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Research Article

Post-Vaccination Adverse-Effect Profile Among Adult Beneficiaries of a Tertiary-Care Hospital in Rajasthan: A Prospective

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ABSTRACT
Background: Robust pharmacovigilance is essential to sustain public confidence in India's COVID-19 immunisation drive. Published data from northern India remain limited, and heterogeneity persists in reporting practices.
Methods: We undertook a six-month, single-centre, prospective, comparative cohort study at Mahatma Gandhi Medical College & Hospital, Jaipur (IEC No. MGMC&H/IEC/JPR/2021/508; 21 June 2021). All consecutive adults (≥18 y) receiving either dose of Covishield™ or Covaxin™ between July-December 2021 were observed on-site for 30 min and contacted telephonically on day 1, 3 and 7. Adverse events following immunisation (AEFI) were graded (mild/moderate/severe) using Government of India guidelines. Primary outcome was cumulative incidence of any AEFI after dose 1 versus dose 2. Predictors were explored using multivariable logistic regression.
Results: Of 613 recipients (mean age 36.4 ± 12.1 y; 53.2 % male), 54.5 % reported ≥1 AEFI after dose 1 versus 35.5 % after dose 2 ($p < 0.001$). Local pain (41 %), fever (23 %), myalgia (13 %), fatigue (12 %) and headache (8 %) predominated. Almost 83 % of AEFI were mild and self-limiting; no anaphylaxis or thromboembolic events were recorded. Independent predictors of systemic AEFI were female sex (aOR 1.43, 95 % CI 1.02-2.00), age <30 y (aOR 1.57, 1.08-2.28) and previous SARS-CoV-2 infection (aOR 1.68, 1.05-2.70).
Conclusion: Both vaccines exhibited favourable short-term safety profiles; reactogenicity declined significantly after the second dose. Active surveillance should be continued to capture rarer, late-onset events and to strengthen public trust.
Keywords: Adverse events following immunisation; Covishield; Covaxin; pharmacovigilance; Rajasthan; prospective cohort
Aim Of Study: To detect, document, assess and report the suspected ADRs in population after administration of 1st and 2nd dose of ChAdOx1 nCoV-19 coronavirus vaccine [Covishield™] in tertiary care hospital Jaipur, India.

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INTRODUCTION

The unprecedented speed of COVID-19 vaccine development raised legitimate concerns regarding safety and the robustness of post-marketing surveillance [2,3]. India initiated mass vaccination on 16 January 2021 using Covishield™ (recombinant ChAdOx1-S) and Covaxin™ (BBV152, whole-virion inactivated) following emergency approval [4]. As of May 2025, more than 2.2 billion doses have been administered nationwide [5]. Although passive AEFI reporting via the Co-WIN platform suggests an incidence of 0.006 %, under-reporting is recognised [6].
Studies from southwest [1], eastern [7] and central India [8] demonstrate predominantly mild reactogenicity; however, regional variations in ethnicity, comorbidities and vaccine-handling practices may influence outcomes. Rajasthan, with its diverse population and high burden of non-communicable diseases, lacks large prospective safety data. Transparent dissemination of local real-world findings is vital to counter misinformation and vaccine hesitancy [3,9].
We therefore conducted a hospital-based, prospective, comparative study to (i) determine the incidence and pattern of AEFI after first and second doses of Covishield or Covaxin, (ii) compare reactogenicity between doses, and (iii) identify demographic and clinical predictors of systemic events in adult beneficiaries of a tertiary-care centre in Jaipur, Rajasthan.

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MATERIALS AND METHODS

Study design, setting and ethics

A prospective, observational, comparative cohort study was undertaken from 1 July to 31 December 2021 at the vaccination clinic of Mahatma Gandhi Medical College & Hospital, Jaipur—a 1 500-bed teaching hospital catering to urban and semi-urban populations. Institutional Ethics Committee approval was obtained (letter No. MGMC&H/IEC/JPR/2021/508). Written informed consent was secured from every participant.

Participants

Inclusion: adults ≥18 y of either sex receiving first or second dose of Covishield™ or Covaxin™ at the study site.

Exclusion: age <18 y, current SARS-CoV-2 infection (RT-PCR-positive), pregnancy, or inability to complete telephonic follow-up.

Data collection and follow-up

Baseline demographics, comorbidities, prior COVID-19, and vaccine details (brand, batch, dose number) were documented. Beneficiaries were observed for immediate reactions for 30 min post-injection. A structured questionnaire, adapted from the MoHFW AEFI reporting form, was administered telephonically on day 1 (24 h), day 3 and day 7. Events were classified as local or systemic and graded (mild: no interference with daily activity; moderate: some interference; severe: hospitalisation or persistent disability).

Outcomes

Primary outcome: cumulative incidence of any AEFI within seven days of vaccination. Secondary outcomes: distribution of specific symptoms, severity profile, comparison between doses, and predictors of systemic AEFI.

Statistical analysis

Data were entered in MS Excel and analysed with SPSS v26. Categorical variables are summarised as counts (%) and compared using χ^2 or Fisher's exact test. Continuous variables are expressed as mean ± SD or median (IQR) and compared using Student's t-test or Mann-Whitney U. Multivariable binary logistic regression (backward LR) generated adjusted odds ratios (aOR) with 95 % CIs. $p < 0.05$ was considered statistically significant.

RESULTS

Participant characteristics

Of 627 eligible individuals, 613 (97.8 %) completed follow-up. Baseline data are shown in **Table 1**. Mean age was 36.4 ± 12.1 y (range 18-79); 12 % had ≥1 comorbidity, hypertension being most common. Covishield constituted 82 % of administered doses.

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Incidence and pattern of AEFI

Overall, 334/613 (54.5 %) reported ≥1 AEFI after dose 1 compared with 186/524 (35.5 %) after dose 2 (Δ 19.0 %, $p < 0.001$). Local reactions dominated (Figure 1). Fever, myalgia and fatigue declined significantly after the second dose (**Table 2**). No severe AEFI or deaths occurred.

Severity

Most events were mild (82.6 %) and resolved within 48 h; 17.4 % were moderate. Two participants visited the emergency department for hydration owing to high-grade fever but were discharged within 24 h. No anaphylaxis, thrombosis with thrombocytopaenia syndrome, myocarditis or Guillain-Barré syndrome was detected.

Predictors of systemic AEFI

On multivariable analysis (**Table 4**), female sex (aOR 1.43), age <30 y (aOR 1.57) and self-reported previous COVID-19 infection (aOR 1.68) independently predicted systemic AEFI. Vaccine brand, comorbidity status and body-mass index were not significant.

Table 1. Baseline Characteristics of Study Participants (N = 613)

Variable	n (%) / Mean ± SD
Age (years)	36.4 ± 12.1
Age <30 y	233 (38.0)
Male	326 (53.2)
Comorbidity (any)	74 (12.1)
- Hypertension	39 (6.4)
- Diabetes mellitus	28 (4.6)
Previous COVID-19	112 (18.3)
Vaccine brand – Covishield	502 (81.9)
Vaccine brand – Covaxin	111 (18.1)
Received second dose	524 (85.5)

Table 2. Frequency of Common Aefi after Each Dose

Symptom	Dose 1 (n = 613)	Dose 2 (n = 524)	p-value
Any AEFI	334 (54.5 %)	186 (35.5 %)	<0.001
Injection-site pain	252 (41.1 %)	155 (29.6 %)	<0.001
Fever	140 (22.8 %)	96 (18.3 %)	0.04
Myalgia	80 (13.1 %)	63 (12.0 %)	0.56
Fatigue	76 (12.4 %)	53 (10.1 %)	0.18
Headache	48 (7.8 %)	40 (7.6 %)	0.92

Table 3. Severity Grading Of Reported Aefi (Combined Doses)

Severity	n	%
Mild	430	82.6
Moderate	91	17.4
Severe	0	0

Table 4. Multivariable Predictors Of Systemic Aefi (N = 613)

Predictor	aOR	95 % CI	p
Female sex	1.43	1.02-2.00	0.039
Age <30 y	1.57	1.08-2.28	0.018
Prior COVID-19	1.68	1.05-2.70	0.031

(Hosmer-Lemeshow p = 0.72; Nagelkerke R^2 = 0.11)

Figure 1 and **Figure 2** present the incidence of any AEFI by dose and the relative distribution of symptom types, respectively.

Figures

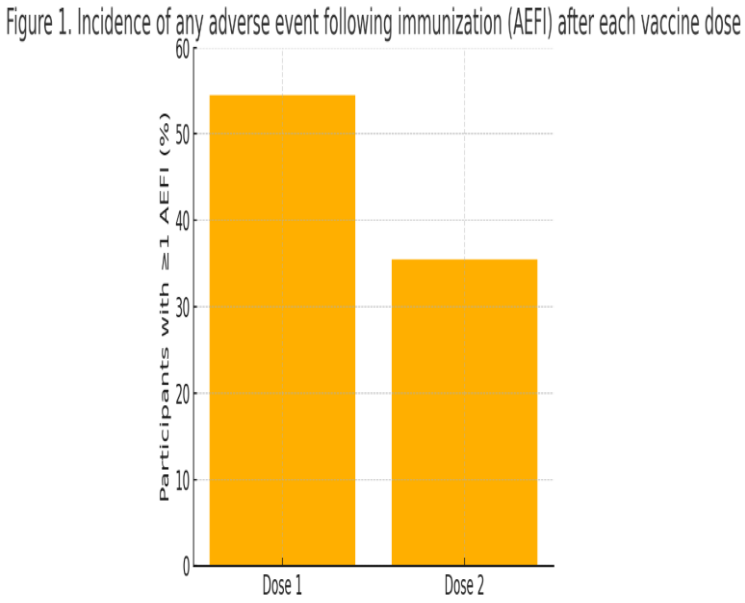

Figure 1. Incidence of Any Adverse Event Following Immunization (Aefi) After Each Vaccine Dose

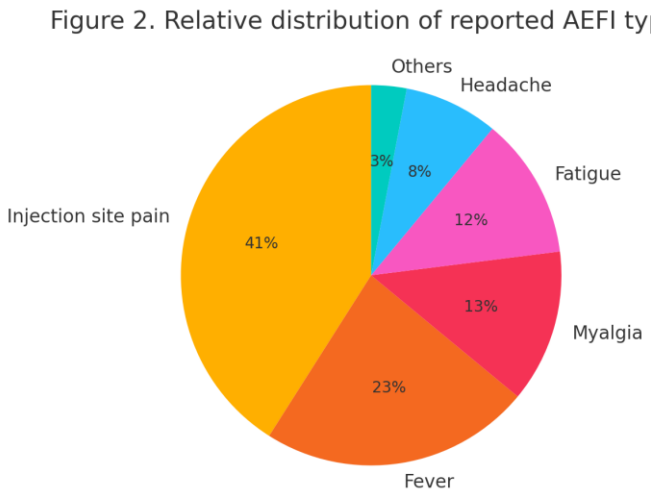

Figure 2. Relative Distribution of Reported Aefi Types

DISCUSSION

Our active-surveillance cohort adds northern Indian data to the burgeoning global literature on COVID-19 vaccine safety. The 54.5 % incidence of at least one self-reported AEFI after the first dose parallels findings from Karnataka (57 %) [1] and Assam (55 %) [7], but exceeds passive Co-WIN estimates [6], highlighting under-reporting in routine systems. The significant decline after dose 2 mirrors observations among healthcare workers elsewhere in India [8] and globally [10], supporting immunological tolerance with successive exposure.

Injection-site pain and fever were predominant, consistent with the established reactogenicity profiles of adenoviral-vector and inactivated vaccines [4,11]. Importantly, no serious events such as TTS or myocarditis were detected—aligning with Indian pharmacovigilance data indicating rates < 0.5 per 100 000 doses [12]. The absence of anaphylaxis may reflect adherence to post-vaccination observation and emergency preparedness protocols.

Women and younger adults experienced more systemic AEFI, corroborating reports from multicentre analyses [9,10] and likely reflecting heightened innate immune responses. Prior SARS-CoV-2 infection also emerged as a predictor, supporting the hypothesis of immune priming leading to amplified cytokine release [13]. Contrary to some studies [14], comorbidity status did not influence reactogenicity, perhaps due to lower absolute numbers or better chronic-disease control in our cohort.

The study's strengths include prospective design, active follow-up, standardised severity grading and robust statistical adjustment. Nevertheless, limitations merit acknowledgement. First, the single-centre setting may limit generalisability. Second, rare serious AEFI require far larger sample sizes and longer follow-up. Third, reliance on self-report introduces recall bias, though short recall windows were maintained. Finally, immunogenicity endpoints were beyond scope; integrating antibody titres could enrich future work.

Our findings support existing evidence attesting to the favourable safety profile of Covishield and Covaxin, and underscore the value of local pharmacovigilance. Continuous, transparent dissemination of real-world safety data can bolster vaccine acceptance, particularly amidst evolving booster policies and emergence of variant-adapted formulations [15]. Expansion of digital AEFI reporting platforms and community engagement should be prioritised.

CONCLUSION

Active, prospective surveillance at a tertiary-care hospital in Rajasthan demonstrated that COVID-19 vaccines used in India are largely safe, with predominantly mild, transient adverse effects that declined after the second

dose. Female sex, younger age and previous COVID-19 infection modestly increased the likelihood of systemic events, but no serious or life-threatening reactions were observed. These data reinforce public-health messaging on vaccine safety and highlight the importance of strengthening pharmacovigilance to detect rare events, sustain public confidence and guide evidence-based immunisation policies.

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