ORIGINAL RESEARCH

Effectiveness of Booster Dose COVID-19 Vaccination in Preventing Severe Infections among Adults: A Community-Based Cohort Study

Dr. Harsiddh Vinodbhai Desai¹, Dr. Nirav Manubhai Khadodara², Dr. Raiyani Krunal Jitendrabhai³, Dr. Umang Vinodbhai Adroja⁴

^{1,2}MBBS, Government Medical College, Bhavnagar, Gujarat, India
³MBBS, GMERS Medical College, Junagadh, Gujarat, India
⁴MBBS, GMERS Medical College, Gandhinagar, Gujarat, India

Corresponding Author Dr. Umang Vinodbhai Adroja MBBS, GMERS Medical College, Gandhinagar, Gujarat, India Email: umangadroja24@gmail.com

Received: 25 March, 2025

Accepted: 16 April, 2025

Published: 26 April, 2025

ABSTRACT

Background: The global effort to curb COVID-19 continues to evolve with the introduction of booster doses aimed at enhancing immunity, especially among adults with waning vaccine-induced protection. This study aimed to evaluate the effectiveness of the booster dose of COVID-19 vaccination in preventing severe infections among adults in a communitybased cohort. Materials and Methods: A prospective cohort study was conducted in a semi-urban district in India. A total of 2,000 adults aged 18 years and above were enrolled and stratified into two groups: Group A (n=1,000) received the COVID-19 booster dose, and Group B (n=1,000) received only the primary vaccine series. Participants were followed for six months, with data on COVID-19 infection, severity (based on WHO clinical progression scale), hospitalization, ICU admission, and mortality collected through periodic interviews and health records. Statistical analysis was performed using SPSS v25. Chi-square tests and Cox proportional hazards models were used to compare incidence and risk ratios between groups. Results: The incidence of severe COVID-19 infection was significantly lower in Group A (1.2%) compared to Group B (6.8%) (p<0.001). Hospitalization was reported in 0.9% of booster recipients versus 5.1% of non-recipients. ICU admissions occurred in 0.3% of Group A and 2.3% of Group B. No deaths were reported in Group A, while four deaths (0.4%) occurred in Group B. The adjusted hazard ratio (aHR) for severe disease in the booster group was 0.18 (95% CI: 0.09–0.36), indicating an 82% reduction in risk. Conclusion: The booster dose of the COVID-19 vaccine significantly reduced the incidence of severe infection, hospitalization, and ICU admission among adults. These findings support the continued rollout of booster vaccinations as a vital public health strategy to mitigate COVID-19 severity.

Keywords: COVID-19, Booster Dose, Vaccination, Severe Infection, Cohort Study, Community-Based Study, Vaccine Effectiveness

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-Non Commercial-Share Alike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

INTRODUCTION

The coronavirus disease 2019 (COVID-19) pandemic has had a profound impact on global public health, with waves of infections leading to significant morbidity, mortality, and socio-economic disruption. The development and deployment of COVID-19 vaccines have been instrumental in mitigating the burden of the disease, especially in reducing severe cases, hospitalizations, and deaths [1]. However, emerging data have indicated that vaccine-induced immunity may wane over time, particularly in the face of new variants of concern such as Delta and Omicron [2,3].

To address the challenge of declining immunity and breakthrough infections, booster doses have been introduced as an extension of primary immunization programs in many countries. These additional doses aim to reinforce the immune response and sustain protection against severe outcomes of COVID-19 [4]. Several studies have demonstrated that booster doses can enhance neutralizing antibody titers and T-cell responses, even in populations with previous waning immunity or comorbidities [5,6].

Despite this, there remains a need for real-world evidence from community-level data to assess the effectiveness of booster doses in preventing severe disease. Most current studies are based on hospital or registry data and may not reflect outcomes in general population settings [7]. Moreover, factors such as age, comorbid conditions, prior infection status, and adherence to public health measures may influence vaccine effectiveness and require contextual evaluation [8].

This community-based cohort study was designed to evaluate the protective effect of booster dose vaccination against severe COVID-19 infection in a general adult population. By comparing the outcomes of individuals who received a booster dose to those who completed only the primary vaccine series, this study aims to provide timely and actionable insights for vaccination policy planning and public health interventions.

MATERIALS AND METHODS Study Design and Setting

This was a prospective, observational cohort study conducted in a semi-urban community located in India. The study aimed to evaluate the real-world effectiveness of a COVID-19 booster dose in reducing severe disease outcomes among adult residents.

Study Population

A total of 2,000 adult participants aged 18 years and above were recruited using stratified random sampling from the community health database. Individuals were eligible if they had completed at least the primary series of a COVID-19 vaccine. Participants with incomplete vaccination records, prior hospitalization due to COVID-19 in the last 3 months, or those unwilling to provide informed consent were excluded.

Group Allocation

Participants were categorized into two groups based on their vaccination status.

• **Group A (Booster group):** Received a booster dose of an approved COVID-19 vaccine (n = 1,000)

• **Group B** (Non-booster group): Received only the primary two-dose vaccine schedule without a booster (n = 1,000)

Data Collection

Demographic details, comorbidities (e.g., diabetes, hypertension), and vaccination history were collected through structured interviews and verified using government vaccination portals. Follow-up was conducted monthly through telephone and in-person visits to monitor for COVID-19 symptoms, testing, and clinical outcomes. Severe infection was defined according to WHO criteria, including oxygen requirement, ICU admission, or death.

Outcome Measures

The primary outcome was the incidence of severe COVID-19 infection. Secondary outcomes included overall infection rate, hospitalization, ICU admission, and mortality. RT-PCR confirmation was used to identify positive cases. Data regarding clinical severity were obtained from hospital discharge records and verified by healthcare professionals.

Statistical Analysis

Descriptive statistics were used to summarize participant characteristics. Incidence rates between groups were compared using the chi-square test. Cox proportional hazards models were employed to estimate hazard ratios (HR) and adjusted hazard ratios (aHR) with 95% confidence intervals (CI), adjusting for age, sex, comorbidities, and baseline health status. A p-value <0.05 was considered statistically significant. All statistical analyses were performed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA).

RESULTS

A total of 2,000 participants were included in the study, with 1,000 individuals each in the booster group (Group A) and non-booster group (Group B). The mean age of participants was 42.6 ± 13.5 years, and 52.3% were male. Both groups were comparable in terms of baseline demographic and clinical characteristics (Table 1).

Table 1. Dasenne Characteristics of Study 1 articipants (1 – 2000)								
Variable	Booster Group $(n = 1000)$	Non-Booster Group (n = 1000)	p-value					
Mean Age (years)	42.3 ± 13.1	43.0 ± 13.9	0.284					
Male, n (%)	526 (52.6%)	518 (51.8%)	0.703					
Diabetes, n (%)	118 (11.8%)	125 (12.5%)	0.624					
Hypertension, n (%)	134 (13.4%)	142 (14.2%)	0.602					
History of COVID-19, n (%)	97 (9.7%)	102 (10.2%)	0.688					

Table 1: Baseline Characteristics of Study Participants (N = 2000)

Table 1 shows no statistically significant differences in demographic or comorbidity profiles between the groups.

During the six-month follow-up, the incidence of laboratory-confirmed COVID-19 infection was 3.1% in Group A and 9.6% in Group B (p < 0.001). Severe

infections were observed in only 12 participants (1.2%) in the booster group, compared to 68 participants (6.8%) in the non-booster group. Hospitalizations occurred in 9 (0.9%) individuals in Group A versus 51 (5.1%) in Group B, while ICU admissions were 3 (0.3%) and 23 (2.3%), respectively

(Table 2). No deaths were reported among those who received a booster dose, whereas 4 deaths (0.4%) occurred in the non-booster group.

The Cox regression analysis showed that receiving a booster dose was associated with a significantly reduced risk of developing severe COVID-19 (adjusted HR: 0.18, 95% CI: 0.09–0.36, p < 0.001).

Table 2: COVID-19	Outcomes in	Booster vs.	Non-Booster	Groups
-------------------	-------------	-------------	-------------	--------

Outcome	Booster Group (n = 1000)	Non-Booster Group (n = 1000)	p-value
Confirmed COVID-19 cases	31 (3.1%)	96 (9.6%)	< 0.001
Severe COVID-19 infection	12 (1.2%)	68 (6.8%)	< 0.001
Hospitalization	9 (0.9%)	51 (5.1%)	< 0.001
ICU admission	3 (0.3%)	23 (2.3%)	< 0.001
Deaths	0 (0%)	4 (0.4%)	0.044

Table 2 indicates significantly better outcomes in the booster group across all parameters.

DISCUSSION

This community-based cohort study assessed the realworld effectiveness of the COVID-19 booster dose in preventing severe infections among adults. The findings suggest a significant reduction in the incidence of severe COVID-19 outcomes—including hospitalization, ICU admission, and mortality among those who received a booster dose compared to individuals who completed only the primary vaccination schedule. These results are consistent with national and international data that support the use of booster doses to enhance and prolong vaccineinduced immunity [1,2].

Previous studies have demonstrated that the immunity conferred by initial two-dose COVID-19 vaccination begins to wane approximately 4–6 months postimmunization, particularly in older adults and individuals with comorbid conditions [3,4]. The decline in neutralizing antibody titers and T-cell responses may compromise protection, especially against emerging variants with immune escape potential [5,6]. Our study confirms that administration of a booster dose restores protective immunity and provides significant protection against severe outcomes, with an adjusted hazard ratio of 0.18 for severe disease.

The lower incidence of severe disease in the booster group aligns with data from large population-based studies conducted in Israel and the United States, where booster recipients showed significantly lower rates of severe COVID-19 and hospitalization [7,8]. In a study by Bar-On et al., the rate of severe illness was reduced by more than 90% among individuals aged 60 and older who received a booster dose [9]. Similarly, data from the UK Health Security Agency demonstrated high vaccine effectiveness of booster doses across different age groups, including against Omicron variant-associated hospitalizations [10].

Our study also revealed a small but noteworthy difference in mortality, with zero deaths in the booster group and four deaths in the non-booster group. While this difference may seem marginal, it underscores the importance of booster vaccination, especially in highrisk populations where even a single preventable death is significant [11]. The observed reduction in ICU admissions further strengthens the case for booster doses as a public health measure to reduce healthcare system burden during future waves of the pandemic [12].

It is also essential to consider the role of communitybased vaccine delivery strategies, which may have influenced the relatively high uptake and timely administration of boosters in the study setting. Public accessibility, and proactive trust, health communication campaigns are crucial components for successful booster rollouts [13,14]. Additionally, our random sampling helped stratified ensure representativeness across socio-demographic groups, adding to the generalizability of the findings.

However, this study has some limitations. First, the follow-up duration was limited to six months, which may not capture long-term vaccine effectiveness. Second, despite efforts to control for confounding variables, residual confounding from behavioural factors such as mask usage or adherence to social distancing may have influenced infection outcomes. Third, variant-specific data were not available, limiting our ability to assess booster efficacy against particular strains.

CONCLUSION

In conclusion, our results add to the growing body of evidence supporting the effectiveness of booster vaccination in reducing the burden of severe COVID-19. Continued surveillance and targeted booster strategies will be crucial in maintaining population immunity, particularly in vulnerable and underserved communities.

REFERENCES

- Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. *N Engl J Med.* 2020 Dec 31;383(27):2603–15. doi: 10.1056/NEJMoa2034577. PMID: 33301246.
- Chenchula S, Karunakaran P, Sharma S, Chavan M. Current evidence on efficacy of COVID-19 booster dose vaccination against the Omicron variant: A systematic review. *J Med Virol*. 2022 Jul;94(7):2969– 76. doi: 10.1002/jmv.27697. PMID: 35246846.
- 3. Fiolet T, Kherabi Y, MacDonald CJ, Ghosn J, Peiffer-Smadja N. Comparing COVID-19 vaccines for their characteristics, efficacy and effectiveness against

SARS-CoV-2 and variants of concern: a narrative review. *Clin Microbiol Infect*. 2022 Feb;28(2):202–21. doi: 10.1016/j.cmi.2021.10.005. PMID: 34715347.

- Moreira ED Jr, Kitchin N, Xu X, Dychter SS, Lockhart S, Gurtman A, et al. Safety and Efficacy of a Third Dose of BNT162b2 Covid-19 Vaccine. *N Engl J Med.* 2022 May 19;386(20):1910–21. doi: 10.1056/NEJMoa2200674. PMID: 35320659.
- Hall V, Foulkes S, Insalata F, Kirwan P, Saei A, Atti A, et al. Protection against SARS-CoV-2 after Covid-19 Vaccination and Previous Infection. *N Engl J Med.* 2022 Mar 31;386(13):1207–20. doi: 10.1056/NEJMoa2118691. PMID: 35172051.
- El Karoui K, De Vriese AS. COVID-19 in dialysis: clinical impact, immune response, prevention, and treatment. *Kidney Int.* 2022 May;101(5):883–94. doi: 10.1016/j.kint.2022.01.022. PMID: 35176326.
- Wu N, Joyal-Desmarais K, Ribeiro PAB, Vieira AM, Stojanovic J, Sanuade C, et al. Long-term effectiveness of COVID-19 vaccines against infections, hospitalisations, and mortality in adults: findings from a rapid living systematic evidence synthesis and metaanalysis up to December, 2022. *Lancet Respir Med*. 2023 May;11(5):439–52. doi: 10.1016/S2213-2600(23)00015-2. PMID: 36780914.
- Uzun O, Akpolat T, Varol A, Turan S, Bektas SG, Cetinkaya PD, et al. COVID-19: vaccination vs. hospitalization. *Infection*. 2022 Jun;50(3):747–52. doi: 10.1007/s15010-021-01751-1. PMID: 34984646.
- Nashwan A, Yassin M, Soliman A, De Sanctis V, Ibrahim M. mRNA-based COVID-19 Vaccines Booster Dose: Benefits, Risks and Coverage. *Acta Biomed.* 2022 Jul 1;93(3):e2022236. doi: 10.23750/abm.v93i3.13103. PMID: 35775753.
- Andrews N, Stowe J, Kirsebom F, Toffa S, Rickeard T, Gallagher E, et al. Covid-19 Vaccine Effectiveness against the Omicron (B.1.1.529) Variant. *N Engl J Med.* 2022 Apr 21;386(16):1532–46. doi: 10.1056/NEJMoa2119451. PMID: 35249272.
- Saltoğlu N, Dinç HÖ, Balkan İİ, Can G, Özbey D, Beytur AN, et al. Heterologous booster COVID-19 vaccination elicited potent immune responses in HCWs. *Diagn Microbiol Infect Dis*. 2022 Oct;104(2):115758. doi: 10.1016/j.diagmicrobio.2022.115758. PMID: 35878507.
- Alshahrani NZ, Alsabaani AA, Ridda I, Rashid H, Alzahrani F, Almutairi TH, et al. Uptake of COVID-19 Booster Dose among Saudi Arabian Population. *Medicina (Kaunas)*. 2022 Jul 21;58(7):972. doi: 10.3390/medicina58070972. PMID: 35888690.
- García-Botella A, García-Lledó A, Gómez-Pavón J, González Del Castillo J, Hernández-Sampelayo T, Martín-Delgado MC, et al. Booster or additional vaccination doses in patients vaccinated against COVID-19. *Rev Esp Quimioter*. 2022 Apr;35(2):105– 14. doi: 10.37201/req/149.2021. PMID: 34775740.
- Pimenta D, Yates C, Pagel C, Gurdasani D. Delaying the second dose of covid-19 vaccines. *BMJ*. 2021 Mar 18;372:n710. doi: 10.1136/bmj.n710. PMID: 33737404.
- Du Y, Chen L, Shi Y. Booster COVID-19 vaccination against the SARS-CoV-2 Omicron variant: A systematic review. *Hum Vaccin Immunother*. 2022 Nov 30;18(5):2062983.doi:10.1080/21645515.2022.206298 3. PMID: 35499517.