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Research Article

Vaccine Breakthrough Infections among COVID-19 Vaccine Recipients: A Retrospective Observational Survey

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A B S T R A C T

Background: The COVID-19 vaccine offers a high level of protection, reducing illness severity, hospitalisation, and death. However, it does not offer 100% protection from re-infection, and individuals have developed re-infections post COVID-19 vaccination, even after being fully vaccinated or having received additional booster doses. These are also known as vaccine breakthrough infections (VBIs).

Aim: This study aimed to determine the incidence of COVID-19 VBIs among the COVID-19 patients receiving care in a rural tertiary care hospital in India.

Methods: This retrospective study was conducted to determine the incidence of VBIs among all clinically suspected COVID-19 patients (N = 2,230) attending SGT Hospital, Haryana, India, from January to August 2022. Demographic characteristics, clinical data, co-morbidities, treatment, and vaccination details were retrieved, and the incidence of COVID-19 VBIs among the patients was analysed. A COVID-19 infection occurring 14 days following a primary series or a primary series with an additional booster dose of any COVID-19 vaccine was considered as VBI.

Results: A total of 261 out of the 327 SARS-CoV-2 RT-PCR positive cases had received COVID-19 vaccination. Among the vaccine recipients, 236 (72.3%) were identified as COVID-19 VBIs based on their vaccination status: fully vaccinated (n = 229) or got an additional precaution dose (n = 7). There was a substantial difference in VBI incidence between those with a previous history of COVID-19 infections and those without. The majority of the VBIs (94.9%) showed mild to moderate symptoms without requiring hospitalisation.

Conclusion: Mild to moderate illnesses without requiring hospitalisation were seen in VBIs demonstrating COVID-19's vaccine-induced protection. Additionally, those with natural SARS-CoV-2 infections had enhanced hybrid immunity.

Keywords: COVID-19, Vaccine Breakthrough Infections, Hybrid Immunity

Introduction

The Coronavirus disease 2019 (COVID-19) pandemic, which is estimated to have caused more than 777 million confirmed cases and more than 7 million fatalities as of January 2025, is considered the greatest pandemic affecting mankind since the 1918 influenza pandemic.[1,2] To combat this health emergency, one of the most important measures undertaken was mass vaccination with effective and safe vaccines providing herd immunity. Globally, 13.64 billion vaccine doses were administered, with approximately 1 billion individuals receiving at least one dose of any of the available COVID-19 vaccines and 229 million being fully vaccinated in India.[1]

The first phase of COVID-19 vaccination in India began on January 16, 2021, using AZD1222-ChAdOx1-S Covishield (a recombinant vaccine manufactured by the Serum Institute of India) and BBV152 Covaxin (a whole virion inactivated vaccine, manufactured by Bharat Biotech, India), prioritising vaccination of healthcare workers (HCWs) and frontline workers (FLWs). Initially, administration of two vaccine doses was recommended with 28 days apart for both vaccines. On January 10, 2022, a precautionary (booster) dose was made available to HCWs, FLWs, and senior citizens (above 60 years of age) with co-morbidities.[3,4] As of August 23, 2022, a total of 2,10,31,65,703 doses had been administered to individuals above the age of 12 years. Of the total vaccinated individuals, 9,40,216,766 had been fully vaccinated, while 8,24,14,428 individuals of 18 to 59 years and 5,83,76,438 individuals of 60+ years, HCWs and FLWs had received a precautionary (booster) dose.[4]

The COVID-19 vaccine offers a high level of protection, reducing illness severity, hospitalisation, and death; however, it does not offer 100% protection, and vaccine breakthrough infections (VBIs) have been known to occur even after the person was fully vaccinated or had received additional booster doses, all over the world, including in India.[3,5–9] Furthermore, the emergence of SARS-CoV-2 variants challenges the efficacy of these vaccinations, with reports of reduced efficacy against variants of concern (VOC).[8] A breakthrough surveillance report conducted in the state of Washington between January 2021 and July 2022 revealed 370,119 VBIs, of which 15% were found to be symptomatic, 3% required hospitalisation, and 0.4% resulted in fatality from COVID-related illness.[9] Prior studies from multiple settings in India have reported as high as 25% of COVID-19 VBIs observed among the HCWs.[6,7,10] Most of the reports of such infections from India were confined to HCWs, with hardly any reports from the general population attending hospitals in rural areas. Thus, the present retrospective study was undertaken to assess the incidence of COVID-19 VBIs among the COVID-19 patients attending a rural tertiary care hospital in Haryana, India.

Materials and Methods

Study Design and Population

This is a retrospective, population-based observational study among the clinically suspected COVID-19 patients attending SGT Hospital, Haryana, India, from January to August 2022. It is an 810-bedded tertiary care teaching hospital with COVID-19 treatment facilities. No informed consent was obtained from the study participants, as the required information was collected as part of the routine services provided to them. The Institutional Ethics Committee of the SGT University, Haryana, approved the study (SEC/FMHS/F/06/02/21/82).

Data Collection

We retrieved the data of 2,230 COVID-19 suspected patients, registered from January 1, 2022 to August 31, 2022 by the Molecular Laboratory, SGT Medical College, Hospital and Research Institute, to the Indian Council of Medical Research (ICMR) COVID-19 data portal. Data regarding the demographic characteristics such as age, sex, etc, previous COVID-19 infections, clinical signs and symptoms such as fever, headache, body ache, diarrhoea, chest pain and others, co-morbidities including hypertension, diabetes, chronic lung, heart or kidney disease, etc., treatment information and vaccination details which included name of vaccine, number of vaccine dose received and date of vaccination, were extracted from electronic health records for all COVID-19 suspected patients who had provided sample for SARS-CoV-2 real-time RT-PCR.

Case Definition

Among the COVID-19 confirmed patients, VBIs were identified based on the vaccination status. A vaccine breakthrough infection is defined as an infection occurring ≥ 14 days after completion of either a primary series or a primary series plus a booster dose of any of the COVID-19 vaccines.[5,11] The detailed clinical case records of all COVID-19 patients with VBIs were retrieved from the Medical Record Department of the SGT Hospital. Based on the signs and symptoms presented by the patients, they were categorised as mild, moderate, severe and critical as described by Hong et al.[12]

Statistical Analysis

Continuous data were analysed and expressed as mean, standard deviation and interquartile range, while categorical data were expressed as frequency percentage, and the chi-square test was performed. A value of p less than 0.05 was considered statistically significant.

Results

Demographic and Epidemiological Characteristics

Data from a total of 2,230 COVID-19 suspected patients who attended SGT Hospital between January 1 and August

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31, 2022, were included in the study. The age group of the patients ranged from 1 to 93 years (mean age: 35.8 ± 17.7 years) with a male:female ratio of 1:0.8. Out of the total cases, 1,511 (67.8%) had received at least one dose of COVID-19 vaccination, of which 1,272 (84.2%) were fully vaccinated with or without a precaution dose. The majority of them had received Covishield (91.5%, 1383/1511), followed by Covaxin (7.6%, 115/1511), and the remaining had received Moderna COVID-19 vaccine (0.3%, 5/1511), Pfizer-BioNTech COVID-19 vaccine (0.3%, 4/1511), and Sputnik V COVID-19 vaccine (0.3%, 4/1511).

Among the study population, 14.7% (327/2230) were diagnosed with COVID-19 infection, as confirmed by rRT-PCR, with the maximum number of cases (73.1%, n = 239) identified in January 2022, followed by a steep fall in February–March and thereafter, a plateau when the number of cases dropped significantly. Thirty-two of them (9.8%) had a previous history of COVID-19 infection prior to vaccination, whereas the remaining patients were infected (laboratory confirmed) for the first time. Out of the previously infected individuals, 25 (78.1%) had received at least one dose of COVID-19 vaccination, and based on their vaccination status, i.e., fully vaccinated with or without precaution dose, 21 (65.6%) of them were classified as having VBIs (Figure 1). Amongst 295 individuals with no prior history of COVID-19 infection, 236 (80%) had received at least one dose of COVID-19 vaccination and 215 (72.9%) were classified as VBIs according to their vaccination status. There was a significant difference in the incidence of VBIs among those with a previous history of COVID-19 infections and those who had never had laboratory-confirmed COVID-19 infections (65.6% vs 72.9%, $p < 0.001$). Thus, the incidence of VBIs among fully vaccinated individuals (n = 1,272) was found to be 19.3% (246/1272).

Incidence of Vaccine Breakthrough Infections

Among the SARS-CoV-2 RT-PCR positive cases (n = 327), 261 had received at least one dose of COVID-19 vaccine, while 66 had not received any COVID-19 vaccine (Figure 1, Table 1). Among the vaccine recipients, 236 (72.3%) cases were identified as COVID-19 VBIs according to their vaccination status, i.e., fully vaccinated (n = 229) or received an additional precaution dose (n = 7). Among these, the majority were Covishield recipients (n = 206). The mean Ct value of the infections was 23 ± 3.4, with no statistical difference in its values between the different types of vaccine recipients ($p > 0.05$). The age group of the patients ranged from 19 to 78 years (mean age: 31.8 ± 12.4 years), among whom, 135 were males and 101 were females, with a male-to-female ratio of 1:0.7. Twelve of them (5.1%) required hospitalisation, while the rest of the patients had attended the outpatient departments. Of the total patients, 31 were HCWs (24 were fully vaccinated and five received additional precaution dose), and the remaining were mostly rural population attending the hospital.

Time Since Vaccination and Vaccine Breakthrough Infections

We analysed the relationship between time since the second dose of Covishield (n = 200) and Covaxin (n = 27) vaccination with incidence of VBIs (Figure 2). The median duration was higher in Covaxin (185 days; IQR: 162.5) compared to Covishield (166 days; IQR: 149.5). Among the vaccine recipients of both vaccines, maximum VBIs were detected between 166 (~5.5 months) and 195 (~6.5 months) days after receiving the second dose of vaccination. However, compared to recipients of other vaccines, recipients of Covaxin had three times more VBIs identified between 15 and 45 days. One case of VBI in Sputnik V vaccinated individuals was detected 134 days after receiving the second dose of vaccination, whereas one individual who received the Moderna vaccine was detected 290 days after receiving the second dose (data not shown in the figure). Infections were detected as early as 15 days among the seven VBIs following an additional precaution dosage (VBI-PD, n = 7), whereas the longest duration between vaccination and VBI detection was 157 days (approximately 5 months) (Figure 3).

Clinical Characteristics

The majority of the patients with VBIs (94.9%, n = 224) had mild to moderate symptoms of COVID-19 without requiring hospitalisation. Prior COVID-19 patients were less likely to exhibit symptoms than naive patients, and none of them required additional oxygen therapy or hospitalisation. Two of the 12 hospitalised patients had chronic lung disease, which was found to be associated with severe symptoms of COVID-19 (Table 2). As expected, the incidence of clinical signs and symptoms was higher in hospitalised groups, with significant differences observed for ~~fever,~~ cough, anosmia, ageusia and anorexia ($p < 0.05$). One of the patients in the hospitalised study group had abdominal pain, and a psychiatric patient reported insomnia and mood disorder. Furthermore, two individuals from the non-hospitalised study reported gastrointestinal symptoms or diarrhoea, which was not observed among any of the hospitalised patients (data not shown in the table). Twelve out of the 236 patients with VBI required hospital admissions (5.1%), with a mean ± SD days of hospital stay of 3.3 ± 2.9 days, and only two of them required ICU admission (0.8%), with 4.5 ± 0.7 days of ICU stay. The majority of the hospitalised patients received antibiotic therapy, with significant differences compared to non-hospitalised patients (91.7% vs 54.9%, $p = 0.01$). One-fourth of the hospitalised patients also received steroid medication in addition to antibiotics, but none of the non-hospitalised patients did.

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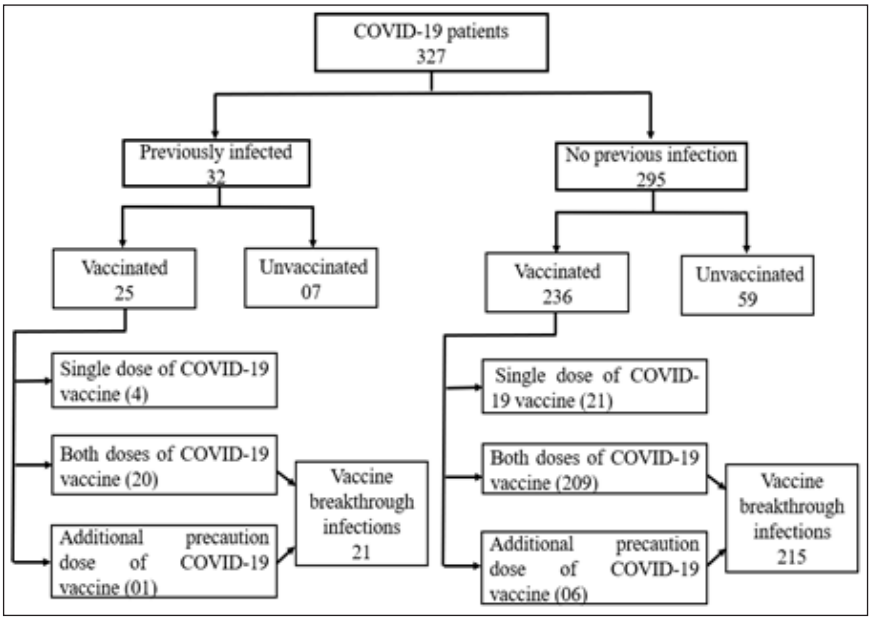

Figure 1.Flowchart Depicting the COVID-19 Suspected Cases between January and August, 2022 Including the Vaccination Details and Vaccine Breakthrough Infections

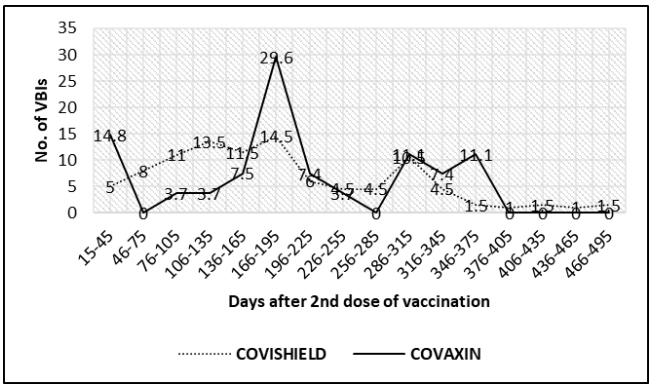

Figure 2.Vaccine Breakthrough Infections with regard to Days-Since Fully Vaccinated with Covishield and Covaxin

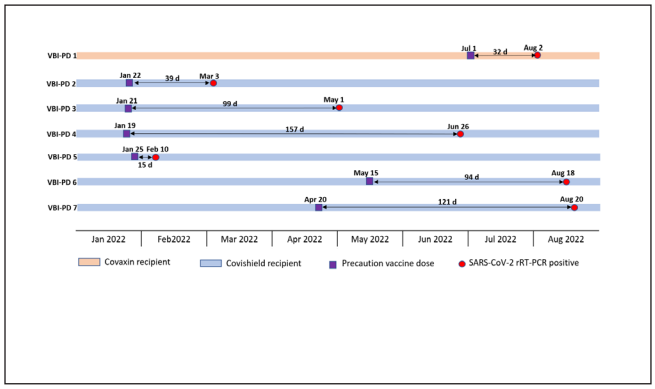

Figure 3.Vaccine Breakthrough Infections with regard to Days-Since Additional Precaution Dose

Table 1.Age-Wise Distribution of SARS-CoV-2 Infected Patients with Their Vaccination Details

N = 327

Age Group (Years)	COVID-19 Vaccination Details of SARS-CoV-2 Infected Patients n						
	Covishield			Covaxin			Not Vaccinated
	1 Dose	2 Doses	Booster	1 Dose	2 Doses	Booster	
< 18	0	0	0	0	0	0	16
18–29	12	118	2	0	17	1	19
30–49	9	59	2	2	10	0	21
50–64	0	14	0	0	0	0	6
≥ 65	2	9	2	0	0	0	4
Total	23	200	6	2	27	1	66

Note: One Moderna fully vaccinated individual belonging to the age group of 18–29 years and one Sputnik V fully vaccinated individual belonging to the age group of 30-49 years had COVID-19 infection.

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Table 2.Underlying Conditions, Clinical Signs, Symptoms and Treatment of COVID-19 Vaccine Breakthrough Infection Patients

Characteristics	Hospitalised Patients with VBIs (N = 12) n (%)	Non-Hospitalised Patients with VBIs (N = 224) n (%)	Statistical Significance p Value
Underlying co-morbid conditions			
Diabetes	1 (8.3)	6 (2.7)	0.300
Hypertension	1 (8.3)	8 (3.6)	0.400
Cardiovascular disease	0 (0.0)	1 (0.4)	-
Chronic lung disease	2 (16.7)	3 (1.3)	< 0.001*
Chronic liver disease	0 (0.0)	1 (0.4)	-
Others	0 (0.0)	3 (1.3)	-
Clinical signs and symptoms			
Fever	12 (100.0)	175 (78.1)	0.400
Cough	8 (66.7)	78 (34.8)	0.030*
Sore throat	6 (50.0)	64 (28.6)	0.100
Breathlessness	3 (25.0)	0 (0.0)	-
Headache	2 (16.7)	11 (4.9)	0.080
Body ache	3 (25.0)	43 (19.2)	0.600
Nasal congestion	6 (50.0)	70 (31.3)	0.200
Chest pain	2 (16.7)	0 (0.0)	-
Anosmia	6 (50.0)	41 (18.3)	0.007*
Ageusia	3 (25.0)	16 (7.1)	0.030*
Anorexia	2 (16.7)	4 (1.8)	0.001*
Hospitalisation			
Stay at hospital (mean ± SD days)	3.3 ± 2.9	0 (0.0)	-
Stay at ICU (mean ± SD days≠)	4.5 ± 0.7	0 (0.0)	-
Treatment			
Antibiotics	11 (91.7)	123 (54.9)	0.010*
Steroids	3 (25.0)	0 (0.0)	-
Oxygenation	3 (25.0)	0 (0.0)	-
BiPap support	2 (16.7)	0 (0.0)	-

Abbreviations: VBIs: Vaccine breakthrough infections, BiPap: Bilevel positive airway pressure

≠Calculated for two patients only who required an ICU stay

*Significant differences between hospitalised patients with VBIs and non-hospitalised patients with VBIs ($p < 0.05$)

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Discussion

With a case fatality rate as high as 25%, the COVID-19 pandemic has caused a global health crisis affecting all demographics, particularly in poorer nations whose healthcare systems are inundated.[13] Thus, to avert the health crisis, a global vaccination campaign was launched. In India, 67.9% of the population has been fully vaccinated, and 15.7% have received a precaution dose to date.[4] A slightly low percentage of the population (57%, 1272/2230) who were fully vaccinated with or without a precaution dose were noted in our study. This may be attributed to the rural population of Haryana's lack of acceptance or vaccine hesitancy, and false perception of reinfection and the harmful effects of the vaccine among the predominant rural population in the study.[14] This is an enduring issue in the vaccination process and has been reported from other parts of the country as well.[15]

Approximately one-fifth of the fully vaccinated patients (236/1272) had VBIs; however, the majority of the cases were mild infections without requiring hospitalisation, thus indicating the vaccine-induced immunity, which provided protection from getting severely ill with COVID-19. There were 261 SARS-CoV-2 RT-PCR positive vaccinated cases during the study period, out of which 236 VBIs were detected, and 78.9% of them had received Covishield. A similar study conducted in eastern India reported 274 VBIs out of 361 SARS-CoV-2 RT-PCR positive vaccinated patients from March to June 2021; most of them (87.2%) had received Covishield.[11] In India, the majority of the population has received Covishield due to their choice of vaccination by personal preference and/ or vaccine availability at the vaccination centres.[3] All of the COVID-19 vaccines available were reported to be associated with VBIs as none was 100% effective in protecting from infections post vaccination.[16] Surveillance on SARS-CoV-2 VBIs in Washington State reported 700,011 cases in ~1.7 years (January 2021 to August 2022).[9] In a community-based study from the US, the prevalence of VBIs was reported as 1% (74/8554) in fully vaccinated adult US residents.[17] Numerous reports on COVID-19 VBIs are available from various countries across the globe; however, the majority of them have been conducted among HCWs. A Japanese study reported the incidence of VBIs as 0.5% among HCWs in a single tertiary care hospital in July–August 2021.[18] In a study from Nepal, the incidence of VBIs was reported to be 10.1% (83/819) among HCWs who were fully vaccinated with Covishield.[19] Studies reported from India are exclusively for HCWs working in different hospitals located in Delhi, Gurugram and Chandigarh with incidence rates ranging between 1.6 and 25%.[6,7,10] A study conducted among the HCWs of a dedicated COVID-19 tertiary care hospital in Delhi showed that nearly one in seven individuals reported experiencing VBIs.[6]

A prior history of COVID-19 infection has been demonstrated to reduce the likelihood of VBIs and severe infection, emphasising the better protective role of hybrid immunity (naturally acquired immunity with vaccine-induced immunity) compared to merely one of the two.[20-22] This is evident in the present study, where the incidence of VBIs was considerably lower among individuals with a prior history of COVID-19 infection compared to naive individuals. Similar findings have been shown in studies from India and other countries, viz., Belgium and the United States, which reported hybrid immunity being associated with significant protection against VBIs.[20,23] Sharma et al. found that naïve HCWs had a 3.8-fold higher risk of contracting COVID-19 infection or reinfection compared to those with a prior history of COVID-19 infection despite vaccination with at least one dose of COVID-19 vaccine.[6]

As the present study was conducted almost a year after the introduction of the COVID-19 vaccination programme in the country, the time since the second dose of vaccination and VBIs were lengthier, with 166 and 185 median days for Covishield and Covaxin recipients, respectively. However, studies carried out within six months after the introduction of the COVID-19 vaccination programme in the country reported VBIs with 45 and 33 median days for Covishield and Covaxin, respectively.[11] In the present study, VBIs were detected as early as 15 days and maximum cases were seen between 166 and 195 days post second dose of vaccination or precaution dose. Reynolds et al. found that the median duration between vaccination and a VBI was 104.5 days (interquartile range: 77–135 days), and there was no variation across vaccine manufacturers, viz. Pfizer, Moderna, or Johnson & Johnson.[17] However, a 2021 study conducted by Coburn et al. revealed that VBIs were uncommon among patients, including HIV-positive individuals in the United States, 9 months (~270 days) after full vaccination (3.8%), demonstrating the vaccine's efficacy against SARS-CoV-2 strains circulating prior to December 31, the same year.[24]

The majority of VBI cases (94.9%) in the present study had mild to moderate symptoms, the most common ones being fever, cough, sore throat, and nasal congestion. Other studies have also revealed as high as > 97% of the cases with mild infection, demonstrating the vaccine-induced protection against COVID-19's severe symptoms and overall infection.[18,25,26] Reynolds et al. reported that fatigue followed by nasal congestion, cough, headache and decreased sense of taste were the most frequently observed symptoms among the patients with VBIs.[17] Anosmia and ageusia were mainly seen in hospitalised patients compared to non-hospitalised ones in the present study. Only 12 (5.1%) cases required hospitalisation, and only two individuals required ICU care. The ICMR had reported a 10% hospitalisation rate in VBI cases, without

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requiring additional oxygen therapy and ICU. In addition, those individuals with hybrid immunity displayed modest symptoms, demonstrating a stronger protective effect in comparison to those without immunity in our study. This finding corroborates other reports by Sharma et al. and Stouten et al., revealing substantial protection provided, resulting in mild symptoms without requiring additional oxygen for recovery among those with a prior history of COVID-19.[6,20]

Conclusion

The majority of the VBIs were mild to moderate infections without requiring hospitalisation, thus indicating the vaccine-induced immunity offered by COVID-19 vaccination. Furthermore, a better protective role of hybrid immunity was seen among those with a history of natural SARS-CoV-2 infections.

Authors' Contributions: LSD contributed to data collection, analysis, and interpretation, and drafting of the manuscript; MS contributed to study conception and design, and drafting of the manuscript; MSH contributed to study conception and design, data analysis, and interpretation, and revision of the manuscript.

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