MEDICAL JOURNAL ARMED FORCES INDIA 77 (2021) S264–S270

Available online at www.sciencedirect.com

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Original Article

COVISHIELD (AZD1222) VaccINe effectiveness among healthcare and frontline Workers of INdian Armed Forces: Interim results of VIN-WIN cohort study

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ARTICLE INFO

Article history:
Received 13 June 2021
Accepted 28 June 2021

Keywords:
COVISHIELD
Covid-19
Vaccine effectiveness
VIN-WIN cohort
Breakthrough infections

ABSTRACT

Background: On 16 Jan 2021, India launched its immunization program against COVID-19. Among the first recipients were 1.59 million Health Care Workers (HCWs) and Frontline Workers (FLWs) of the Indian Armed Forces, who were administered COVISHIELD (Astra Zeneca). We present an interim analysis of vaccine effectiveness (VE) estimates till 30 May 2021.

Methods: The VIN-WIN cohort study was carried out on anonymized data of HCWs and FLWs of Indian Armed Forces. The existing surveillance system, enhanced for COVID-19 monitoring, was sourced for data. The cohort transitioned from Unvaccinated (UV) to Partially Vaccinated (PV) to Fully Vaccinated (FV), serving as its own internal comparison. Outcomes studied in the three groups were breakthrough infections and COVID related deaths. Incidence Rate Ratio (IRR) was used to compare outcomes among the three groups to estimate VE.

Results: Data of 1,595,630 individuals (mean age 27.6 years; 99% male) over 135 days was analysed. Till 30 May 21, 95.4% and 82.2% were partially and fully vaccinated. The UV, PV and FV compartments comprised 106.6, 46.7 and 58.7 million person-days respectively. The

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https://doi.org/10.1016/j.mjafi.2021.06.032

number of breakthrough cases in the UV, PV and FV groups were 10061, 1159 and 2512; while the deaths were 37, 16 and 7 respectively. Corrected VE was 91.8–94.9% against infections.

Conclusion: Interim results of the VIN-WIN cohort study of 1.59 million HCWs and FLWs of Indian Armed Forces showed a ~93% reduction in COVID-19 breakthrough infections with COVISHIELD vaccination.

Introduction

The COVID-19 pandemic produced the swiftest ever worldwide healthcare effort. Though initially intimidated by rising numbers, the multi-pronged response focused on understanding transmission, disease and Non-Pharmacological Interventions (NPIs) in the population.[1] This was followed by search for effective treatments.[2] The focus next shifted to planning for mass vaccination. Vaccine development, which had hitherto taken a decade or more, was now telescoped to a few months.[3] The Pfizer vaccine was the first to get emergency use authorization by Food and Drug Administration in USA, followed by Moderna.[4] Initial vaccine efficacy data was provided by the manufacturers.[5,6] Some early studies of vaccine effectiveness among population have been carried out in a few countries.[7,8]

In India, two vaccine candidates, COVISHIELD (Astra Zeneca) and COVAXIN (Bharat Biotech), were accorded emergency use approval on 03 Jan 2021.[9] COVISHIELD (ChAdOx1 nCoV-19) is an adenovirus vector-nonreplicating virus vaccine carrying recombinant spike protein of SARS-CoV-2. It had shown acceptable safety profile in phase I/II trials and an efficacy of 74% in preventing infections in interim analysis of phase III trials.[10–12] The effectiveness of this vaccine among the Indian population requires to be established. Effectiveness has been defined as reduced risk of infection or disease among individuals which is attributed to vaccination, in real world conditions.[13] World Health Organization has provided interim guidance for evaluation of COVID-19 vaccine effectiveness.[14]

When COVID-19 vaccination commenced in India, all healthcare workers (HCWs) and frontline workers (FLWs) were initially vaccinated.[15] Armed Forces personnel were vaccinated rapidly, affording a unique opportunity to study vaccine effectiveness among a large cohort in India. The VIN-WIN study aimed to evaluate the effectiveness of COVISHIELD vaccine on occurrence of breakthrough infections and COVID-19 related deaths. Here we provide the interim results after 4.5 months of vaccination drive.

Materials and methods

The VIN-WIN cohort study was carried out on anonymized data of HCWs and FLWs of the Armed Forces. The existing surveillance system, which had been enhanced for COVID-19 monitoring, was sourced for data. The vaccination drive commenced on 16 Jan 2021 and the second dose was administered four weeks later, from 13 Feb 2021. Data recorded for the VIN-WIN study included date-wise parameters from 16 Jan to 30 May 21 regarding number of persons vaccinated with first dose, second dose, date of testing positive for COVID-19 and deaths due to COVID-19.

Individuals were tested for COVID infection according to prevailing policy which was uniformly applicable across the cohort. They were tested with molecular diagnostic tests (RT-PCR or Rapid antigen) if they developed symptoms of illness or were high risk contacts of confirmed COVID-19 cases or related to travel requirements. Symptomatic individuals who tested negative by rapid antigen test, were confirmed using RT-PCR. Those who tested positive by either test were considered as cases. Individuals were considered unvaccinated (UV) from 16 Jan 21 till their status changed to partially vaccinated. They were deemed partially vaccinated (PV) and fully vaccinated (FV) two weeks after the first and second vaccine dose respectively. Any person (PV or FV) who tested positive for COVID-19 after vaccination, was labelled as a case of breakthrough infection. All deaths among COVID-19 positive individuals were counted as COVID-19 related deaths. Over the study period, three groups were naturally formed as most UV individuals moved sequentially to PV and FV compartments. Data from individuals was censored on 30 May 2021 or if they tested COVID-19 positive at any point in time.

Population at risk for groups was calculated in terms of person-days. If one person remained in a group for 100 days or 2 persons for 50 days each, both were counted as 100 person-days. Crude incidence rates (IR) were calculated for each group by dividing the total number of cases by the population at risk in that group. Crude Incidence Rate Ratio (IRR) was calculated for PV/UV and FV/UV. Confidence intervals were estimated.[16] The population experienced a changing risk of infection over time that was determined by the progress of the pandemic. Thus, corrected IR and IRR were calculated to account for the changing risk and the composition of the three groups on a daily basis. This correction was done by using two different methods.

1. Method # 1:
   a. Daily IR of infections/deaths for each group (UV/PV/FV) was calculated by dividing the number of daily cases by population at risk in the group on that day.
   b. Mean of daily IR was calculated for each group.
   c. Ratio of means PV:UV and FV:UV was calculated yielding corrected IRR #1. This method followed the sequence Daily IR → Mean→ Ratio.

Table 1 – Impact of vaccination on cases and deaths (16 Jan–30 May 2021).

	Un-vaccinated	Partially Vaccinated	Fully Vaccinated
Numbers at start of study	1,595,630	0	0
Numbers vaccinated	–	1,523,347 (95.4%)	1,312,938 (82.2%)
Duration of observation (person days)	106,594,492	49,653,918	58,674,639
Total cases	10,061	1159	2512
Total Deaths	37	16	7
Crude Incidence rate (cases per million person days)	94.4	23.3	42.8
Corrected Incidence Rate (cases per million)	512.9	25.4	26.2

2. Method # 2: In this method an adaptation of time-dependent Cox analysis was used.[17] Risk of infection, which was a time-varying risk factor, was accounted for by calculating the Relative Risk (RR) between PV/UV and FV/UV, on a daily basis. Weighted mean of IRR was calculated. The steps were -
   a. Daily IR of infections/deaths for each group (UV/PV/FV) was determined.
   b. Daily ratio of PV:UV and FV:UV was then calculated.
   c. Weighted mean of these ratios yielded corrected IRR # 2. This method followed the sequence Daily IR→ Ratio → Mean.

VE was calculated as 1 - IRR. Method # 1 yielded corrected IR, Absolute Risk reduction (ARR) and Number needed to vaccinate (NNV). Both methods yielded corrected IRR and Vaccine effectiveness (VE). Median time to breakthrough infection was calculated in the PV and FV groups. The effect of partial or complete vaccination was assumed to be constant as long as the individual remained in that group.

Ethics clearance was obtained from Institutional ethics committee. Data was collated using MS Excel and analysed using Python scripts NumPy, SciPy and Lifelines modules. Differences in IRR between the groups were tested for statistical significance using Z-test. A p-value of less than 0.05 was considered significant.

Results

A total of 1,595,630 (~1.59 million) HCWs and FLWs located all across India formed the VIN-WIN study cohort. They had a mean age of 27.6 (SD 6.16) years and had minimal co-morbidities. They were predominantly males (99%).[18] The mean duration between the 1st and 2nd dose in cases who tested COVID positive subsequently was 31.43 (SD 7.23) days.

The VIN-WIN cohort was observed from 16 Jan to 30 May 2021 for 135 days. The UV, PV and FV compartments comprised 106.6, 49.7 and 58.7 million person-days respectively (Table 1, Fig. 1a). By 30 May 2021, a total of 95.4% (1,523,347) had been at least partially vaccinated, while 82.2% (1,312,938) had been fully vaccinated (Table 1, Fig. 1b). The number of fresh COVID-19 infections in the cohort among the UV, PV and FV groups were 10061, 1159 and 2512 respectively (Fig. 2a). The daily IR (per million) for cases is depicted in Fig. 2c. The crude and corrected IR for cases is shown in Table 1 and Fig. 3a and b, while the IRR and VE (crude and corrected) is depicted in Table 2. Among the fully vaccinated, corrected VE as calculated by both the methods ranged from 91.8 to 94.9% for breakthrough infections (Table 2). The ARR for breakthrough infections was 486 per million and the NNV to prevent one case was 2054.

During the study period, deaths in the UV, PV and FV groups were 37, 16 and 7 respectively (Fig. 2b). The daily incidence of deaths is depicted in Fig. 2d. Mean age of those who died was 43.17 (SD 8.22) years and 40% (24/60) of them had one or more co-morbidities. Crude IRRs of COVID related deaths for PV/UV and FV/UV were 0.93 (95% CI: 0.48–1.71) and 0.34 (95% CI 0.13–0.78) respectively. Corrected IRRs (method #2) for PV/UV and FV/UV were 0.13 (95% CI: 0.001–19.34) and 0.02 (95% CI: 0.00 to >100) respectively. Vaccine effectiveness relating to prevention of COVID related deaths was 98.53% (95% CI: 0.00–99.99). The wide

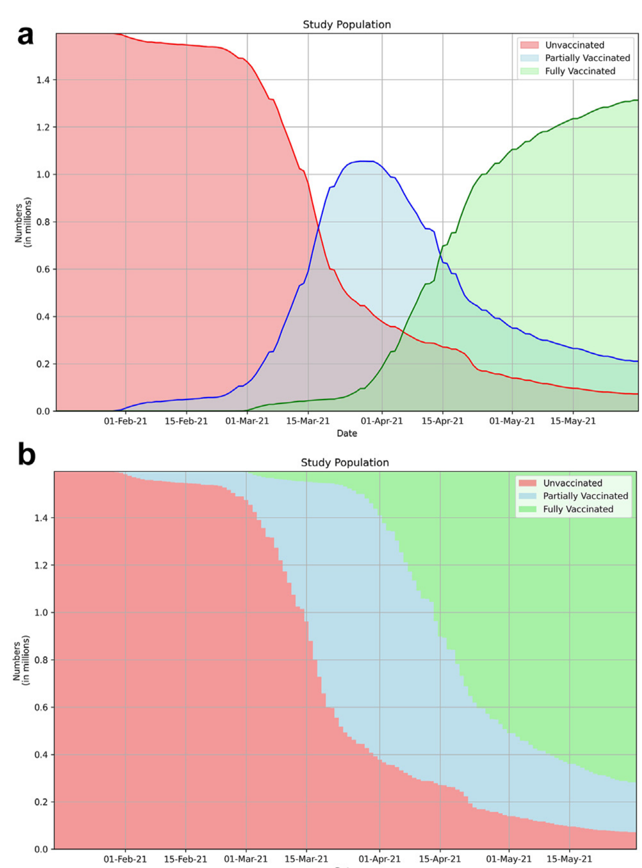

Fig. 1 – a: Vaccine drive among HCWs and FLWs of Indian Armed Forces (16 Jan–30 May 2021). b: VIN-WIN cohort: Un-vaccinated (UV) – Partially vaccinated (PV) – Fully vaccinated (FV).

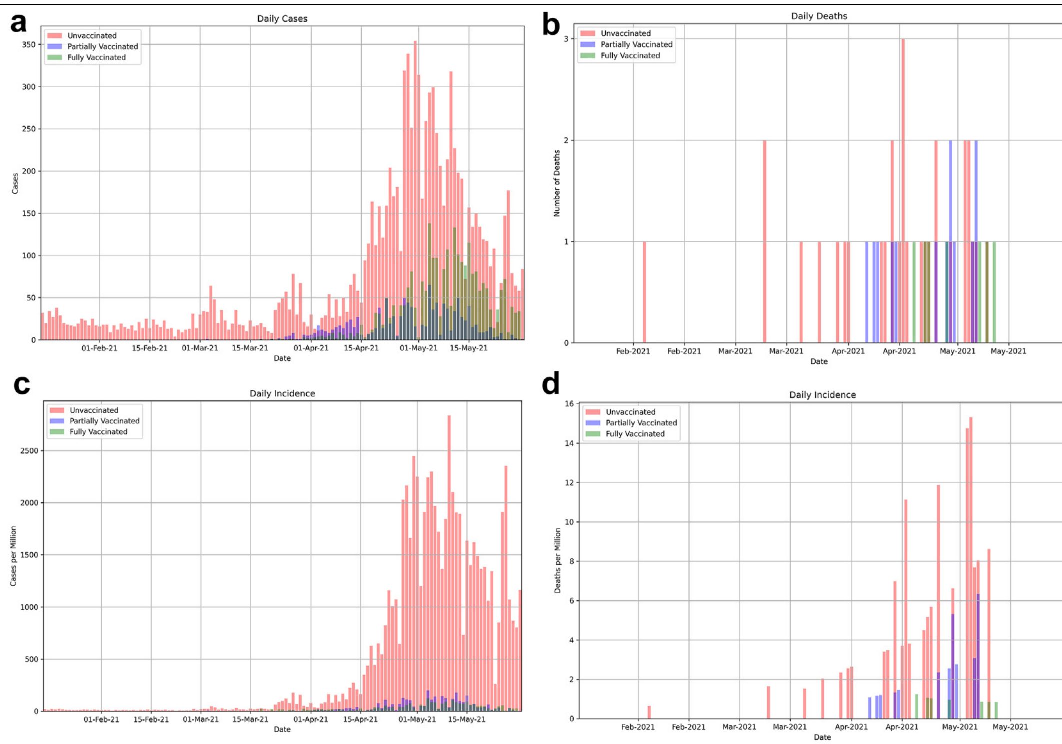

Fig. 2 – a: COVID infections in cohort: daily cases. b: COVID infections in cohort: daily deaths. c: Corrected Incidence rates (cases per million). d: Corrected Incidence rates (deaths per million).

confidence intervals observed in corrected IRR and VE which occurred due to very few deaths in the vaccinated group, did not allow meaningful conclusions to be drawn (Fig. 2d).

The number of daily breakthrough cases among the partially and fully vaccinated is depicted in Fig. 4a. The mean age of patients with breakthrough infections was 33.16 (SD 8.46) years. Median time to infection after the first dose was 21 days (95% CI: 19–22) and after second dose was 31 days (95% CI: 30–33) (Fig. 4b and c).

Discussion

The VIN-WIN study, conducted among 1.59 million HCWs and FLWs of Indian Armed Forces showed that vaccination with COVISHIELD reduced the risk of breakthrough infections by around 91–94% (Table 2). Studies from across the world have yielded various results.[12,19,20] (Table 3) Vaccination was shown to reduce hospitalization by 88% in a large cohort of 1.3 million in Scotland.[7] Other studies showed a 60–70% reduction in breakthrough infections.[12,19,20] Due to the very small number of deaths in the vaccinated groups, the observed confidence intervals were extremely wide. Thus, no valid statistical inference could be drawn.[20]

In the initial period of pandemic, the Armed Forces followed a vigorous contact tracing policy in 2020. A large number of asymptomatic cases were thus detected which is reflected in the higher rate of infections compared to the Indian population (Fig. 5a). In the first wave, despite the higher detection of infections, deaths in the Armed Forces were lower than in the Indian population (Fig. 5b). During the second wave, while both cases and deaths surged across the country

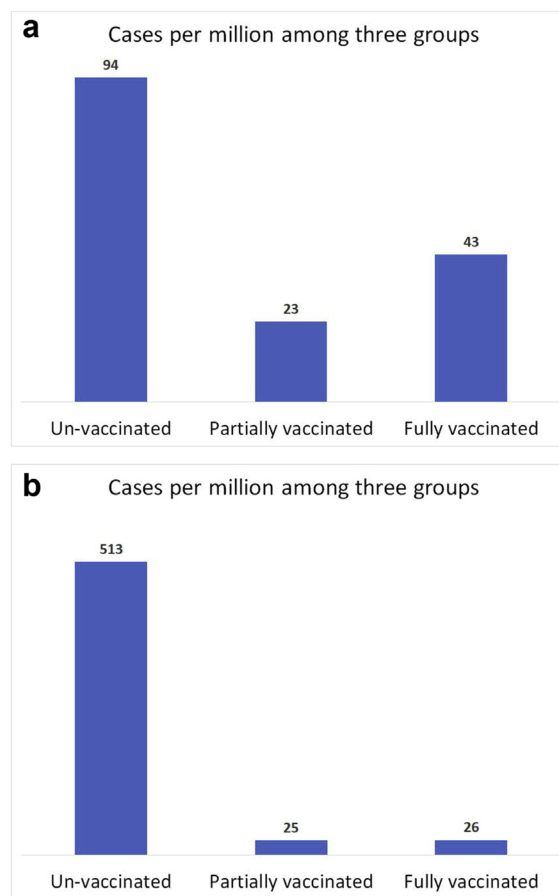

Fig. 3 – a: Crude Incidence rate, b: Corrected Incidence rate.

Table 2 – Vaccine effectiveness (Crude and Corrected) in VIN-WIN cohort.

Cases	Crude Incidence Rate Ratio (IRR)	Crude Vaccine Effectiveness (VE)	Corrected Incidence Rate Ratio (IRR)*		Corrected Vaccine Effectiveness (VE)		Absolute Risk Reduction (ARR)	Number Needed to Vaccinate (NNV)
			Method# 1	Method# 2	Method# 1	Method# 2	Method# 1	Method# 2
PV: UV	0.253 (0.232–0.262)	75.2% (73.8–76.8)	0.049 (0.033–0.073)	0.057 (0.039–0.082)	95.13% (92.72–96.74)	94.35% (91.78–96.11)	487	2051
FV:UV	0.454 (0.434–0.474)	54.6% (52.6–56.6)	0.051 (0.034–0.075)	0.082 (0.060–0.112)	94.93% (92.49–96.58)	91.81% (88.79–94.02)	486	2054

(which had larger proportion of unvaccinated population compared to the VIN-WIN cohort), there was a discernible lower incidence of both among the Armed Forces (Fig. 5a and b). The only major way in which VIN-WIN cohort differed was the very high rate of vaccination.

When the first wave peaked in India on 16 Sep 2020 with 97,894 fresh COVID cases, the Armed Forces had 485 cases that day. The maximum number of daily fresh cases in the first wave among Armed Forces personnel was 686 on 19 Sep 2020. However, in the second wave, when fresh cases in India climbed to 414,188 on 06 May 2021, the Armed Forces experienced only 386 fresh cases, with a peak of 496 on 04 May 2021. The number of fresh cases in the Armed Forces did not rise in the second wave as was expected.

Studies have shown a better response among younger population with various vaccines ranging from 95 to 100%, compared to 60–70% among the elderly populations.[5,21,22] This study was carried out on a relatively young cohort with a mean age of 27.6 years which might have contributed to the higher observed vaccine efficacy.

In this study, the same set of individuals moved across the three groups over 135 days of observation, allowing for internal comparison as they transitioned from one vaccination status to the next. Over 82% of the cohort had been fully vaccinated by 30 May 2021. Though a few personnel did retire from service during the course of the study or died from other causes, they were less than 0.1% of the entire cohort and were not taken into consideration.

The study has certain limitations. The VIN-WIN cohort differed from the Indian population. While the mean age of this cohort (27.6 years) was similar to that of the Indian population, the confidence interval was much narrower as it did not represent almost 50% of the population (age <18 years ~40% and >60 years~10%).[23] Also, it was a predominantly

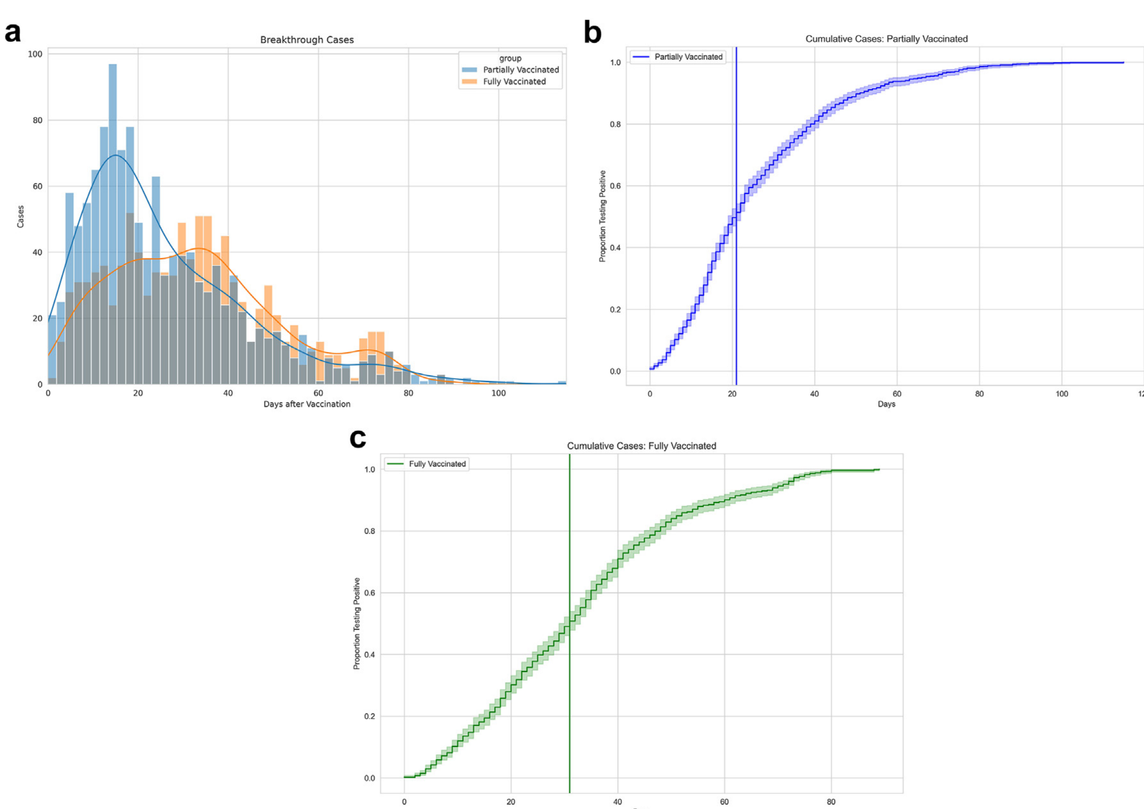

Fig. 4 – a: Breakthrough infections: COVID cases after first and second vaccine dose. b: Cumulative COVID cases among partially vaccinated. c: Cumulative COVID cases among fully vaccinated.

Table 3 – COVISHIELD vaccine efficacy/effectiveness studies.

	VIN-WIN Study	Bernal et al.	Voysey et al.	Madhi et al.	Vasileiou et al.
Country	India	UK	UK, Brazil, South Africa	South Africa	UK
Sample characteristics	Males Mean age 27.6	Age >70	Age >18	18-65, HIV negative	Mean age 65
Sample Size	1,595,630	156,930	11,636	2026	1,331,993
Type of study	Cohort	Case control	RCT	RCT	Cohort
Outcome measures	Vaccine Effectiveness. Cases, Deaths	Vaccine Effectiveness. Cases, Hospitalisation	Vaccine Efficacy. Cases	Vaccine Efficacy. Cases	Vaccine Effectiveness. Hospitalisation after 1 dose
Results	Reduction of 95.4% in cases	Reduced odds of 73% in cases, 43% in admissions	Reduction of 62.1% in cases	Reduction of 21.9% cases against B.1.351 variant	Reduction of hospitalisation by 88%

male cohort comprising of individuals with minimal co-morbidities. Thus, the results of this study may not generalize across the entire population which includes elderly, children, females and those with co-morbidities. Vaccine effectiveness may or may not be similar in these sub-groups. However, the ~93% vaccine effectiveness seen in this study is quite promising. Similar results may be expected among healthy females.

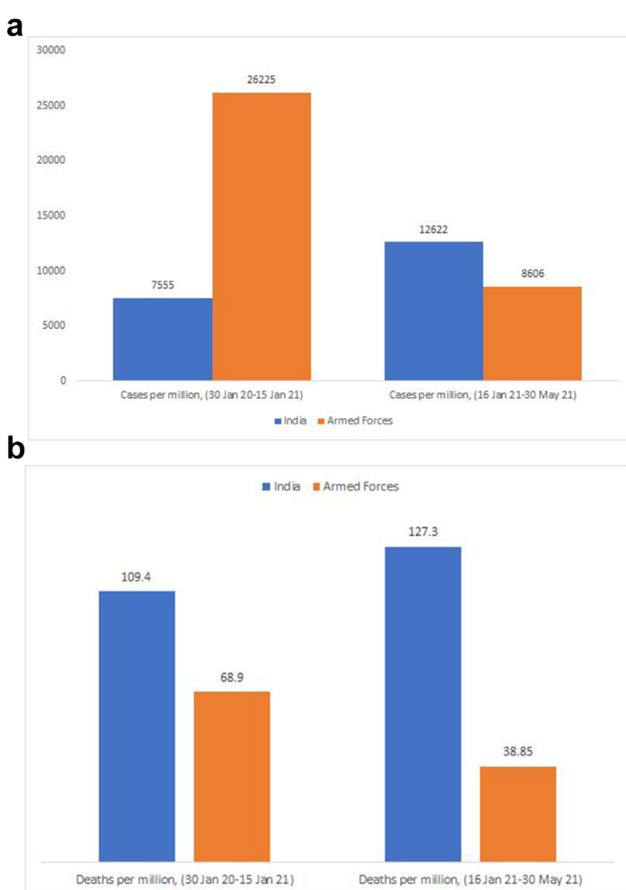

Fig. 5 – a: COVID infections (cases per million) before and after vaccination drive: Indian population vs. Armed Forces. b: COVID related deaths (deaths per million) before and after vaccination drive: Indian population vs. Armed Forces.

As it was surveillance data that was analysed, details of the more than 1.58 million individuals who did not become COVID positive during the course of the study was only available as summary statistics. Hence, we were unable to perform a Cox proportional hazard regression. All HCWs and FLWs were included in the vaccination drive regardless of an individual's serological or previous COVID positive status. We are thus unable to quantify the impact of the previous infection on vaccine effectiveness. Additionally, though the reduction in deaths appears promising, the extremely small numbers of deaths among the vaccinated leads to very wide confidence intervals for corrected IRR and VE, and needs to be interpreted with caution. A possible limitation is also that vaccine effectiveness was analysed for a gap of four weeks between the two doses, not 6–12 weeks as recommended by the manufacturer.

The study has many strengths. This is the largest study from India evaluating COVID vaccine effectiveness so far. This study method, which utilised existing surveillance data to evaluate vaccine effectiveness, offered the advantage of low cost. There was almost no attrition or loss to follow-up, with preservation of herd structure throughout the study. This cohort also had negligible vaccine refusal rate resulting in more than 95% being at least partially vaccinated. This study was carried out on Armed Forces population which is representative of the ethnic heterogeneity of India. The existing infrastructure, functioning processes and swift implementation in the Armed Forces, allowed for effective data gathering and policy implementation. The second wave struck during the latter half of the study, changing the risk of infection on an almost daily basis. We used two methods of calculating corrected IRR that enabled us to take the changing epidemiological situation into consideration. The difference seen between crude and corrected IRR is a reflection of this (Table 2).

To conclude, the VIN-WIN cohort study comprising 1.59 million HCWs and FLWs of the Indian Armed Forces which was observed from 16 Jan – 30 May 21, has shown a ~93% reduction in COVID-19 infections as a result of the vaccination drive.

Disclosure of competing interest

The authors have none to declare.

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