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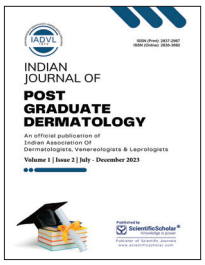

Original Article

Dermatological Adverse Effects of Covid-19 Vaccine among Healthcare Workers: Findings from a Tertiary Care Hospital in Northern India

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ABSTRACT

Objectives: The objective of this study was to identify the cutaneous manifestations that developed after covid-19 vaccination, with Covaxin and Covishield, in healthcare workers (HCW) and to identify any associated factors.

Materials and Methods: A cross-sectional study was conducted over 3 months using an online and offline questionnaire that was circulated among the HCW working at a tertiary care hospital in Delhi. All the vaccinated HCWs who gave consent (n = 676) (n = number of participants) were included in the study. Data were summarised in an excel sheet and then analysed using SPSS, version 25.

Results: Out of the 676 vaccine recipients, a higher number of participants were vaccinated with Covishield compared to Covaxin. Only 14 (2.0%) subjects developed new adverse dermatological manifestations following either vaccination. A higher incidence of adverse reaction was observed with Covaxin than with Covishield, but the difference was not significant. A significantly higher number of vaccinated paramedical workers developed new dermatological manifestations in the study period [P-value (probability value)] (P = 0.018).

Conclusion: Our study demonstrated a low rate of cutaneous adverse reactions following vaccination with either Covaxin or Covishield. Further studies are hence needed to corroborate our findings.

Keywords: Covid-19 vaccines, Healthcare workers, Adverse effects

INTRODUCTION

India kick–started its drive for covid-19 vaccination on 16 January, 2021. Healthcare workers (HCW) and other frontline workers were among the first beneficiaries of the world's largest vaccination drive.[1,2] In the early 2021, India approved two vaccines namely, Covaxin (manufactured by Bharat Biotech International Limited, Hyderabad, India) and Covishield (manufactured by Serum Institute of India Pvt. Ltd. Pune, India).[3]

With more and more vaccines getting approval, India now has five emergency approved vaccines with many other indigenous vaccines underway.[4,5] The vaccines approved in India are undergoing clinical trials and the data collected so far is promising with high efficacy and safety.[6] The most common side effects of the various vaccines were mild and short-lasting, with significant adverse effects being rare.[7]

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Table 1: Demographic and other characteristics of the study participants (*n*=676).

Characteristics	Number of participants (*n*)	Percentage
Sociodemographic characteristics		
Gender		
Male	405	59.9
Female	271	40.2
Mean age (years)	22.9±6.9	
Religion		
Hindu	603	89.2
Muslim	35	5.2
Sikh	11	1.6
Christ	15	2.2
Buddhist	12	1.8
Designation		
Undergraduate	550	81.4
Postgraduate	64	9.5
Consultants	33	4.9
Paramedical	29	4.3
Vaccination related characteristics		
Vaccine doses received		
Only first dose	33	4.9
Both first and second dose	531	78.6
First, second and booster	112	16.6
Type of vaccine		
Covaxin	243	35.9
Covishield	429	63.5
Sputnik	4	0.6
Skin related previous disease status		
Previous history of allergy to mask, gloves and sanitiser		
No	607	89.9
Mask	22	3.3
Gloves	16	2.4
Sanitiser	31	4.6
Prior chronic dermatological condition		
No	626	92.6
Acne/acne vulgaris	14	2.1
Psoriasis	9	1.3
Urticaria	8	1.2
Seborrhoeic dermatitis	9	1.3
Fungal infection	3	0.4
Vitiligo	2	0.3
Lichen planus	2	0.3
Medial canalicular dystrophy	1	0.1
Contact dermatitis	1	0.1
Sarcoidosis of skin	1	0.1
Autoimmune disease		
No	667	98.7
Allergic rhinitis	1	0.1
Ankylosing spondylitis	1	0.1
Atopy	1	0.1
Dermatomyositis	2	0.3
Hashimoto thyroiditis and IBD	2	0.3
Liver disease	1	0.1
Sarcoidosis of lungs and skin	1	0.1

IBD: Inflammatory bowel disease

Table 2: Distribution of variables between those vaccinated with Covishield and Covaxin (*n*=672).

Characteristic	Covaxin	Covishield	*P*-value
Sociodemographic characteristics			
Gender			
Male	159 (39.5)	244 (60.5)	0.030
Female	84 (31.2)	185 (66.8)	
#Mean age (years)	22.3±6.32	23.26±7.30	0.023
*Religion			
Hindu	217 (36.1)	384 (63.9)	0.294
Muslim	15 (45.5)	18 (54.5)	
Sikh	01 (9.1)	10 (90.9)	
Christ	05 (33.3)	10 (66.7)	
Buddhist	05 (41.7)	07 (58.3)	
Designation			
Undergraduate	212 (38.8)	334 (61.2)	0.006
Postgraduate	12 (18.8)	52 (81.3)	
Consultants	08 (24.2)	25 (75.8)	
Paramedical	11 (37.9)	18 (62.1)	
Vaccine related variables			
Vaccine doses received			
Only first dose	13 (40.6)	19 (59.4)	0.510
Both first and second dose	185 (35.0)	343 (65.0)	
First, second and booster	45 (40.2)	67 (59.8)	
Other variables			
History of allergy to PPE components			
No allergy	220 (36.5)	383 (63.5)	0.606
Allergy to masks, gloves or sanitiser	23 (33.3)	46 (66.7)	
History of prior chronic dermatological condition			
No	229 (36.8)	393 (63.2)	0.212
Yes	14 (28.0)	36 (72.0)	
*Autoimmune disease			
No	239 (36.0)	424 (64.0)	0.729
Yes	04 (44.4)	05 (55.6)	

#*t*-test, *Fisher's exact test, Figure in parenthesis indicate %, PPE: Personal protective equipment, *P*-value: probability value

The immunogenic effects of vaccines can lead to the development of various dermatoses and the covid-19 vaccines also seem to follow this dictum.[8] Cutaneous reactions were reported after messenger ribonucleic acid-based vaccines in the United States, with delayed local reactions being the most common.[9] Preliminary findings from trials of other vaccines from other parts of the world also report such manifestations.[10] There is a dearth of published literature describing cutaneous adverse effects of covid-19 vaccines in India with only two case series reporting a number of cutaneous reactions to Covishield and Covaxin.[11,12]

The lack of sufficient data on this topic has created apprehension and doubt among the general public as well as among HCWs. The present study aimed to fill this gap by describing the cutaneous manifestations developing after the two most commonly used covid-19 vaccines in India (Covishield and Covaxin) in HCW and the factors associated with the development of cutaneous manifestations. Furthermore, this study, explored the morbidity, if any, caused to the individuals with chronic dermatological disease due to vaccination.

MATERIALS AND METHODS

Study setting, period and design

A cross-sectional study was conducted over 3 months to find out any dermatological manifestations developed after receipt of covid-19 vaccine among HCWs, working at a tertiary care hospital in Delhi.

Sample size

No published literature for adverse dermatological manifestations post-covid-19 vaccination was available. Hence, assuming the prevalence of any adverse dermatological manifestation to be 50% (maximum possible for any disease), the minimum sample size came out to be 384 with an error rate of 5%.

Table 3: Association between developments of dermatological manifestation with various variables (*n*=676).

Characteristic	No dermatological manifestation	New dermatological manifestation	*P*-value
Demographic profile			
Gender			
Male	395 (97.5)	10 (2.5)	0.374
Female	267 (98.5)	4 (1.5)	
#Mean age (years)	22.73±6.9	25.43±9.4	0.153
*Religion			
Hindu	590 (97.8)	13 (2.2)	0.801
Muslim	34 (97.1)	01 (2.9)	
Sikh	11 (100.0)	0 (0.0)	
Christ	15 (100.0)	0 (0.0)	
Buddhist	12 (100.0)	0 (0.0)	
*Designation			
Undergraduate	542 (98.5)	8 (1.5)	0.018
Postgraduate	62 (96.9)	2 (3.1)	
Consultants	32 (97.0)	1 (3.0)	
Paramedical	26 (89.7)	3 (10.3)	
*Type of vaccine received			
Covaxin	235 (96.7)	8 (3.3)	0.224
Covishield	424 (98.6)	5 (1.4)	
Pfizer	04 (100.0)	0 (0.0)	
Vaccine related variables			
*Vaccine doses received			
Only first dose	33 (100.0)	0 (0.0)	0.862
Both first and second dose	520 (97.9)	11 (2.1)	
First, second and booster	109 (97.3)	3 (2.7)	
Other variables			
*History of allergy to PPE components			
No allergy	596 (98.2)	11 (1.8)	0.164
Allergy to masks, gloves or sanitiser	66 (95.7)	3 (4.3)	
*History of prior chronic dermatological condition			
None	612 (97.8)	14 (2.2)	0.615
Yes	50 (100.0)	0 (0.0)	
*Autoimmune disease			
None	653 (97.9)	14 (2.1)	1.000
Yes	9 (100.0)	0 (0.0)	

#*t*-test, *Fisher's exact test, Figure in parenthesis indicate %, *P*-value: probability value

Inclusion criteria

All vaccinated HCW working at the institution who gave consent were included in the study.

Data collection tool and method

Data collection was done with the help of a pretested, semi-structured and bilingual (English and Hindi) google form. The link for the google form was shared among the HCWs through various social media platforms. Those who could not be reached through these platforms were contacted for a telephonic or a physical interview.

The google form had information about the study and an e-consent was taken before starting the collection of information. Those who had participated in physical interviews were provided with all the information about the study and their consent was taken before data collection. Contact details of the primary investigator were provided to the participants who wanted any clarifications thereof. If someone preferred a telephonic interview over filling out a google form, they were contacted at their convenience and interviewed.

The first section of the questionnaire collected the demographic details of the participant. The next section asked about the vaccination details and history of covid-19 infection. The third section collected information about the dermatological manifestations (if any) experienced by the participant post-vaccination.

Table 4: Flare-up in previous disease conditions among participants who had previous disease conditions.

Characteristics	*n*	Flare-up	
		Yes	No
Previous history of allergy to mask, gloves and sanitiser (*n*=69)			
Mask	22	0 (0.0)	22 (100.0)
Gloves	16	0 (0.0)	16 (100.0)
Sanitiser	31	1 (3.2)	30 (96.8)
Prior chronic dermatological condition (*n*=50)			
Acne/acne vulgaris	14	1 (7.1)	13 (92.9)
Psoriasis	9	3 (33.3)	6 (66.7)
Urticaria	8	0 (0.0)	8 (100.0)
Seborrhoeic dermatitis	9	0 (0.0)	9 (100.0)
Fungal infection	3	0 (0.0)	3 (100.0)
Vitiligo	2	0 (0.0)	2 (100.0)
Lichen planus	2	0 (0.0)	2 (100.0)
Medial canalicular dystrophy	1	0 (0.0)	1 (100.0)
Contact dermatitis	1	0 (0.0)	1 (100.0)
Sarcoidosis of skin	1	0 (0.0)	1 (100.0)
Autoimmune disease (*n*=9)	None of the autoimmune disease showed flare-up in condition		

Figure in parenthesis indicate %

Ethical considerations

The study was initiated after receiving ethical clearance from the Institute Ethics Committee. Participants were enrolled in the study only after their informed consent had been obtained.

Data analysis

Data collected through google forms were summarised in an excel sheet. Data were analysed using SPSS, version 25 for windows available with the institution. Qualitative variables were expressed as proportions and quantitative variables were summarised as mean and standard deviation. Chi-square test, fisher's exact test and *t*-test were used to determine if a relationship existed between the variables and $P \leq 0.05$ was taken for declaring any significant difference.

RESULTS

Total 684 responses were received, among them 8 (1.16%) participants did not receive any covid-19 vaccine; hence, 676 participants were included in the final analysis. Out of 676, 429 (63.5%) received Covishield, 243 (35.9%) participants received Covaxin and 4 (0.6%) received Pfizer vaccine. Demographic characteristics and other parameters related to the study participants are presented in [Table 1].

Significantly more males and females were vaccinated with Covishield compared to Covaxin. ($P = 0.030$). Significant ($P = 0.023$) age difference was found among the recipients of Covishield and Covaxin with the mean age of getting vaccinated with Covishield being 23.26 ± 7.30 and for Covaxin being 22.3 ± 6.32 years. This is probably due to the fact that only Covaxin was approved for those below 18 years in the vaccination drive at the time of conducting this study. Among all groups of HCW studied, more subjects were vaccinated with Covishield than Covaxin. No statistically significant difference was found between the two vaccine groups in terms of sociodemographic and clinical parameters, as shown in [Table 2].

Out of 676 vaccine recipients, 14 (2.0%) subjects developed adverse dermatological manifestations including acne vulgaris, urticaria and increased hair loss. Types of different adverse dermatological manifestations developed post-vaccinations are given in [Figure 1]. Only 3.3% of the participants developed new skin manifestations after receiving Covaxin, while 1.4% developed new skin manifestations after receiving Covishield, ($P = 0.224$). Thus, no significant difference was observed between the developments of a new dermatological manifestation between the two vaccine groups. Development of adverse dermatological manifestation was found to be highest (10.3%) among paramedical staff ($P = 0.018$). Association between development of an adverse manifestation and other variables is given in [Table 3].

Flare-up of previous disease conditions post-vaccination among participants is detailed in [Table 4]. Flare-up in symptoms was found in one patient with the previous contact allergic dermatitis to sanitiser, one case of acne and three cases of psoriasis. None of the systemic autoimmune diseases flared post-vaccination.

DISCUSSION

This study identified that only 2% of participants developed a dermatological adverse effect post-vaccination. A higher percentage of Covaxin recipients developed these adverse

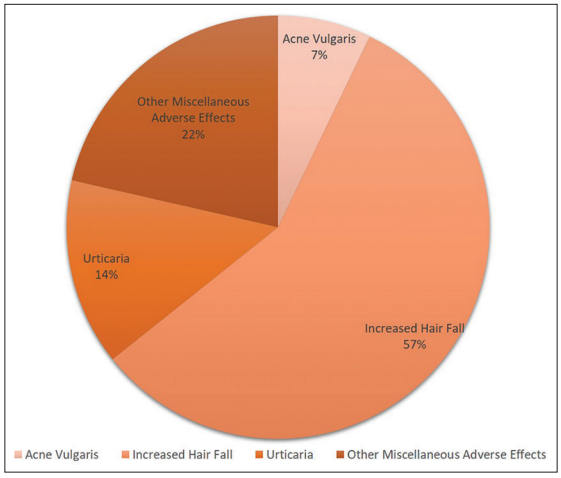

Figure 1: New dermatological manifestations reported by the participants.

drug reactions as compared to the recipients of Covishield with no significant difference between the vaccine groups. Increased hair fall was the most common adverse effect reported.

Another study from northern India, by Das *et al*., reported a slightly lesser incidence (1.23%) of adverse cutaneous reactions to covid-19 vaccines. In their study, 50 patients reported an adverse cutaneous reaction to vaccines, the most common adverse event being telogen effluvium, followed by urticaria.[13] Bawane *et al*. reported a higher incidence of cutaneous reaction in Covishield recipients (86.7%) as compared to Covaxin (13.3%). This was in contrast to our study with a much lower overall incidence (2%) and no significant difference between the two vaccine groups.[14] A systematic review from Iran showed that reaction at the local injection site was the most common cutaneous adverse effect observed after Covid vaccination. Their study showed that most of the reactions were self-limiting and do not hamper vaccination.[15]

Limitations

Our study population included only HCW, out of which most (81.4%) were undergraduate students [Table 1]. Hence, the extrapolation of our results to the entire population is doubtful. Furthermore, the questionnaire method is dependent on the participant's level of understanding and knowledge of the disease which can be a source of error in diagnosis of dermatological manifestations. Finally, while we tried to establish a temporal link between the vaccine and development of a new dermatological manifestation, further studies with more diverse study groups are needed to confirm this aspect. The lack of follow-up in our study also limits our understanding of the nature of the cutaneous reactions after vaccination.

CONCLUSION

This study identified an overall low incidence of dermatologic adverse effects following Covishield and Covaxin vaccines, with no significant difference in adverse events between the two vaccine groups. This study definitely adds to the existing knowledge regarding dermatological adverse effects post-covid-19 vaccines.

This study highlights the dermatological safety of the two vaccines.

Declaration of patient consent

Patient's consent not required as patients identity is not disclosed or compromised.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The author(s) confirms that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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Journal Statistics

Journal Stats

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Submission to Acceptance days		40.45 [0, 124]
Acceptance to Publication days		35.26 [10, 67]
Submission to Publication days		74.52 [10, 156]
Acceptance Rate		
	Based upon number of Submissions	35.23%
	Based upon number of Decisions	42.47%
Rejection Rate		
	Based upon number of Submissions	47.73%
	Based upon number of Decisions	57.53%