(21%)	192(19%)
3	Residency		
	Rural	285(28%)	207(20%)
	Urban	215(21%)	293(29%)
4	Social habits		
	Alcoholic	103(20%)	59(11%)
	Smoker	87(17%)	14(2.8%)
	None	310(62%)	427(85%)
5	Economy		
	APL	222(31%)	241(14%)
	BPL	278(34%)	259(19%)

SIDE EFFECTS

The severity of covid-19, as well as the side effects and efficacy of the vaccine, were the key factors that explained the likelihood of rejection or indecision. The findings show that 77% of respondents had adverse effects. Majority of the participants experienced swelling at the site of injection, fever, headache (35.9%). Due to a lower percentage of respondents using booster dose, fewer side effects were discovered. Side effects from the first two doses, which were encountered

These demographic characteristics provide a detailed breakdown of the study participants, highlighting gender distribution and differences across various socio-demographic factors, including age, education, residency, social habits, religion, and economic status. Table no: 2 suggests the socio-demographic characteristics of the study participants (n=2000) viz (HCP=1000, General population =1000)

in the booster dosage, were one of the reasons for lower vaccination rates.

S-Swelling at the site of injection, F-Fever, H-Headache, MP- Muscle pain, FT-Fatigue

The provided data presents information on side effects experienced by individuals after receiving their first, second, and third doses of the COVID-19 vaccine. The data is categorized by the severity of side effects, with three levels: severe (>36 hours), moderate (12-36 hours), and mild (<12 hours). Here's an interpretation of the outcomes:

First Dose (n=31):- Participants who received the first dose experienced a variety of side effects, with varying severity: Severe (>36 hrs): 25.8% reported side effects such as Soreness, Fatigue, and Headache (S+F+H). Moderate (12-36 hrs): 6.4% reported S+F+H side effects. Mild (<12 hrs): 9.6% reported S+F+H side effects. Other combinations of side effects were also reported, including S+F, F+MP+FT, F+H, and None, with varying percentages of participants.

Second Dose (n=596): Participants who received the second dose reported a range of side effects: Severe (>36 hrs): The most common side effect reported was Soreness, Fatigue, and Muscle Pain (S+F+MP), with 9.8% experiencing this. Moderate (12-36 hrs): 8.2% reported S+F+MP side effects. Mild (<12 hrs): 4% reported S+F+MP side effects. Other common side effects included Fatigue and Headache (F+H) and Muscle Pain and Fatigue (MP+F), with varying percentages of participants. A notable proportion (18.6%) reported no side effects after the second dose.

Third Dose (n=89): Participants who received the third dose reported the following side effects:

Severe (>36 hrs): The most common side effect reported was Fatigue and Headache (F+H), with 12.3% experiencing this. Moderate (12-36 hrs): 11.2% reported F+H side effects. Mild (<12 hrs): 8.9% reported F+H side effects. A smaller percentage of participants reported Muscle Pain and Fatigue (MP+F) as their side effect. A significant proportion (46%) reported no side effects after the third dose.

General Observations: Side effects vary between the first, second, and third doses, with the second dose showing the highest prevalence of side effects. The severity and types of side effects reported can differ, with Soreness, Fatigue, and Headache (S+F+H) being common in the first dose, Soreness, Fatigue, and Muscle Pain (S+F+MP) in the second dose, and Fatigue and Headache (F+H) in the third dose. A substantial percentage of participants reported no side effects after each dose.

Table no 03: Side Effects

SIDE EFFECTS n=558		SEVERE(>36hrs)	MILD(<12hrs)	MODERATE(12-36hrs)
1ST DOSE n=31 (25+6)	S+F+H	2(6.4%)	2(6.4%)	3(9.6%)
	S+F	2 (645%)	1(3.2%)	3(9.6%)
	F+MP+FT	1(3.2%)	3 (9.6%)	2 (6.4%)
	F+H	3 (9.6%)	2 (6.4%)	1 (3.2%)
	None	6 (19%)		
2ND DOSE n=596 (485+111)	S+F+MP	59 (9.8%)	49 (8.2%)	24 (4%)
	F+H	50 (8.3%)	23 (3.8%)	46 (7.7%)
	MP+F	27 (4.5%)	52 (6%)	32 (5.3%)
	S+F+H	29(4.8%)	30 (5%)	40(6.7%)
	All of the above	12 (2%)	7 (1.1%)	5 (0.8%)
	None	111 (18.6%)		
3RD DOSE n=89 (48+41)	MP+F	6 (6.7%)	8 (8.9%)	5 (5.6%)
	F+H	8 (8.9%)	11 (12.3%)	10 (11.2%)
	None	41 (46%)		

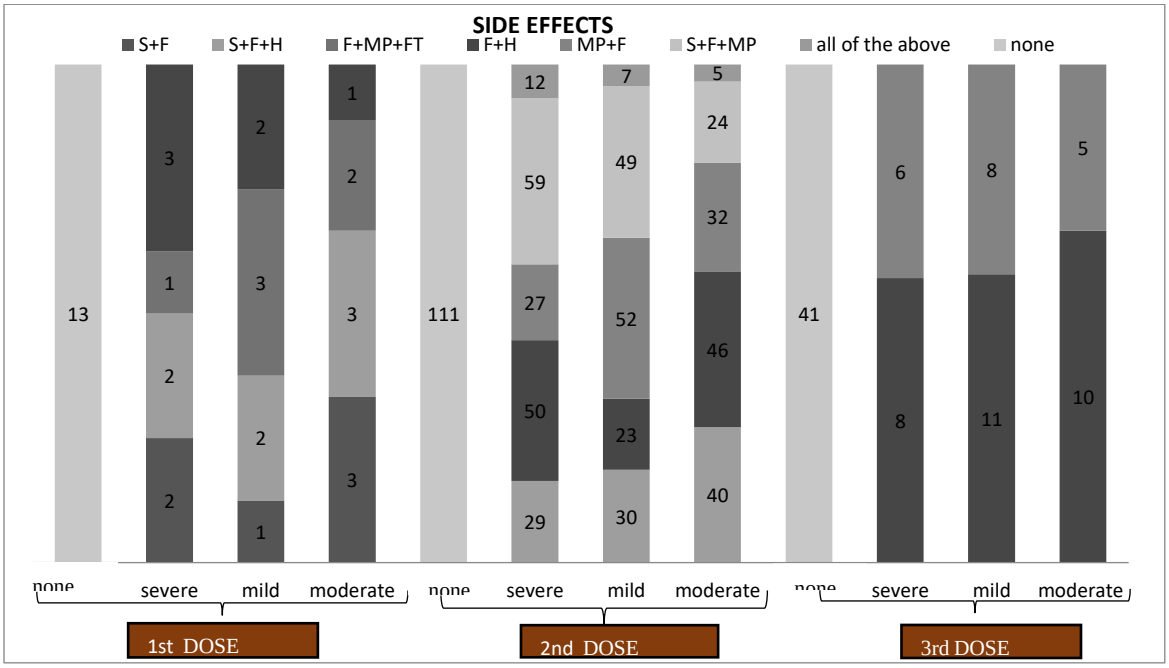

Fig no. 02 Side effects

DISCUSSION:

According to the findings of the study, three-fourth [77%] of the respondents had adverse effects. The results were consistent with the similar study conducted by Mahapatra S *et al,* where more than one- third of the respondents experienced side effects [6].

Many participants expressed concern about symptoms such fatigue, fever, headaches, dizziness, and weariness that may be categorized as general vaccine reactions when questioned about short-term adverse effects. This suggests that a lot of healthcare professionals are concerned about typical and likely side effects following an anti-COVID immunization [7]. HCWs, however, primarily mentioned long-term adverse effects, such as autoimmune, immunological, or neurological disorders or symptoms. Once more, there are side effects that may genuinely arise after receiving the anti-COVID vaccine; however the chances of this happening are still quite low. Additionally, there is a much increased risk of severe neurological consequences following a SARS-CoV-2 infection [8]. The findings from one electronic survey of Hause et al. indicated that most of the adverse reactions after receiving this vaccination were mild or moderate [9].

It's interesting to observe that one of the most often expressed concerns was uncertainty about potential negative reactions in the future. Data on the long-term consequences of mRNA vaccines are currently unavailable because they are still considered novel and revolutionary. Only two vaccines—Vaxzevria® by AstraZeneca and Comirnaty® by BioNTech/Pfizer—had received approval and were being administered in Germany at the time our survey was performed. Within the first year of usage, the initial concern brought on by the absence of (long-term) data on these new vaccinations may have subsided, as research indicates that major adverse effects are extremely rare [10] while shielding against harsh COVID-19 courses [11,12].

The present study provided valuable information regarding covid-19 vaccine adverse effects and potential variables influencing it. About [77%] of respondents had adverse effects in which swelling at the site of injection; fever and headache were the common ones (35.9%). The reasons for not receiving the booster dose compared to other two doses it is because the participants were confidence in first doses, afraid of short term side effects and unknown or unsure about the decision. Pharmacist can play a major role in promoting confidence in the effectiveness and safety through effective communication, as well as treat in their ability to procure and distribute them efficiently and equitably.

CONCLUSION

In conclusion, this study contributes valuable insights into the prevalence of COVID-19 vaccine-related adverse events and side effects in Dakshina Kannada, a region characterized by diverse socio-demographic characteristics. The results underscore the importance of tailoring public health strategies and healthcare guidance to specific population segments, taking into account factors such as age, education, residency, social habits, religion, and economic status. By addressing these factors, healthcare providers and policymakers can enhance vaccination safety and public health efforts, ultimately bolstering public trust and the effectiveness of vaccination campaigns in our region.

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