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RESEARCH

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A joinpoint regression model to determine COVID-19 virulence due to vaccination programme in India: a longitudinal analysis from 2020 to 2022

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Abstract

Background In late 2019, coronavirus disease, an acute respiratory illness caused by the novel coronavirus (SARS-CoV-2), was designated COVID-19 and declared a pandemic. The interim guidance for prevention is through voluntary quarantine, mandatory quarantine, personal protective measures and maintaining social distance in public places. However, considering the severity and rapid spread of the disease to various countries, vaccine development was the last option to cope with the dire consequences. As of 14 Feb 2023, approximately 756 million people were infected with COVID-19 and 6.84 million deaths. As of 30 Jan 2023, around 1317 crores of vaccine doses were administered worldwide. In India, as of 15 Feb 2023, there were approximately 44.15 million infected persons due to COVID-19 and 5,30,756 deaths (1.2%). Considering the high case fatality rate and population size, the Government of India (GOI) implemented the COVID vaccination programme on 16 Jan 2021. As of 15 Feb 2023, approximately 220.63 crores of vaccine doses were administered.

Methods We applied joinpoint regression analysis to determine the virulence of COVID-19 cases concerning their daily percentage change (DPC) and average DPC (ADPC) during India's prevaccination and vaccination phases. We considered the database of daily reporting of COVID-19 cases covering 1018 days (19 Mar 2020 to 31 Dec 2022) that included both prevaccination and vaccination phases.

Results Three joinpoint regression analyses adequately fit the data and identified four segments during the prevaccination and vaccination phases. Although the DPC value was 6.4% (95% confidence interval [CI]: 4.7 to 8.3) in the initial period of 50 days, the ADPC value significantly declined to 1.6% (95% CI 1.3 to 1.8) at the end of the prevaccination phase. During the vaccination phase, the model identified two significant segment periods that coincided with the waves of SARS-CoV-2 and Omicron Delta variants. The corresponding DPC values were 4.6% (95% CI 4.2 to 4.9) and 21.6% (95% CI 15.1 to 28.4), respectively. Despite these waves, COVID vaccination significantly reduced the ADPC value (−1.6%; 95% CI −1.7 to −1.5).

Conclusions We demonstrated the lockdown and vaccination phases significantly reduced ADPC. Furthermore, we quantified the severity of SARS-CoV-2, the Delta and the Omicron variant. The study findings are significant from an epidemiological perspective and can help health professionals to implement appropriate control measures.

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Keywords COVID-19, Vaccination, Joinpoint regression, India, Daily percentage change, Average daily percentage change, SARS-CoV-2, Omicron, Longitudinal analysis

Background

COVID-19 pandemic phase to vaccine development stage

In late 2019, coronavirus disease, an acute respiratory illness caused by the novel coronavirus (SARS-CoV-2), was first identified in Wuhan City, China (Fan et al. 2020; Muniz-Rodriguez et al. 2020), and spread acceleratedly crossing borders and became a global health concern. As a result, the World Health Organization (WHO) designated the disease as COVID-19 and declared it a pandemic on 11 Mar 2020. The virus that causes COVID-19 is believed to spread mainly from person to person through respiratory droplets produced when an infected person coughs or sneezes. Transmission of SARS-CoV-2 from asymptomatic individuals (or individuals within the incubation period) has also been described. Unfortunately, no medication was approved by the Food and Drug Administration (FDA) to treat the disease. The interim guidance published by the WHO on 7 Mar 2020 states that preventing COVID-19 from spreading is through voluntary quarantine (self-quarantine), mandatory quarantine (private residence, hospital and public institutions), other methods such as personal protective measures (hand hygiene, wearing medical face masks) and maintaining social distance in the public places. Considering the severity and rapid spread of the disease to various countries, in addition to these preventive measures, the WHO guided to impose a social lockdown phase in countries with high population densities. Simultaneously, the WHO advised all the health authorities in the respective countries to adopt integrated approaches such as mass screening, treating and quarantining the suspected individual to reduce the disease within a manageable level. In certain European countries (Hashim et al. 2022) with a high prevalence of COVID-19, a policy of universal screening of pregnant women for COVID-19 before admission to the labour ward was enforced. Due to the diversion of all healthcare funds towards COVID-19 disease control, there was a severe economic loss, particularly in the countries that imposed a lockdown phase, which restricted travel, workforce and trading. Apart from this, social life includes human services (overburden of medical and clinical personnel, lack of treatment facilities for other non-communicable diseases and lack of medications facilities in medical shops) and organizing social functions was drastically affected (Mishra et al. 2020). The WHO advised the pharmaceutical companies to develop a vaccine against COVID-19 to cope with these dire consequences. As a result, as of 8 Apr 2022, WHO has evaluated a list of vaccines (AstraZeneca/Oxford vaccine, Johnson and Johnson, Moderna, Pfizer/BionTech, Sinopharm, Sinovac, Covaxin, Covovax, Nuvaxovid and CanSino) developed in different companies and recommended that these vaccines against COVID-19 have met the necessary criteria for safety and efficacy.

Vaccination status in India

According to the World Health Organization (WHO) coronavirus (COVID-19) dashboard, as of 14 Feb 2023, approximately 756 million people were infected with COVID-19 and 6.84 million (0.9%) people died globally (https://covid19.who.int/). As of 30 Jan 2023, around 1317 crores of vaccine doses were administered worldwide. In India, as of 15 Feb 2023, there were about 44.15 million infected persons, accounting for 4.7% of the adult population (aged 15 to 64 years) and 5,30,756 deaths (1.2%) (https://www.mohfw.gov.in/). Considering the high case fatality rate and population size, the Government of India (GOI) implemented the COVID vaccination programme on 16 Jan 2021 with the indigenously developed vaccines Covaxin and Covishield. As of 15 Feb 2023, approximately 220.63 crores of vaccine doses were administered.

Vaccination impact evaluation

Studies conducted in various countries have demonstrated the beneficial effects of the vaccination programme on mortality and other factors (Moghadas et al. 2021; Rovetta 2022; Chen et al. 2022; Watson et al. 2022; Notarte et al. 2022). In India, using a database of a particular period, the vaccine impact study observed the trend of infection growth (Adhikary et al. 2022).

Limited studies have assessed vaccination efficacy concerning relative risk (Bhatia and Abraham 2021), vaccine hesitancy (Chandani et al. 2021; Dhalaria et al. 2022) and the Peltzman effect (Juyal et al. 2021). In addition, these studies have provided information on community behaviours regarding vaccine acceptance and identified hesitancy factors for enhancing compliance in the community. However, no study in India has yet determined the virulence level of COVID-19 due to vaccine implementation by joinpoint regression analysis approach as applied in other studies (Siqueira et al. 2020; Khaleghi et al. 2022; Rovetta 2022). Therefore, using joinpoint regression analysis, this study evaluated the virulence of COVID-19 cases in terms of daily percentage change (DPC) and average daily percentage change (ADPC) during the prevaccination and vaccination implementation phases. The study findings can provide information on the duration at which disease severity will change direction for further timely action to prevent disease spread.

Methods

Database

Daily national-level reports of COVID-19 confirmed cases, recoveries, and deaths are available on the website of the Ministry of Health and Family Welfare (MoHFW), GOI (https://www.mohfw.gov.in/) or in daily COVID-19 Situation Reports (https://covid19.who.int/) published by the WHO. Although the first case of COVID-19 was reported on 30 Jan 2020 (MoHFW), the GOI started recording the daily increase in indigenous cases from 19 Mar 2020. Therefore, expecting a significant surge in COVID-19 cases caused by human contact, the GOI imposed a nationwide lockdown from 25 Mar 2020 to 1 Jun 2020. However, because lockdown is not a long-term and sustainable solution to control the rapid disease spread, the GOI followed WHO guidelines and implemented a vaccination programme from 16 Jan 2021; the programme is continuing to date. Therefore, in this study, we considered new cases recorded on 19 Mar 2020 as index cases (coded as Day 1) for COVID-19 transmission in India. To determine DPC and ADPC during the prevaccination phase (19 Mar 2020 to 15 Jan 2021), accounting for 303 days, and the vaccination phase (16 Jan 2021 to 31 Dec 2022), accounting for 715 days, daily recorded new cases formed the database. The data are available on the MoHFW, GOI website (https://mohfw.gov.in/) and WHO's COVID-19 situation reports (https://covid19.who.int/). Based on daily information on the MoHFW website, we created day-wise essential data by using an Excel spreadsheet for 1018 days (19 Mar 2020 to 31 Dec 2022).

Statistical analysis

Many studies have employed joinpoint regression procedures in various domains (Chaurasia 2020; Guimarães et al. 2020; Khaleghi et al. 2022; Rovetta 2022). Although time series models can efficiently project long- and short-term variations in the effects of exogenous variables, incidence projection using joinpoint regression is employed instead of these models (https://surveillance.cancer.gov/joinpoint/).

We performed joinpoint regression analysis to detect trend changes in each line segment and overall lines, whether increasing or decreasing. The trend parameters are DPC and ADPC, with statistical significance. The DPC can be calculated from COVID-19 new cases (y) on day 't' to '$t+1$' as follows:

$$\text{DPC} = \left(y_{t+1} - y_t\right)/y_t \times 100$$

Furthermore, the number of joinpoints began from 0 and progressively increased to determine whether adding additional joinpoints significantly improved the model's fitness. Finally, DPC and ADPC were estimated using the joinpoint regression approach to investigate the vaccination programme's impact. We used Joinpoint version 4.2.0.2, a free software (https://surveillance.cancer.gov/joinpoint/) developed by the Statistical Methodology and Applications Branch, National Cancer Institute, USA (Institute, 2015).

After log transformation, we considered daily confirmed COVID-19 cases as a count variable (dependent), the corresponding day as the interval variable, and the vaccination phases (prevaccination and vaccination) as the categorical variable. Because the daily recording of new cases is likely to be randomly distributed, we considered the standard error of the count variable as a Poisson variance. We selected the grid search method by considering a maximum of 3 joinpoints and determined the number of discrete locations tested to identify the best model fit. We decided on the best model that determines the number of joinpoints following the most negligible value of the traditional modified Bayesian Information Criterion (BIC). Using the t-independent test, we tested the significance of all the parameters related to joinpoint regression analysis under the null hypothesis that they are all zero. Similarly, we tested the DPC and ADPC values at the significance level of $P<0.05$.

Results

Figure 1 depicts three days' moving average values and observed data during the study period.

In both the prevaccination and vaccination phases, the three joinpoint model was identified as the best model with the lowest modified BIC values of 2.16 and 4.51, respectively. Table 1 presents the estimated joinpoint, 95% confidence interval (CI), and the corresponding regression coefficients estimation. All coefficients differed significantly ($P<0.001$) from the zero value. During the prevaccination phase of 303 days, the best model identified the four segments. The lower and upper ends of the four segments were 1–50, 50–133, 133–182, and 182–303 days, respectively. Table 2 lists the segment-wise estimated DPC and overall ADPC values with 95% CI.

DPC values were significantly ($P<0.001$) different from the zero value in all four segment periods. During the first segment period, the DPC value was 6.4% (95%

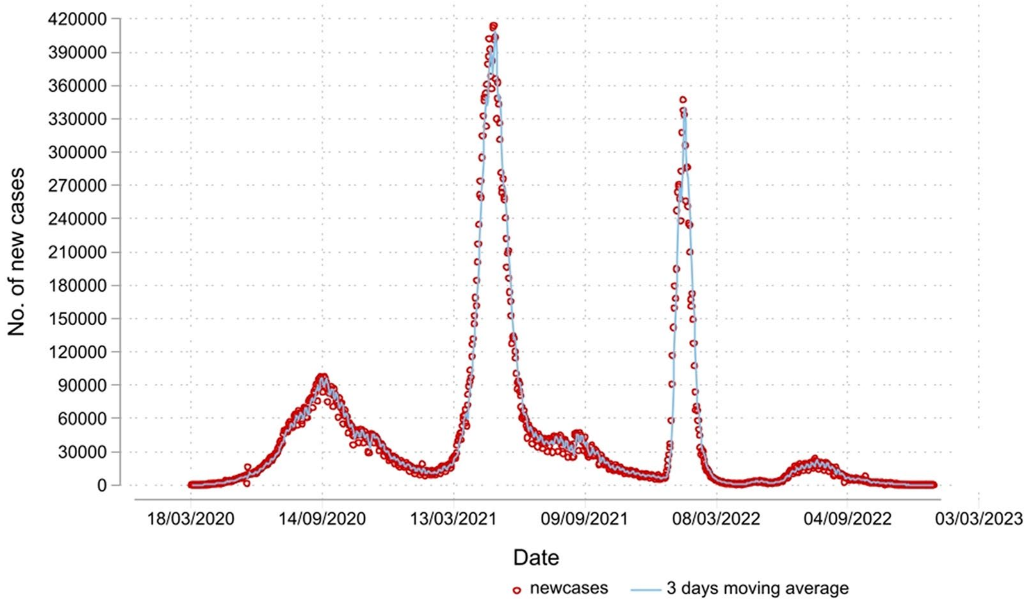

Fig. 1 Day-wise, COVID-19 new cases during the study period (19 Mar 2020 –31 Dec, 2022) along with three days moving average values

Table 1 Estimated joinpoints and estimated regression coefficients of joinpoints regression during pre-vaccination and vaccination period

Vaccination phase	Joinpoint	Estimated joinpoints (days)	95% confidence limits		Regression coefficients	Parameter estimation (S.E)	*P*-value
			Lower	Upper			
Pre-vaccination (n = 303) 19/03/2020 to 15/01/2021	1	50 (7/5/2020)	24 (11/4/2020)	135 (31/7/2020)	Intercept 1	5.03 (0.32)	< 0.001
	2	133 (29/7/2020)	127 (23/7/2020)	184 (18/9/2020)	Intercept 2	6.54 (0.09)	< 0.001
	3	182 (16/9/2020)	179 (13/9/2020)	273 (16/12/2020)	Intercept 3	9.12 (0.12)	< 0.001
					Intercept 4	14.03 (0.06)	< 0.001
					Slope 1	0.06 (0.01)	< 0.001
					Slope 2	0.03 (0.001)	< 0.001
					Slope 3	0.01 (0.001)	< 0.001
					Slope 4	− 0.01 (0.0002)	< 0.001
					Slope 2–Slope 1	− 0.03 (0.009)	< 0.001
					Slope 3–Slope 2	− 0.02 (0.001)	< 0.001
					Slope 4–Slope 3	− 0.03 (0.001)	< 0.001
During vaccination (n = 715) 16/01/2021 to 31/12/2022	1	407 (29/4/2021)	403 (25/4/2021)	410 (2/5/2021)	Intercept 1	− 5.44 (0.68)	< 0.001
	2	643 (21/12/2021)	635 (13/12/2021)	650 (28/12/2021)	Intercept 2	20.80 (0.22)	< 0.001
	3	665 (12/1/2022)	661 (8/1/2022)	668 (15/1/2022)	Intercept 3	− 117.36 (18.28)	< 0.001
					Intercept 4	23.41 (0.35)	< 0.001
					Slope 1	0.04 (0.002)	< 0.001
					Slope 2	− 0.02 (0.0005)	< 0.001
					Slope 3	0.19 (0.03)	< 0.001
					Slope 4	− 0.02 (0.0005)	< 0.001
					Slope 2–Slope 1	− 0.06 (0.002)	< 0.001
					Slope 3–Slope 2	0.21 (0.03)	< 0.001
					Slope 4–Slope 3	− 0.21 (0.03)	< 0.001

Table 2 Daily percentage change (DPC) and average daily percentage change (ADPC) in the new cases of COVID-19 during the study period (19/3/2020–31/12/2022)

Vaccination phase	Segment	Lower endpoint	Upper endpoint	DPC/ADPC	95% confidence limits		*P*-Value*
					Lower	Upper	
Pre-vaccination period (19/3/2020–15/1/2021)	1	1 (19/3/2020)	50 (7/5/2020)	6.4	4.7	8.3	< 0.001
	2	50 (7/5/2020)	133 (29/7/2020)	3.3	3.1	3.4	< 0.001
	3	133 (29/7/2020)	182 (16/9/2020)	1.3	1.1	1.5	< 0.001
	4	182 (16/9/2020)	303 (15/1/2021)	− 1.4	− 1.4	− 1.3	< 0.001
	Overall (ADPC)	1 (19/3/2020)	303 (15/1/2021)	1.6	1.3	1.8	< 0.001
Vaccination period (16/1/2021–31/12/2022)	1	304 (16/1/2021)	407 (29/4/2021)	4.6	4.2	4.9	< 0.001
	2	407 (29/4/2021)	643 (21/12/2021)	− 2.0	− 2.0	− 1.9	< 0.001
	3	643 (21/12/2021)	665 (12/1/2022)	21.6	15.1	28.4	< 0.001
	4	665 (12/1/2022)	1018 (31/12/2022)	− 1.6	− 1.7	− 1.5	< 0.001
	Overall (ADPC)	304 (16/1/2021)	1018 (31/12/2022)	− 0.22	− 0.40	− 0.04	< 0.001

The best model during the pre-vaccination phase was based on a three joinpoints regression model with the least modified Bayesian Information Criterion (2.16)

The best model during the vaccination phase was based on a three joinpoints regression model with the least modified Bayesian Information Criterion (4.51)

CI 4.7–8.3). The direction of DPC in the subsequent two segment periods was similar to that in the first segment with less virulence, which was 3.3% (95% CI 3.1–3.4) and 1.3% (95% CI 1.1–1.5) during the second and third segments, respectively. In the last segment period, the DPC tended to decline, with a value of less than zero (− 1.4%;

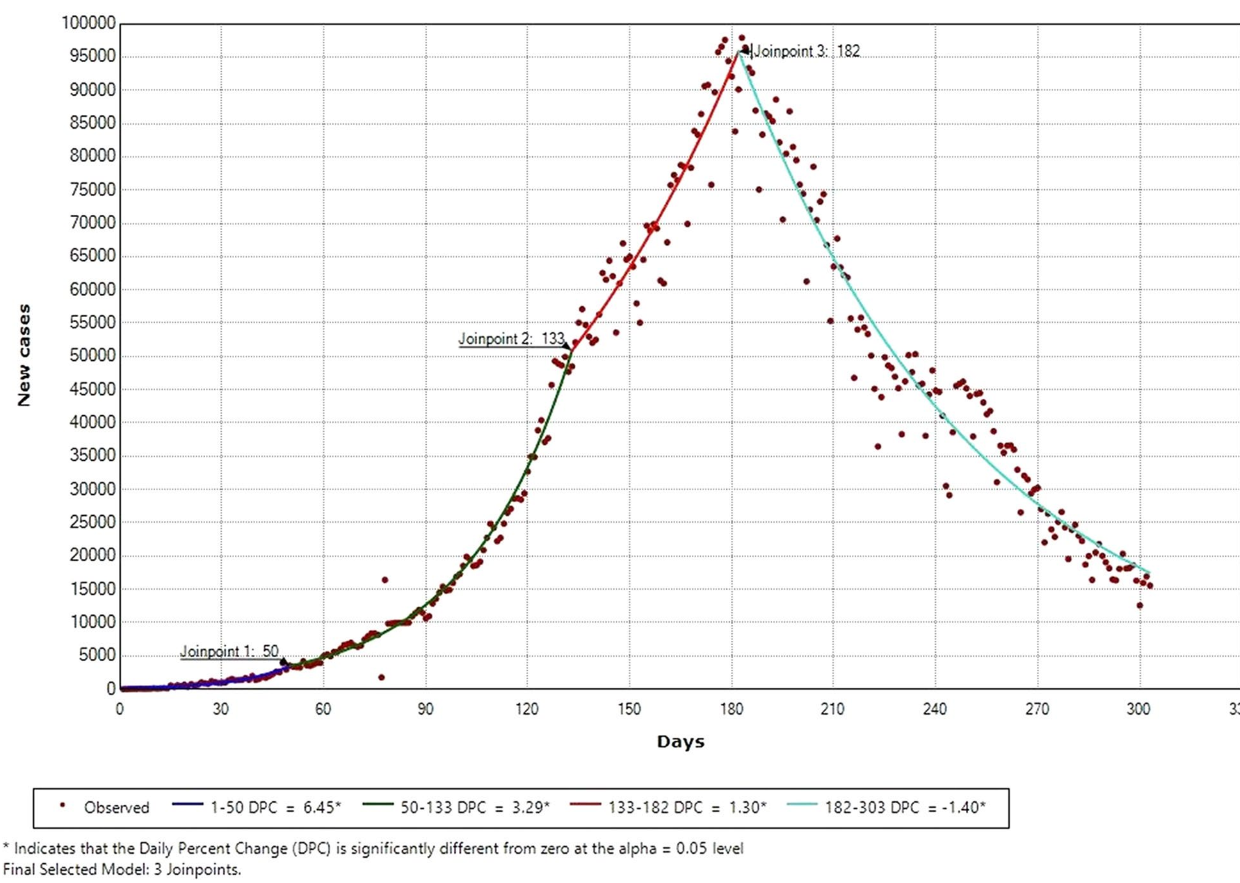

Fig. 2 Daily percentage change in COVID-19 new cases during different segment periods of the pre-vaccination phase by three joinpoints regression model

95% CI − 1.4 to − 1.3). However, the ADPC value of 1.6% (95% CI 1.3 to 1.8) revealed an increasing trend during the prevaccination phase. Figure 2 depicts the predicted values of new COVID-19 cases and observed values.

During the vaccination period of 715 days, the three joinpoint models identified four segments. The four segments' corresponding to the lower and upper ends were 304–407, 407–643, 643–665, and 665–1018 days, respectively. Table 2 lists DPC and ADPC values with 95% CI. During the first segment of the vaccination phase (104 days), the impact of vaccination was not evident. By contrast, the DPC value increased to 4.6 (95% CI 4.2–4.9), which is approximately 72% of the 6.4 observed during the first segment of the prevaccination phase. However, in the second segment of the vaccination phase, the vaccination's effect was highly significant (*P* < 0.001), as evidenced by a decreasing trend in the DPC value (− 2.0; 95% CI − 2.0 to − 1.9). The active vaccination drive could not sustain the declining pattern for the next three weeks (segment 3), which rose to the highest level (21.6; 95% CI 15.1 to 28.4) since the pandemic started in India (Fig. 3). However, during the last segment of the vaccination phase, we observed a marked decline in the DPC value (− 1.6; 95% CI − 1.7 to − 1.5). Despite repeated waves of COVID-19, the sustainable vaccination activity resulted in a significant (*P* < 0.001) reduction of the ADPC value (− 0.22; 95% CI − 0.40 to − 0.04).

Discussion

To handle the COVID-19 pandemic situation effectively, India, the second most populous country, anticipated a significant rise in COVID-19 cases and implemented various approaches, including screening, testing, treating, and quarantining suspected individuals to limit disease transmission. Besides these measures, India enforced a national-level lockdown for 70 days (25 Mar 2020 to 31 May 2020) and has implemented the vaccination programme since 16 Jan 2021. As a result, two COVID-19 vaccines, namely Covaxin and Covishield, were approved and are widely used in India (Das et al. 2022).

Different studies (Moghadas et al. 2021; Chen et al. 2022; Watson et al. 2022; Notarte et al. 2022) have assessed the vaccination's impact on COVID-19 transmission severity. In India, a reduction in mortality due

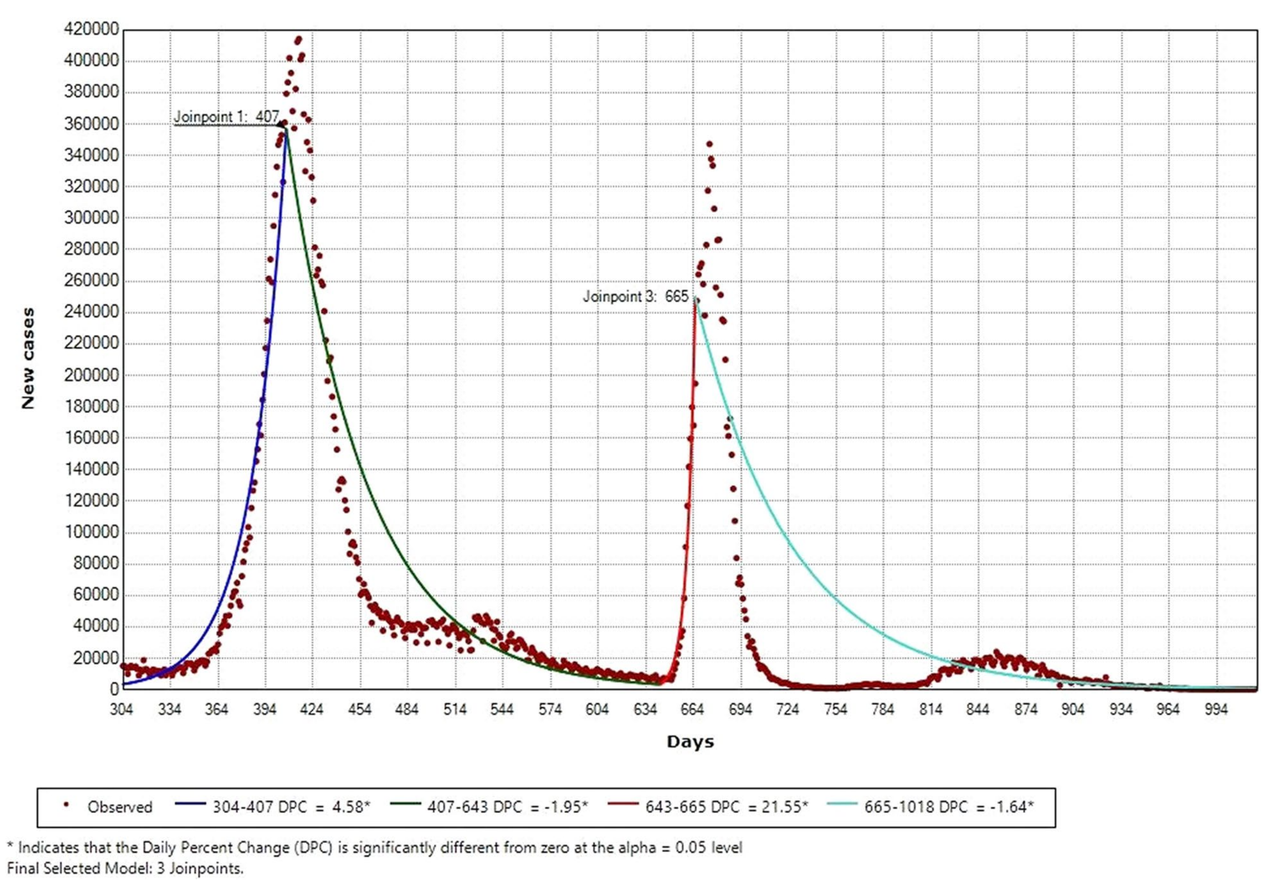

Fig. 3 Daily percentage change in COVID-19 new cases during different segment periods of the vaccination phase by three joinpoints regression model

to COVID-19 vaccination was demonstrated by mathematical modelling (Watson et al. 2022). A short-duration study reported decreased mortality in patients who received prior vaccination (Abhilash et al. 2022). However, to our knowledge, no study has quantified time segments with significant changes occurring in the trend of COVID-19 cases over a long period that covers both the prevaccination and vaccination phases. In an earlier study (Guimarães et al. 2020) using joinpoint regression analysis, the behaviour/trend of COVID-19 infections in Brazilian cities was assessed, and it concluded that there was an exponential increase in May 2020 and subsequent reduction of cases in 20 cities due to implementation of social distancing restriction.

Similarly, in another study (Al Hasan et al. 2020), joinpoint regression analysis was used in main land China to assess the outbreak trend of COVID-19 cases by considering one month data of early outbreak. To assess the impact of COVID-19 dangerous using a data of 27 European countries (Rovetta 2022), the joinpoint regression applied to compare annual mortality rates before and after COVID-19 outbreak. To examine the trend of Covid-19 incidence, the joinpoint regression analysis was applied for a period of 56 weeks data in Babol city of Northern Iran (Khaleghi et al. 2022).

Given these studies that applied joinpoint regression for various objectives, we used the same approach to identify the number of segments with the estimated DPC in each segment period of an extensive database for 1018 days that covered both prevaccination and vaccination phases.

Among the four segments identified using the three joinpoint regression model, two segments of 50 and 83 days (Fig. 2) covered the lockdown phase. A 50% reduction was noted in the rate of increase in DPC from the first segment period (6,4%) to the second segment period (3.3%). This implies that the lockdown phase significantly reduced new cases, and the trend continued until the third segment period (29 Jul 2020 to 16 Sept 2020), which revealed a DPC value of 1.3%. The marked reduction could be due to multipronged attacks, such as social distancing, lockdowns in the hotspot states of the country, increasing testing and treatment facilities, and insisting on personal hygienic measures (e.g. wearing a face mask and frequent hand sanitisation). With a DPC of 1.3%, on the day of the upper limit of the third segment period (16 Sept 2020), 90,000 new cases were recorded. After that, a significant decline in DPC (− 1.4%) during the fourth segment period demonstrated that the combined activities substantially reduced new cases, possibly during the last five months of the prevaccination phase. However, all the segment-specific DPC estimates accounted for overall ADPC value increases (1.6%; 95% CI 1.3 to 1.8). The execution of successful lockdowns and other activities rapidly reduced new cases. Although few studies (Perumal 2022; Shankar et al. 2022) have highlighted the impact of the lockdown phase in various forms, this study quantified the rate of changes over time between different stages.

The vaccination phase that covered 715 days unravelled four segment periods by the three joinpoint regression model. Although the DPC was below the zero value in the last segment period of the prevaccination phase, in the next 3.5 months of the vaccination drive, it increased significantly to 4.6% (Fig. 3), implying that the initial vaccination period of approximately four months did not exert any impact. This finding can be due to the outbreak of the second wave, which started in the middle of March 2021. According to the MoHFW, GOI, as on 29 Apr 2021, the vaccine coverage was abysmally low (~ 15.5 crores). Therefore, during the second wave that covered the first segment period (16 Jan 2021 to 29 Apr 2021), the focus was only on the vaccination drive; no other activities, such as lockdown, were implemented. A study (Kar et al. 2021) indicated that the lack of coordination among the state, centre, and national institutes contributed to inadequate responses to COVID-19 during the second wave caused by the Delta variant (B.1.617) a muted SARS-CoV-2 (Kunal et al. 2021).

Vaccine hesitancy and refusal were higher during the second wave (Anandraj et al. 2021). All these cavities led to increased COVID-19 cases and deaths in India. Despite these hindrances, during the second segment period (29 Apr 2021 to 21 Dec 2021), the vaccination coverage crossed approximately 139 crores and significantly reduced new COVID-19 cases with a DPC value of − 2.0% (95% CI − 2.0 to − 1.9). In addition, certain states conducted mass vaccination programmes in camp mode to enhance vaccine coverage. However, despite the integrated approach, the declining trend was not observed during the third segment period, which lasted for approximately three weeks due to the sudden surge in the third COVID-19 wave caused by the Omicron (B.1.1.529), a highly muted SARS-CoV-2 variant (Baig et al. 2022). The estimated DPC during the third wave was 21% (95% CI 15.1 to 28.4), demonstrating that the severity of the Omicron Delta variant was approximately five times higher than that of the SARS-CoV-2 variant, due to which our DPC estimate was 4.6%. Present study results corroborate statements on different variants of COVID-19 (Kunal et al. 2021; Baig et al. 2022). To date, no quantification on the severity of the Omicron variant and the current analysis has provided sufficient evidence regarding the highest DPC during the study period. As of 31 Jan 2022 (close to the upper limit of the third segment period), the vaccine coverage crossed 1800 million doses. It significantly reduced the rate of increase during the fourth segment period that started from the second week of January 2022. Although two waves of COVID-19 with two deadly variants (SARS-CoV-2 and Omicron) created havoc in the second most populous country, with the dedicated efforts of the GOI, the overall ADPC value (−0.22; 95% CI −0.40 to 0.04) during the vaccination phase declined significantly.

Conclusions

We demonstrated that lockdown and vaccination significantly reduced ADPC. Furthermore, we quantified the severity of SARS-CoV-2, the Delta, and the Omicron variants using the state-of-the-art joinpoint regression technique. The study findings are significant from an epidemiological perspective and can help health professionals to implement appropriate control/preventive measures to contain the severity of the disease.

Abbreviations

WHO	World Health Organization
COVID-19	Coronavirus Disease 2019
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
FDA	Food and Drug Administration
GOI	Government of India
DPC	Daily percentage change
ADPC	Average daily percentage change
CI	Confidence interval
MoHFW	Ministry of Health and Family Welfare
BIC	Bayesian information criterion
SE	Standard error

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Author contributions
VP conceptualised the idea of applying the new technique. Moreover, he was responsible for maintaining the database on COVID-19, analysing, and preparing the manuscript's final version.

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Availability of data and materials
All the data used in the present study are available on the following websites; MoHFW | Home. https://www.mohfw.gov.in/. WHO Coronavirus (COVID-19) Dashboard. https://covid19.who.int/

Declarations

Ethics approval and consent to participate
This study used public domain data from the MoHFW, GOI and the WHO COVID MONITOR. Furthermore, the author is from India and therefore did not require ethical approval to use his country's data.

Consent for publication
Not applicable.

Competing interests
The author declares that there was no competing interest.

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