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Assessing Covid Vaccine Side Effects Among Greater Noida Students: A Retrospective Study On Health Impacts

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Abstract

Background

The global COVID-19 pandemic prompted the development of vaccines, with India approving Covishield and Covaxin. Covishield, a viral vector-based vaccine, and Covaxin, an inactivated virus vaccine, underwent rigorous trials. The nationwide vaccination campaign began in January 2021, initially targeting healthcare workers before expanding. Both vaccines have shown efficacy in preventing COVID-19, with stringent monitoring ensuring safety

Meterial and method: A pilot study of purposive sampling among 40 students to confirm the feasibility and acceptability of the study. Data were collected using demographic profile, likert scale questionnaire, based on objective hypothesis to be treated using frequency comparative & inferential statistics using spss 28.

Results: Majority of participants were below 20 years old (54.0%), predominantly female (61.0%), and enrolled in BSc nursing (67.3%), with most in their first year (69.0%) and having received Covishield (69.0%). Significant associations ($p < 0.05$) were found between age and gender with various side effects, while comorbidities showed significant associations with some side effects. No significant associations were observed with the number of vaccine doses except for fever in Covaxin recipients.

Conclusion

This study sheds light on the side effects of Covishield and Covaxin vaccinations. Different demographics displayed varying symptom profiles, revealing statistically significant associations with age, gender, number of doses, and co-morbidities. These insights underscore the need to factor in demographic variables for effective vaccination strategies and post-vaccination symptom monitoring to ensure safety and efficacy.

Keyword: covid 19, covishield, covaxin, side effects, vaccinated students, & demographic variable.

INTRODUCTION

The advent of the novel coronavirus, SARS-CoV-2, in December 2019 precipitated the swift proliferation of COVID-19, resulting in a global pandemic.[1] In response to this unprecedented public health crisis, researchers worldwide embarked on a race to develop effective vaccines to combat the virus. In India, two vaccines received approval for emergency use: Covishield and Covaxin.[2]

Covishield, developed by Oxford-AstraZeneca and manufactured by the Serum Institute of India (SII), utilizes a viral vector-based approach. This vaccine employs a weakened version of a common cold virus (adeno virus), derived from chimpanzees, to deliver the genetic material of the SARS-CoV-2 spike protein into the body.[3] This triggers an immune response, leading to the production of antibodies against the virus. Clinical trials for Covishield involved thousands of participants across different age groups and diverse populations in multiple countries.[9]

On the other hand, Covaxin, developed by Bharat Biotech in partnership with the Indian Council of Medical Research (ICMR) and the National Institute of Virology, is an inactivated virus vaccine.Covaxin contains killed SARS-CoV-2 virus particles that cannot cause the disease but can stimulate an immune response. The clinical trials for Covaxin involved multiple phases, including Phase 1, Phase 2, and Phase 3 trials, which assessed the safety, immunogenicity, and efficacy of the vaccine. Phase-III trials of Covaxin commenced on November 16, 2020, encompassing 26,000 volunteers at 25 sites across India.[9]

Both Covishield and Covaxin underwent rigorous testing to ensure their safety and efficacy.[2] The clinical trial data from outside India demonstrated an efficacy rate of 70.42% for Covishield. Similarly, safety and immunogenicity data from trials on animals and 800 human subjects during Phase-I and Phase-II showed Covaxin to be safe and effective. Bharat Biotech has accumulated a stockpile of 10 million doses of Covaxin and intends to add another 10 million by February 2021. The firm has set a goal to manufacture 150 million doses by July-August 2021, with an ultimate objective of reaching a total of 700 million doses by the end of the year.[2]

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In India, the nationwide vaccination campaign commenced on January 16, 2021, initially focusing on prioritizing healthcare workers, frontline workers, and individuals above the age of 60. Subsequently, the campaign expanded to include those above the age of 45, and eventually, it opened up for the general population aged 18 and above.[3] Monitoring systems were implemented to track and manage any potential side effects of the vaccines.[4]
The rollout of Covishield and Covaxin marked significant milestones in India's fight against the COVID-19 pandemic. These vaccines offered hope for controlling the spread of the virus and mitigating its impact on public health and the economy.[5] However, ongoing surveillance and research remain essential to monitor vaccine efficacy,[6] identify any emerging variants of concern, and address challenges in vaccine distribution and administration.[7] Through collaborative efforts between government agencies, pharmaceutical companies, and healthcare professionals, India continues to navigate the complexities of vaccine deployment and pandemic management.[8]

MATERIAL AND METHODS

A quantitative retrospective study involving 400 students at Sharda School of Nursing Science (SSNSR) from April 4-9, 2023, assessed research feasibility without issues. Subsequent data collection for the main study at SSNSR from April 10-20, 2023, targeted vaccinated students, who completed consent forms, Subject Information Sheets, demographic surveys, and Likert scales. Participants meeting inclusion criteria (belonging to Sharda University and present during data collection) were included, while those unwilling or unavailable were excluded.

Data collection and Outcome measures:

The investigator administered face-to-face demographic questionnaires and Likert scale questionnaires after obtaining informed consent. Demographic information collected included age, gender, year of study, type and number of vaccination doses, and existing co-morbid conditions such as diabetes, hypertension, and thyroid issues. The Likert scale questionnaire consisted of 13 questions. The tool's reliability was confirmed with 40 subjects from the School of Nursing Science, achieving a coefficient of 0.85.

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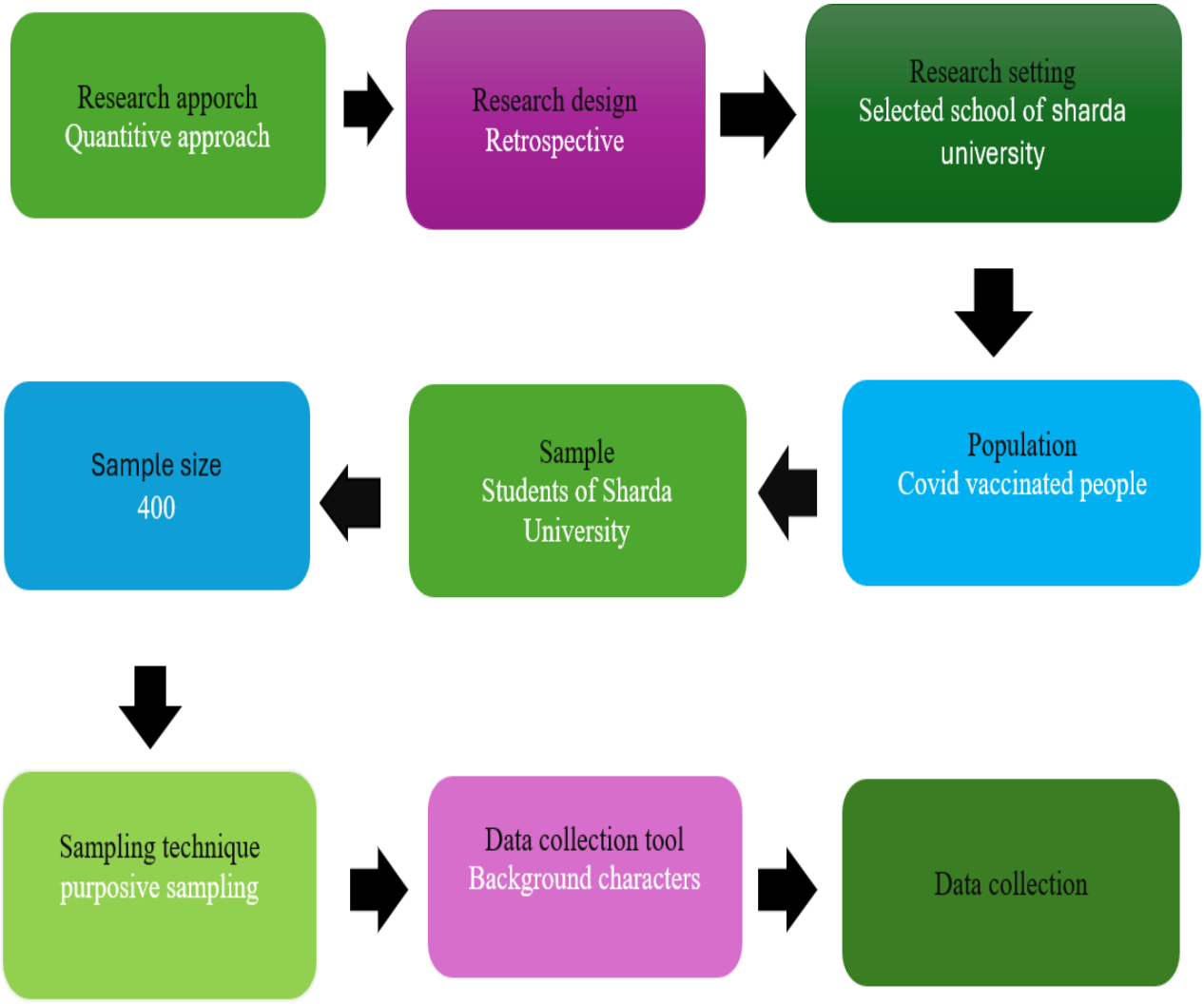

Fig-2: Schematic Presentation of Research Design

Sample size

The sample for the research study consists of students of Sharda University, Greater Noida, and Uttar Pradesh. The sample size determined for this study was 400, calculated using the given formula.

n=4pq/d2

p=Expected Proportion (From Previous-30% of them had covid side effects)

q=1-p

d= Precision p=30% (i.e., 0.30) q=1-p=1-0.30=0.70 d=6%=0.06

n=400

RESULTS

Section 1(Baseline characteristics of post vaccination student and faculty)

Using demographic Performa, data was collected on age, gender, course, year of study ,type of vaccination, year of study, type of vaccination, any co-morbid condition.

Table1 Demographic characteristics of study participants

	Frequency (n) (400)	**Percentage (%)**
Age in years		
< 20 years	216	54
>20 years	184	46
Gender		
Male	156	39
Female	244	61
Course		

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BSc Nursing	269	67.3
PB Bsc	18	4.5
GNM	113	28.2
Year of study		
1st year	179	69
2nd year	74	18.5
3rd year	98	24.5
4th year	49	12.3
Type of vaccination		
Covishield	277	69.3
Covaxin	123	30.7
No of Doses		
Single Dose	37	9.3
Double Dose	314	78.5
Triple Dose	49	12.3
Co- Morbid condition		
DM	9	2.3
HTN	4	1
Thyroid	28	7
Nil	354	88.5

Figure 1 indicate that, majority (54.0%) of the participants were in the age group of below <20 years, most (61.0%) of them were females, majority (67.3%) of them were from B.Sc. nursing ,most 69% were from 1st year , and majority (69.0%) of them taken Covishield, most 78.5% have taken double dose, & most 88.5% having no comorbid condition.

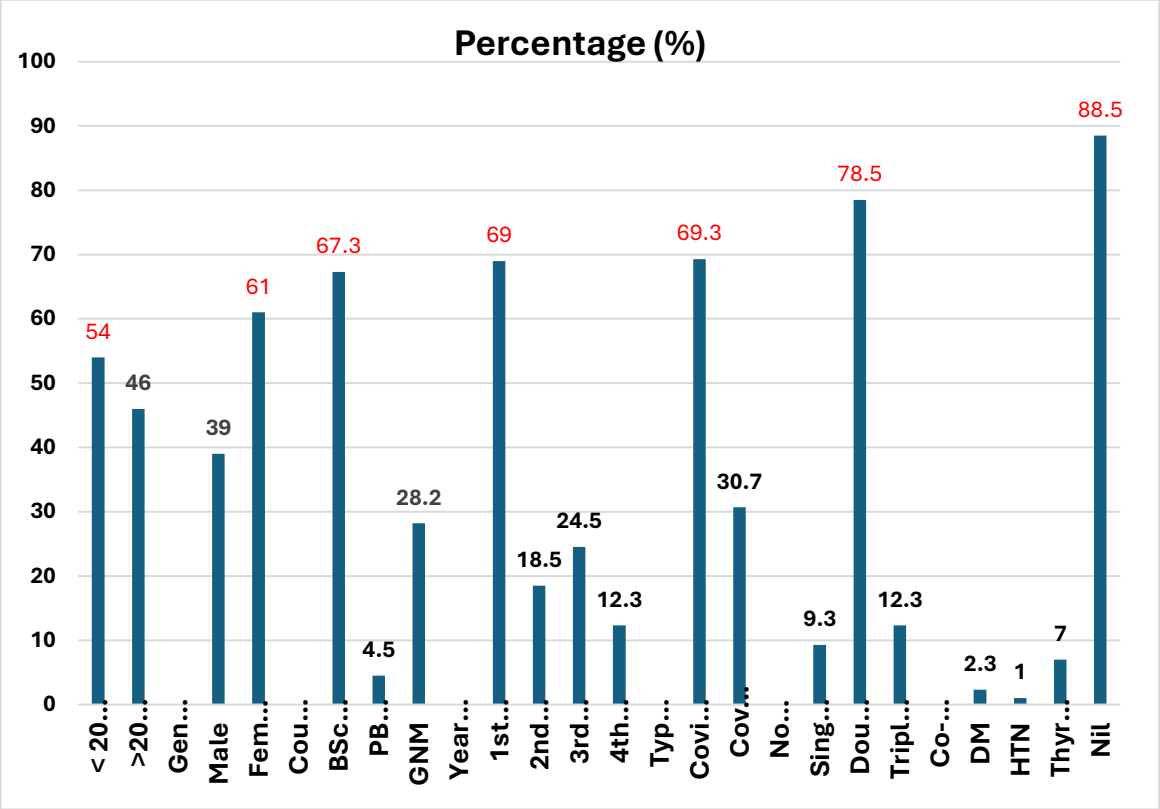

Figure 1. Frequency and percentage distribution based on background variable.

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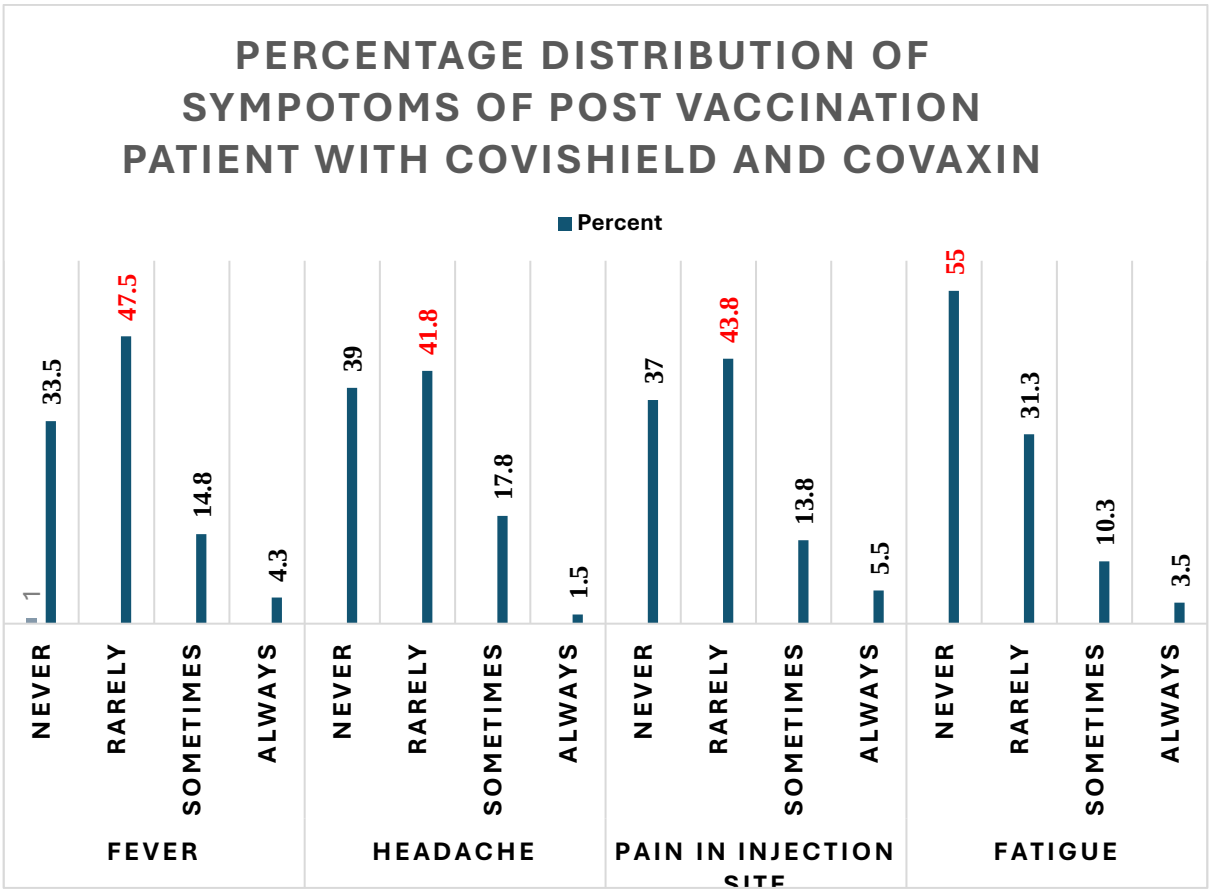

Figure2. Frequency and percentage distribution of symptoms of post vaccination patient with Covishield and Covaxin

The present study showed that the majority rarely experienced fever (47.5%), headache (41.8%), and pain at the injection site (43.8%). Furthermore, most patients (55%) reported never experiencing fatigue. This finding aligns with a descriptive cross-sectional study conducted at Kathmandu Medical College and Teaching Hospital, which also highlighted the prevalence of pain at the injection site (80.90%), fatigue (44.09%), and headache (19.54%) among vaccinated individuals.

Table 1 Comparison of the side effects between Covishield and Covaxin vaccination among the participants (N=400)

SYMPTOMS	Type of vaccination			
	Covishield (n=277)		Covaxin (n=123)	
	Frequency	Percent	Frequency	Percent
1.Fever				
Never	75	27.1	59	48
Rarely	142	51.3	48	39
Sometimes	43	15.5	16	13
Always	17	6.1	0	0
2.Headache				
Never	98	35.4	58	47.2
Rarely	121	43.7	46	37.4
Sometimes	52	18.8	19	15.4
Always	6	2.2	0	0
3.Pain in injection site				
Never	91	32.9	57	46.3
Rarely	123	44.4	52	42.3
Sometimes	41	14.8	14	11.4
Always	22	7.9	0	0

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4.Chest pain				
Never	246	88.8	120	97.6
Rarely	26	9.4	3	2.4
Always	4	1.8	0	0
Sometimes	10	3.6	5	4.1
5.Fatigue				
Never	122	44.0	98	79.7
Rarely	105	37.9	20	16.3
Sometimes	36	13.0	5	4.1
Always	14	5.1	0	0

The present study showed that Covishield recipients rarely experienced fever (51.3%), headache (91.7%), and injection site pain (93.1%), while Covaxin recipients mostly never had fever (48%), headache (97.6%), and injection site pain (46.3%). Fatigue was infrequent among Covaxin recipients (55%).This aligns with a cross-sectional survey at Guntur Medical College, where most recipients reported local pain and tiredness as common side effects of both vaccines, without significant differences in COVID-19 infection rates between Covaxin and Covishield recipient

Table 2 Comparison of the side effects between no. of doses in Covishield vaccination among the participants (N=277)

SYMPTOMS	**Covishield (n=277)**					
	Single dose		**Double dose**		**Triple dose**	
	n	**%**	**n**	**%**	**n**	**%**
1.Fever						
Never	0	0	65	30.8	10	30.3
Rarely	29	87.9	98	46.4	15	45.5
Sometimes	4	12.1	31	14.7	8	24.2
Always	-	-	-	-	-	-
2.Headache						
Never	15	45.5	70	33.2	13	39.4
Rarely	14	42.4	95	45.0	12	36.4
Sometimes	0	0	40	19.0	8	24.2
Always	-	-	-	-	-	-
3.Pain in injection site						
Never	14	42.4	61	28.9	16	48.5
Rarely	15	45.5	106	50.2	2	6.1
Sometimes	0	0	29	13.7	8	24.2
Always	0	0	0	0	7	21.2
4.Chest pain						
Never	33	100.0	187	88.6	26	78.8
Rarely	0	0	19	9.0	7	21.2
Always	0	0	5	2.4	0	0
Sometimes	0	0	6	2.8	0	0
5.Fatigue						
Never	10	30.3	87	41.2	25	75.8
Rarely	19	57.6	78	37.0	8	24.2
Sometimes	4	12.1	32	15.2	0	0
Always	0	0	14	6.6	0	0

The present study showed varied side effects among recipients. Most single-dose recipients rarely had fever (87.9%) and headache (45.5%), while a majority of double-dose recipients reported rare occurrences of injection site pain (50.2%). Notably, most single-dose recipients did not experience fatigue (75.8%). These findings align with a cross-sectional study in Pathanamthitta District, Kerala, highlighting common post-vaccination symptoms among Covishield recipients,

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including pain at the injection site (79.8%), myalgia (67.2%), and fatigue (64.6%). These insights are valuable for COVID-19 vaccination health promotion initiatives.

Table 3 Comparison of the side effects between no. of doses in Covaxin vaccination among the partici (N=123)

SYMPTOMS	Covaxin (n=123)					
	Single dose		Double dose		Triple dose	
	n	%	n	%	n	%
1.Fever						
Never			59	57.3	0	0
Rarely	3	75.0	29	28.2	59	57.3
Sometimes	1	25.0	15	14.6	0	0
Always	-	-	-	-	-	-
2.Headache						
Never	2	50.0	45	43.7	11	68.8
Rarely	1	25.0	40	38.8	5	31.3
Sometimes	1	25.0	18	17.5	0	0
Always	-	-	-	-	-	-
3.Pain in injection site						
Never	0	0	46	44.7	11	68.8
Rarely	3	75.0	44	42.7	5	31.3
Sometimes	1	25.0	13	12.6	0	0
Always	-	-	-	-	-	-
4.Chest pain						
Never	4	100.0	100	97.1	16	100.0
Rarely	0	0	3	2.9	0	0
Always	0	0	0	0	0	0
5.Fatigue						
Never	3	75.0	79	76.7	16	100.0
Rarely	1	25.0	19	18.4	0	0
Sometimes	0	0	5	4.9	0	0
Always	-	-	-	-	-	-

The majority (57.3%) of double and triple-dose recipients rarely experienced fever, with most (68.8%) of triple-dose recipients reporting no headaches. Additionally, 75.0% of single-dose recipients rarely felt pain at the injection site, and all triple-dose recipients reported no fatigue. These findings are supported by a study by PD Yadav and S Mohandas, showing COVAXIN's effectiveness against Delta and Omicron variants, with reduced viral load and disease severity, particularly in the three-dose group.

Variables	Side effects/symptoms (p-values)												
	Fever	Head ache	Pain at Injection site	Chest Pain	Shortness of Breath	Fast Heart Beat	Blurred Vision	Leg swelling	Abdominal pain	Easy Brushing	Fluttering	Skin Rash	Fatigue
Age	0.001 (S)	0.001 (S)	0.57 (NS)	0.004 (S)	0.001 (S)	0.01 (S)	0.43 (NS)	0.08 (NS)	0.002 (S)	0.04 (S)	0.001 (S)	0.008 (S)	0.001 (S)
Gender	0.002 (S)	0.005 (S)	0.001 (S)	0.02 (S)	0.001 (S)	0.02 (S)	0.001 (S)	0.10 (NS)	0.01 (S)	0.10 (NS)	0.001 (S)	0.09 (NS)	0.001 (S)
No. of doses	0.001 (S)	0.53 (NS	0.001 (S)	0.03 (S)	0.001 (S)	0.001 (S)	0.001 (S)	0.53 (NS)	0.17 (NS)	0.53 (NS)	0.001 (S)	0.11 (Ns)	0.001 (S)
Co-morbidities	0.001 (S)	0.001 (S)	0.10 (NS)	0.52 (NS)	0.65 (NS)	0.49 (NS)	0.76 (NS)	0.81 (NS)	0.72 (NS)	0.81 (NS)	0.001 (S)	0.04 (S)	0.001 (S)

Table 4 Association between side effects of Covishied vaccination with background variable of participants (n=277)

The data from Table 4 revealed significant associations between Covishield vaccination side effects and participant background variables. Age, gender, number of doses, and comorbidities all showed statistically significant associations

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with side effects, except for specific symptoms such as pain at the injection site, blurred vision, leg swelling, easy brushing, and skin rash ($p>0.05$). These findings are consistent with a cross-sectional study by Remlabeevi A and Mathew, involving 4402 healthcare workers. The study reported adverse events in 63.3% after the first dose and 24.3% after the second dose, with body ache (17.9%) and headache (15.1%) being the primary symptoms after the first dose. Notably, asthma showed an increased risk of symptoms following the first dose.

Table 5 Association between side effects of Covaxin vaccination with background variable of participants(n=123)

Variables	Side effects/symptoms (p-values)										
	Fever	Headache	Pain at Injection site	Chest Pain	Shortness of Breath	Fast Heart Beat	Blurred Vision	Abdominal pain	Fluttering	Skin Rash	Fatigue
Age	0.47 (NS)	0.31 (NS)	0.006 (S)	0.04 (S)	0.02 (S)	0.006 (S)	0.002 (S)	0.002 (S)	0.62 (NS)	0.04 (S)	0.08 (NS)
Gender	0.55 (NS)	0.16 (NS)	0.95 (NS)	0.35 (NS)	0.001 (S)	0.001 (S)	0.001 (S)	0.001 (S)	0.006 (S)	0.17 (NS)	0.03 (S)
No. of doses	0.001 (S)	0.26 (NS)	0.10 (NS)	0.74 (NS)	0.46 (NS)	0.71 (NS)	0.63 (NS)	0.62 (NS)	0.66 (NS)	0.60 (NS)	0.28 (NS)
Co-morbidities	0.001 (S)	0.001 (S)	0.001 (NS)	0.001 (S)	0.83 (NS)	0.001 (S)	0.92 (NS)	0.92 (NS)	0.89 (NS)	0.85 (S)	0.001 (S)

The data presented demonstrates significant associations ($p<0.05$) between Covaxin vaccination side effects and participant demographics, analyzed using chi-square tests. Among 532 participants, 39.3% experienced adverse events post-vaccination, with local tenderness being the most common after the first dose (39.3%), while fever prevailed after the second dose (22.2%). Notably, a significant association ($p < 0.05$) was discovered between the second dose of Covaxin and local tenderness, consistent with findings supported by Mittal, Amit, and Bhavna Jain, where 39.3% of participants experienced adverse events post-vaccination. These results reinforce the understanding of Covaxin's safety profile, indicating important insights for vaccination strategies

DISCUSSION

The current study indicates that most vaccinated students, 54%, are under 20 years old, with 61% being female and 69% in their first year. The majority, 69%, received Covishield, 78.5% had taken a double dose, and 88.5% have no comorbid conditions. The study found that the majority rarely experienced fever (47.5%), headache (41.8%), and pain at the injection site (43.8%), with 55% never experiencing fatigue. Covishield recipients rarely experienced fever (51.3%), headache (91.7%), and injection site pain (93.1%), while Covaxin recipients mostly never had fever (48%), headache (97.6%), and injection site pain (46.3%). Fatigue was infrequent among Covaxin recipients (55%). Most single-dose recipients rarely experienced fever (87.9%) and headache (45.5%), while double-dose recipients rarely reported injection site pain (50.2%). Single-dose recipients mostly did not experience fatigue (75.8%). Among double and triple-dose recipients, 57.3% rarely experienced fever, with 68.8% of triple-dose recipients reporting no headaches, and 75.0% of single-dose recipients rarely felt pain at the injection site. All triple-dose recipients reported no fatigue. Significant associations were found between Covishield side effects and variables such as age, gender, number of doses, and comorbidities, though some symptoms showed no significant associations ($p>0.05$). Covaxin side effects had significant associations with demographics ($p<0.05$). Among 532 participants, 39.3% experienced adverse events post-vaccination, with local tenderness most common after the first dose (39.3%) and fever after the second dose (22.2%).

This study is supported by An observational study in Vijayawada, Andhra Pradesh, analyzed responses from 412 management students and faculty using SPSS software. The majority (55.3%) believe Covaxin has fewer side effects, 27.9% see no significant differences, and 16.7% believe Covishield has fewer side effects. The study concludes that opinions vary on the vaccines' efficacy, effectiveness, and side effects. The government should use media to dispel myths and promote the vaccines.[10]

An observational study focuses on analyzing adverse event reports and monitoring the safety of COVID-19 vaccines in South Korea. The study does not involve any intervention or experimental manipulation, but rather examines and analyzing adverse event (AE) reports from an online reporting platform and SMS-based surveillance.From February 2021 to June 2022, a total of 471,068 AEs were reported out of 125,107,883 administered doses. Non-serious AEs accounted for 96.1% of reports, while serious AEs made up 3.9%. Among participants in the SMS-based tracking, a higher incidence of adverse events rate was observed for the third vaccine dose compared to primary doses. The study identified cases of anaphylaxis, thrombosis with thrombocytopenia syndrome (TTS), myocarditis4.(1 per 1,000,000 doses), pericarditis(1.7 per 1,000,000 doses), and fatal outcomes associated with vaccination. Overall, most reported AEs were non-serious and of mild intensity, with young adults and females showing a higher rate of reporting AEs.[11]

An online cross-sectional survey was conducted over a month with 1800 individuals who had received at least one dose of the Covid vaccine at KIMS Hospital, Hubballi, Karnataka. The research aimed to assess the incidence of side effects from Covishield and Covaxin vaccines in India and their association with comorbidities and post-vaccination Covid-19 infection. The most commonly reported adverse effects were fever, headache, and generalized body pain.The prevalence

of post-vaccination Covid-19 infection was higher in Covishield recipients compared to Covaxin, and this difference was statistically significant. However, the reported side effects were generally mild, and no significant variation was found based on comorbidities. Continued adherence to Covid Appropriate Behavior is crucial due to the persistently high prevalence of infection after vaccination.[12]

CONCLUSION

This research study provides valuable insights into the side effects of Covishield and Covaxin vaccinations among participants. Covishield and Covaxin exhibited varying side effect profiles, with some symptoms showing statistically significant associations with age, gender, number of doses, and co-morbidities. The findings highlight the importance of considering demographic factors in vaccination programs and monitoring post-vaccination symptoms to ensure vaccine safety and effectiveness.

Declaration of conflict of Interest:
The authors declare no conflict of interest.

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