

Robust Protective Effect of COVID-19 Vaccination in India—Results of Survey in the Midst of Pandemic's Second Wave

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Abstract



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Keywords

- ▶ covishield
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- ▶ Buridean's ass
- ▶ analysis paralysis
- ▶ vulture journalism
- ▶ inflammatory fake news

Introduction Our objective was to document the incidence of COVID-19 in vaccinated health care professionals and related personnel.

Method We conducted an online survey to ascertain the incidence of COVID-19 symptoms, reverse transcriptase polymerase chain reaction (RT-PCR) positivity, effect on normal activity, need for anti-COVID-19 medication, hospitalization, and death among individuals who had completed both doses of COVID vaccination at least 2 weeks earlier.

Results A total of 351 unique valid responses were received. Among the 340 people who had been vaccinated in India, 5% (17/340) had COVID-19 symptoms, 4.7% (16) became COVID-19 RT-PCR positive, 12 (3.5%) had sickness preventing normal daily activity, 2.65% (9) required anti-COVID-19 medication, and 1.18% (4) required hospitalization. Among family members living with the survey responders, the corresponding incidence was even lower. There was one death in this group.

Discussion Being health care professionals, the responders would be at higher risk of daily exposure to COVID-19. Even in this high risk group, the vaccine efficacy is good. Vulture journalists should stop spreading fake news and misinformation that makes people hesitate taking the vaccine or be afflicted analysis paralysis. Every person who chooses to remain unvaccinated increases the risk for our entire community. We also need to follow universal precautions (wearing mask, physical distancing, handwashing) diligently without letting down our guard.

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Introduction

In April 2021, India was in the grip of the second wave of the COVID-19 pandemic.¹ Social media was full of misleading and often fake news, feeding a frenzy of fear.² There was a perception that vaccination against COVID-19 was of questionable benefit.³ On the one hand, media was clamoring about shortage of vaccine doses, and on the other hand, vaccines were being unutilized and wasted.⁴ We therefore decided to conduct a survey among health care professionals and allied personnel to ascertain the true protective value of COVID-19 vaccination. The results of that survey are being presented here.

Methods

We devised a brief multiple-choice questionnaire (MCQ) for an online survey.⁵ The questions were deliberately kept simple, so that responders could complete the survey in less than 5 minutes. For the poll, a unique online Google form was developed for automatic online collection of responses (with time stamp; downloadable as a linked Google spreadsheet; Google, Mountain View, CA). This online survey poll was designed for health care professionals and allied colleagues in our country to document their real-world experience regarding the incidence and severity of COVID-19 infections in vaccinated individuals who they knew personally. These included questions specifically for subjects who had completed the last dose of their COVID-19 vaccination at least 2 weeks ago and would presumably avail of the full benefit of the vaccine. We asked whether any of such individuals had symptoms attributable to COVID, had a positive reverse transcriptase polymerase chain reaction (RT-PCR) report, experienced symptoms that interfered with normal activity, required anti-COVID medication, was hospitalized, and succumbed to death associated with COVID-19 infection. Responses were required separately for self, family members staying in the same house, and others (friends/family) who were staying elsewhere.

The survey links were shared via WhatsApp or email with health care professionals who had previously registered for and participated in our online continuing medical education (CME) programs.⁶ Responses were collected between April 9 and 11, 2021 (over a period of 48 hours; at a time when our country was in the midst of the pandemic's second wave). The results were evaluated for completeness of response (all questions were compulsory) and duplicates entries removed (based on the emails provided by participants). The remaining unique answers were tabulated and analyzed. Replies from incorrect or dummy emails were also removed. For replies that indicated experience of deaths or hospitalization in vaccinated persons, additional details were requested.

The average household size in India has been reported to be 4.8, with some states showing as high as 6 (Uttar Pradesh).^{7,8} For this manuscript, on a conservative basis, we have assumed the family size (individuals living in the same house) as three people. We decided on this, so that the protective effect of the vaccine would not be overestimated. For the question related to circle of friends and family members (not living under the same roof), such an assumption was not possible and hence was not attempted.

Results

We received a total of 363 survey responses. Of these, we identified 11 duplicate answers and one reply from a dummy/incorrect email address. Thus, we had 351 valid unique answers that could be analyzed. This included 336 health care professionals and 15 allied colleagues (working in health care facilities). The vaccine received by these individuals was Covishield in 319 and Covaxin in 21.³ The remaining 11 had received other vaccine outside India (Pfizer or Moderna).

On follow-up, one responder had given details of a person (known to him but not staying with him) whose death due to COVID-19 occurred within 2 weeks from his second dose. This was also removed from the analysis.

The protective effects of 340 individuals who were vaccinated in India are shown in **Table 1**. Less than 5% (17/340) responding individuals developed symptoms that could be attributable to COVID-19 or became COVID-19 RT-PCR positive (16; 4.7%). Occurrence of symptoms preventing normal daily activity was seen in 12 (3.5%) individuals. Those requiring anti-COVID-19 medication (9; 2.65%) or hospitalization (4; 1.18%) were even lower. All the features mentioned above occurred in people who had received Covishield vaccine. No such incidence was reported by responders who received Covaxin.

Using a conservative approach, we assumed the minimum family size to be three people (couple plus one child or parent) staying in the same house. Hence, the denominator for family size was taken as 351×3 , that is, 1053. The protective effect for responders (self) plus family members staying in the same house are shown in **Table 2**. For all the parameters, the protective effect was robust and higher. There was one death in a fully vaccinated family member staying in the same house as the survey responder.

Table 3 shows data regarding responses by individuals regarding others known to them but not residing in the same house (family and friends). Since it is impossible to guess the size of their circle of friends and family members, no denominator is mentioned. A total of 12 deaths have been mentioned by survey responders in such fully vaccinated individuals; 59 had required hospitalization;

Table 1 Experience of survey responders (self) who have been vaccinated in India against COVID-19

Sr. no.	Description	Total	Covishield	Covaxin
1	Total responders	340	319	21
2	Symptoms of COVID-19	17 (5%)	17	0
3	COVID-19 RT-PCR positivity	16 (4.7%)	16	0
4	Symptoms preventing normal activity	12 (3.5%)	12	0
5	Requiring anti-COVID medication	9 (2.65%)	9	0
6	Requiring hospitalization	4 (1.18%)	4	0

Abbreviation: RT-PCR, reverse transcriptase polymerase chain reaction.

Table 2 Experience of survey responders amongst their family members staying with them (including self) who have been vaccinated against COVID-19

Sr. no.	Description	Total
1	Conservatively estimated denominator (351 × 3)	1053
2	Symptoms of COVID-19	27 (2.56%)
3	COVID-19 RT-PCR positivity	19 (1.80%)
4	Symptoms preventing normal activity	15 (1.42%)
5	Requiring anti-COVID medication	15 (1.42%)
6	Requiring hospitalization	06 (0.57%)
7	Leading to death	01 (0.09%)

Abbreviation: RT-PCR, reverse transcriptase polymerase chain reaction.

Table 3 Experience of survey responders among others known to them but not staying with them and who have been vaccinated against COVID-19 (denominator unknown)

Sr. no.	Description	Total
1	Symptoms of COVID-19	150
2	COVID-19 RT-PCR positivity	152
3	Symptoms preventing normal activity	121
4	Requiring anti-COVID medication	097
5	Requiring hospitalization	059
6	Leading to death	012

Abbreviation: RT-PCR, reverse transcriptase polymerase chain reaction.

97 needed anti-COVID-19 medication; 121 had symptoms that prevented normal daily activity; and 152 had COVID-19 positivity on RT-PCR testing.

Discussion

While dealing with a pandemic (like the ongoing COVID-19), there are three outcomes possible. The virus dies a natural death, natural infection leads to herd immunity that starts protecting the population, or production of vaccines that are used to produce immunity against the virus.⁹ History has shown us that vaccination is an important tool. Almost all scientific bodies and organizations have published guidelines in peer-reviewed medical journals, stating that everyone should take the COVID-19 vaccine at the first available opportunity.^{3,5}

As of May 9, 2021, globally there are 8 COVID-19 vaccines approved for full use, another 6 approved for limited use, and 27 undergoing large scale phase 3 efficacy testing.¹⁰ An additional 86 are in early phase clinical trials.

Why then were 46 lakh vaccine doses wasted in India—enough to vaccinate half the population of Bengaluru, a large metro city⁴? The reason is vaccine hesitancy.^{2,11}

A lot of questions, misgivings, and doubts have been fuelled by sensational headlines, misquoted statements, and even fake/manufactured news in the media, including social media.¹² Vulture journalists have no qualms in photoshopping old images from unrelated events and claiming

they are related to COVID-19 pandemic.^{13,14} The infodemic is everywhere. Closer to home, Barkha Dutt jumped onto this bandwagon by claiming that her dying father's last words to her were "I'm choking, treat me."¹⁵ We are wondering how a patient being treated by India's greatest experts at the prestigious Medanta Hospital on ventilator support could speak. Also, did she manage to enter a restricted area (ICU), putting the lives of other patients at risk? Such misguided, one-sided narratives have not even spared so-called respected international medical journals.¹⁶

Both Covishield and Covaxin have been available in India since January and March 2021, respectively. Bharat Biotech's Covaxin is a whole virion inactivated vaccine, which holds a place of pride as the first vaccine developed in India, having completed the phase 3 study involving 25800 participants and is now approved in 9 countries.¹⁷ Astra Zeneca's vaccine (known as Covishield in India) has been developed in collaboration with Oxford University, UK, and its largest manufacturing site is Serum Institute of India. It has been approved in 98 countries—more than any other COVID-19 vaccine, including Pfizer and Moderna vaccines.

People who question the approval for these two vaccines before the completion of phase 3 trials demonstrate their ignorance regarding the global regulations for emergency use authorization. Let us make a categorical statement that there was no haste in giving approval for both these vaccines. To make it clear to the readership, let us specify that global regulations require that 50% of the participants in the phase three study have reached the milestone of a 2-month follow-up after receiving their final dose of the vaccine¹⁸

Questions have also been raised about the protective effect of the vaccines. Numbers have been thrown around without understanding their meaning. Even health care academicians, who are used to in-depth analysis of data, seem to have missed the point. From public health point of view, there is a clear distinction between all events and clinical meaningful events. When vaccination is used on a mass scale, with the objective of developing herd immunity, the goal is to prevent serious illness, prevent hospitalization, and prevent death.¹⁹ An RT-PCR test positivity in a vaccinated person who is asymptomatic cannot be called a failure.

Published data has shown that both Covishield and Covaxin protect almost everyone when clinically meaningful endpoints are used. Our survey data verifies the same, only 2.65% of vaccinated individuals required anti-COVID-19 medication and only 1.18% of them required hospitalization (→Table 1). This is the data of the responders regarding their own selves. Hence, it is the most robust and reliable data. It is also data pertaining to health care professionals and allied hospital staff. This is the population at the highest risk of exposure to COVID-19 on a daily basis. If our data shows that the vaccine is protecting them in such a robust clinically meaningful manner, its protective effect is likely to be even higher for other persons. This is also confirmed by the data regarding family members staying under the same roof (→Table 2). These people might have a lesser direct exposure to patients but still at higher risk than "normal" individuals not in daily contact with hospital workers.

Yet their needs for anti-COVID-19 medication (1.42%), hospitalization (0.57%), or leading to death (0.09%) are very low. Data regarding friends and other is a real-world snapshot of the wider picture. While it might be difficult to interpret completely without knowing the denominator (number of people at risk), the data are still useful to improve our understanding (→ Table 3).

Let us take the example of the death of an infectious disease specialist which was circulating on social media not too long ago. A big hue and cry was made because he allegedly died of COVID-19, even though he was vaccinated.²⁰ The actual facts are otherwise. He was a retired 81-year-old who had received two doses of vaccine in the US. One month later, he travelled to India. He got infected with COVID-19 on April 8, 2021, for which he was hospitalized for 4 days, was recovering and chose to take discharge against medical advice. At no time did he have severe COVID-19 and require oxygen or ventilation. On April 28, 2021, he died of a massive cardiac infarction. His comorbidities included diabetes mellitus and coronary artery disease for which he had undergone stenting several years ago.²¹

Some questions still remain regarding the efficacy of vaccines in special subsets of patients. For example, will the vaccine work against mutant viruses. But occurrence of mutation is not new. It happens all the time, and we have learned how to deal with it while upgrading annual vaccines against the influenza virus. Will booster be required? Will vaccines need to be tweaked? Will we need an annual shot? These are questions only time can answer.

Besides efficacy, a key deciding factor is safety. Today, data from COVID-19 vaccinated individuals represents millions of recipients. While side effects may occur in as many as half of the individuals, majority are mild, transient, and do not require any pharmacological intervention. They are exactly like the side effects associated with other vaccines used for decades—local injection site issues (like pain, itching, redness, swelling) as well as systemic symptoms (like body ache, muscle stiffness, soreness, headache, nausea and vomiting). Many a times, more significant reactions have been reported, but their relationship or relatedness to the vaccine have been rarely proven. In summary, COVID-19 vaccines are safe in almost everyone.¹⁹

Analysis paralysis, like the proverbial Buridan's ass, leads to postponement of a decision till it is too late.^{22,23} For all those living on hope that a superior solution is a short step away, and stall in its endless pursuit, do not understand the concept of diminishing returns.

The bottom line is that every individual who chooses to remain unvaccinated increases the risk for the entire community. In the ongoing COVID-19 pandemic, our objective is to reduce or prevent severe disease or death. To achieve that, all of us need to be vaccinated as quickly as possible. Before and after vaccination, we also need to continue taking necessary universal precautions (wearing mask, physical distancing, handwashing). Letting the guard down is like playing Russian roulette.²⁴

Conflict of Interest

None declared.

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