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Navigating Breakthroughs: A Thorough Investigation of Vaccine Failure Rates and Clinical Outcomes in COVID-19 Breakthrough Scenarios

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***Abstract*— *Introduction**: Coronavirus was discovered in Wuhan, China, as the cause of an epidemic of potentially fatal unusual pneumonia (COVID-19). **Aim**: to investigate the causes and prognostic variables of breakthrough COVID-19 infections in persons who have received all recommended vaccinations for COVID-19. **Methods**: The trial includes a variety of individuals, including Beijing-Sinopharm, Oxford-AstraZeneca, Pfizer-BioNTech, and others, who have finished receiving their second doses of the COVID-19 vaccine. The cohort consists of 42 individuals, with a mean age of 44.3 years and a preponderance of males (78.6%). The assessment of risk factors, which included cardiovascular problems, underlying disorders, and aging, revealed a complex knowledge of susceptibility. Of the vaccinations listed, Pfizer-BioNTech was responsible for the greatest number of breakthrough cases. 90.5% of the PCR viral RNA genes tested positive in the laboratory, with a D-dimer range of 510–11000 ng/ml. Variable levels of lung involvement were highlighted by radiological results, which are essential for determining the severity of the disease. The effect of breakthrough infections was highlighted by classifying most breakthrough cases (57.2%) as severe/critical. **Results**: The breakthrough infections happened in various age groups, with the 60–69 age group having the highest concentration. Nonetheless, the research indicates an 85.7% survival rate, highlighting the possibility of favorable results even in extreme situations. The distinctive features of the breakthrough instances in Babylon, Iraq, are shown through a comparison analysis with research conducted internationally. **Conclusion**: The study emphasizes how crucial it is to keep an eye on radiological and clinical indicators to completely understand the dynamics of breakthrough infections. A thorough understanding of the factors driving vaccine failure is provided, enabling future vaccination tactics and public health initiatives. These factors include vaccine-specific, patient-related, and demographic variables.*

***Keywords*—** *SARS-CoV-2, vaccine failure, COVID-19, Breakthrough infections, outcomes, demographics, risk factors, vaccination strategies, D-dimer.*

I. INTRODUCTION

A new coronavirus was discovered in Wuhan, China, in December 2019 as the cause of an epidemic of potentially fatal unusual pneumonia, which was eventually dubbed "coronavirus disease 2019 (COVID-19). Subsequently, the virus was found to have several dangerous strains throughout the world.[1, 2] As a result, the scientific community demanded that vaccinations be developed immediately.[3, 4] Even though the COVID-19 vaccine is the only treatment that can stop the pandemic, there are still a lot of unanswered questions regarding the vaccine's efficacy and safety, allergic reactions, and long-term side effects. Additionally, there are concerns about whether the vaccine can spread COVID-19 infection, as well as whether it can cause blood clots, heart problems, menstrual issues, and other health issues.[3]

A future pandemic is predicted to cost easily over a trillion dollars, which justifies significant investment and consideration. We have had to work hard to learn about pandemics and their costs. What can we infer from worldwide triumphs and failures in the fight against COVID-19? Although it is uncommon, vaccine failure with SARS-CoV-2 vaccinations can occur in specific circumstances. Vaccine failure is defined as the incidence of a certain vaccine-preventable disease in a person who has received all recommended vaccinations, taking into account the natural delay for protection to develop following immunization and the incubation time.[5]Following the first or second dose of the COVID-19 vaccine, vaccine failure may occur five to forty-two days following the shot.[6]

SARS-CoV-2 vaccinations have typically been successful in lowering significant COVID-19 unfavorable outcomes, such as intensive care unit hospitalization and mortality, notwithstanding the occasional occurrences of vaccine failure[7]. Further study is necessary to identify the causes of vaccine failure and to create plans for enhancing vaccine efficacy in every patient.

The current study aims to identify the risk factors and outcomes related to breakthrough infections, following early anecdotal reports of infections among individuals who have received all recommended vaccinations. The research could offer current perspectives on how the immune system works, which could enhance how well people respond to certain vaccinations or lead to the creation of biomarkers that indicate vaccination effectiveness.

II. MATERIALS AND METHODS

Using a specific information case sheet created to match the COVID-19 vaccination failure, this observational cohort study was carried out. Special medical specialists in these hospitals conducted interviews with the attendance patients who were selected from the two primary teaching hospitals in Babylon between June 2021 and January 2022. Based on an earlier definition, the pneumatologists and doctors who treat COVID-19 cases created the selection criteria.[5]Consequently,

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42 out of 2481 patients who were admitted to the study had already received their second dose of the COVID-19 vaccine (which was part of the Iraqi regimen that included Oxford-AstraZeneca, Pfizer-BioNTech, and Beijing-Sinopharm). [11,12] These patients had also lived away from areas where there was a high risk of virus exposure, were otherwise healthy and immunocompetent, and had not shown any symptoms of infection until at least five to forty-two days after the vaccination. Regardless of its intensity, the COVID-19 infection breakthrough is included[(8-11)].

Forty-two individuals with COVID-19 breakthrough infections due to vaccination failure were included in the study. The most common symptoms that were reported between five and forty-two days after the second vaccination dose were cough, fever, chest pain, and dyspnea. In addition to studies such as PCR for the virus RNA genes from nasopharyngeal swabs, D-dimer (a protein fragment (small piece) that's made when a blood clot dissolves in your body), CBC, and CT scan, the diagnosis was confirmed based on the patient's history and clinical presentation[(6)].

The Helsinki Declaration was followed when conducting the study. There are no identifiable personal data in the study database. Before the administration of the information sheets, the patients gave their consent ([14])

III. RESULTS

Table 1 presents a summary of the demographic features of patients who contracted COVID-19 breakthrough infections following vaccination. The participants' ages ranged from 30 to 79 years old on average. Males make up 78.6% of breakthrough cases, and the male-to-female ratio is 3.7:1. There are breakthrough infections in all age groups, but they are more common in the 60–69 age range. Of the cases, approximately fifty percent had no underlying medical conditions. An important risk factor is still aging (14 out of 42 cases). Three out of 42 cases, or a lesser percentage, had ischemic heart disease.

TABLE 1: basal demographic features of the COVID-19 infection breakthrough (N=42)

Variables			Statistics
Sex	Male N (%)		33 (78.6)
	M:F ratio		33/9 (3.7: 1)
Age/ years	Overall mean		44.3
	Age categories	30-39	3 (7.1)
		40-49	9 (21.4)
		50-59	9 (21.4)
		60-69	15 (35.7)
		70-79	6 (14.2)
Risk factors	No underlying disease		18 (42.8)
	Aging		14 (33.3)
	Arteriosclerosis		3 (7.1)
	DM		3 (7.1)

Several vaccination versions had breakthrough cases reported; of the designated vaccines, Pfizer-BioNTech had the greatest number of incidents (Table 2).

Individuals with breakthrough COVID-19 infections appear to come with a wide variety of reactions and presentations, according to the laboratory and radiographic results shown in Table 3.

TABLE 2: Distribution of COVID-19 breakthrough according to the versions of the vaccinations

Vaccine Versions	No (%)
Pfizer-BioNTech	36 (85.7)
Oxford-AstraZeneca	3 (7.1)
Beijing-Sinopharm	3 (7.1)

TABLE 3: laboratory and radiological findings of COVID-19 patients with breakthrough

Laboratory Investigations	No (%)
Positive for PCR virus RNA genes	38 (90.5)
Negative then, positive	4 (9.5)
D-dimerng/ml	510-11000
Leukocytosis 1 x 1000^3	1000-8000
Percent of positive pulmonary involvement by CT scan	
20%	6 (14.3)
30%	9 (21.4)
50%	3 (7.1)
60%	9 (21.4)
75%	3 (7.1)
80%	9 (21.4)
90%	3 (7.1)

TABLE 4: Distribution of COVID-19 breakthrough cases according to the severity and outcomes

COVID-19 Breakthrough Severity and Outcomes		No (%)
Infection severity	Mild	9 (21.4)
	Moderate	9 (21.4)
	Severe/Critical	24 (57.2)
Outcomes	Survivors	36 (85.7)
	Deaths	6 (14.3)

TABLE 5: Comparison table of reports from several countries compared to the current study regarding COVID-19breakthrough

Country	Author, year	References no	Vaccine Failure per thousand vaccines
Iraq, current study	Ali J. 2024	-----	0.17
United Kingdom	Maxime T. et al, 2022	(12)	54
USA	Jasvinder S. et al, 2021	(13)	23.1
Egypt	Alice A. et al, 2022	(14)	5
India	Chandra M. et al, 2022	(15)	10.1
Estonia	Tatjana M. et al, 2023	(16)	0.8
USA	Adeel A. et al, 2021	(6)	0.55
Palestine	Moriah B. et al, 2021	(17)	2.6
United Kingdom	Erin W. et al, 2021	(18)	26

For PCR viral RNA genes, the majority of people with breakthrough infections (90.5%) tested positive, while the lower percentage of people (9.5%) first tested negative but later tested positive. D-dimer levels in breakthrough cases are reported within a range of 510 ng/ml to 11000 ng/ml. The percentage of positive pulmonary involvement by CT scan at different levels is also shown in the table. The distribution shows that there are differences in the degree of pulmonary

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involvement, from 20% to 90%. In breakthrough cases, this data is essential for determining the disease's severity and course.

The distribution of breakthrough cases according to severity and results is displayed in Table 4. A little over 21.4 percent of the breakthrough cases were classified as mild, 21.4 percent as moderate, and 57.2 percent of breakthrough cases were classified as severe/critical.

IV. Discussion

One of the most important aspects of human immunization programs is the management of vaccine side effects. No vaccination can completely prevent infection, not even the COVID-19 vaccine. Revolution Infections with COVID-19 are predicted; COVID-19 vaccinations follow suit and do not indicate that the shots are ineffective. Covid-19 was the focus of the most recent immunization research. It was divided roughly into simple and sophisticated. The two types of complex vaccination adverse effects are vaccine failure and enhancement of the disease.[19, 20]

Although vaccines can prevent infections even in areas with high vaccination rates, emerging strains of COVID-19 can escape the immune response, making them less effective in preventing severe infections.[21-23]Of those hospitalized with COVID-19, at least one-third are vaccinated persons. Consequently, COVID-19 remains a threat.[24, 25]Evidence is required to identify and treat those who are most vulnerable to severe infections using antiviral therapy, booster shots, and preexposure prophylaxis. There is a significant degree of ambiguity surrounding the planning of vaccination policies for the future, and research investigating the long-term protection afforded by vaccination or booster injection regimens has shown inconsistent findings[26-28]

Men account for 78.6% of breakthrough cases. The male-to-female ratio is 3.7:1, suggesting a possible gender-related susceptibility to breakthrough infections. According to our findings, reports have been released[15, 29]. In contrast, two studies recently carried out in Egypt Hussein et al. [14] and Estonia et al.[16] revealed a majority of female participants.

Numerous studies report breakthrough infections in a range of age groups. According to the current study, aging is still a significant risk factor, accounting for 14 out of 42 cases and having a larger concentration in the 60–69 age range. This is consistent with earlier findings that suggest older people may be more vulnerable to breakthrough infections[6, 14, 16, 30].

Nearly half of the cases in which participants were involved had no underlying medical issues, suggesting that breakthrough infections can impact people who do not already have a medical condition. This was in line with the results of two earlier Egyptian surveys.[14, 29] Comorbidities, however, were a significant risk factor in several other trials assessing the COVID-19 breakthrough [15, 16, 30, 31] across age groups. Furthermore, 3 out of 42 patients have diabetes mellitus identified as a risk factor, emphasizing the significance of treating comorbidities in preventing breakthrough infections. Only 3 out of 42 instances have an arteriosclerosis connection, highlighting the variety of risk factors.

Ninety-five percent of those with breakthrough infections had positive PCR viral RNA gene tests. This suggests that the situations under study involved active viral replication. The smaller percentage (9.5%) of people who tested negative at first but later tested positive could indicate that some people's PCR results were delayed or that the virus load gradually rose.

D-dimer levels in breakthrough cases are reported within a range of 510 ng/ml to 11000 ng/ml. High D-dimer values, especially those at the upper end of this range, may indicate a hypercoagulable state linked to severe COVID-19 cases and indicate an increased risk of blood clotting.[2-4, 32]A common biomarker for thrombosis and disseminated intravascular coagulation (DIC) is D-dimer.[1, 33, 34]Close monitoring of these values is essential for identifying individuals at increased risk of problems and guiding appropriate medical interventions, given the possible relevance of elevated D-dimer levels. Additionally, it is in line with the general knowledge that COVID-19 can cause hyperinflammatory and prothrombotic states, highlighting the significance of thorough clinical evaluations in the management of breakthrough cases[35].

The bulk of cases were categorized as critical or serious, suggesting that breakthrough infections have a significant effect on people. In about 21.4% of the breakthrough cases, the severity was mild, meaning that the patients usually had mild symptoms and might not need to be hospitalized. However, 21.4% of instances were categorized as moderate, meaning that they had a moderate degree of severity, would have more prominent symptoms, and that people might need to see a doctor. However, many people made it out alive, highlighting the significance of receiving treatment as soon as possible and the possibility of recovery even in the most circumstances. Planning for healthcare, allocating resources, and conducting additional studies to comprehend the variables impacting the severity of breakthrough infections all depend on this information.

A brief description of vaccine failure rates in different parts of the world may be found in Table 5. Variations between nations can be caused by various reasons, such as the vaccinations given, the research methods, the demographics of the population, and the frequency of new mutations. The information emphasizes how crucial it is to continue research and surveillance to spot global trends in breakthrough infections.

A few probable explanations of vaccine failure have been hypothesized by researchers looking into COVID-19, and these could include the following. Firstly, type of COVID-19 vaccination: various vaccines may have variable levels of efficacy, and some people may respond different ways to a particular immunization shot.[36](2) SARS-CoV-2 preceding infection: certain people may reveal a robust immunity, nonetheless others may still not respond reasonably to the vaccine[36]Individual variations: in certain people, an immune system that is weakened from underlying comorbidities might make it intolerable for them to create a vigorous immune defense toward the immunization. Morawska, 2022,[10]Demographic features: the elder peoples may be less expected to build a strong immunity against the vaccination.[36]Treatment regime: some medicines or therapies

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may hinder body immune capability there by modulate body reaction to the vaccination.

The present work underlines how significant it is to consider risk factors and demographic issues to comprehend the pathophysiology of COVID-19 breakthrough. It focuses to the multifaceted associations among numerous risk variables that may be elaborate in the scenarios of COVID-19breakthrough, for instance sex, age, comorbid conditions. The information could aid in launch public health initiatives, vaccines development, and conduct more analyses on the variables manipulating the viral breakthrough.

V. CONCLUSION

The current work evaluates patients who have completed the recommended dosages of COVID-19vaccines and presented with COVID-19breakthrough, by analyzing vaccine efficacy or adverse effects. The study also sheds light on the factors driving breakthrough infections, by using a prosperity of clinical, demographic, and lab data, providing significant visions into the complex nature of predisposition.

Clinical implication

The study emphasizes the health providers and physicians for risk factor determination and cautious monitoring for COVID-19 viral breakthrough. Policymakers must modify immunization campaigns based on data on real-world effectiveness, and clinicians managing breakthrough cases should take patient demographics and comorbidities into account. These revelations facilitate a more sophisticated approach to public health interventions and support ongoing international cooperation and research initiatives aimed at improving vaccine efficacy.

Ethical Approval: All procedures prepared in studies including human patient's participants were following the ethical standards of College of Medicine Babylon University, (IRB: COV-Ali: 00210-11-2020).

Informed Consent: Informed consent was obtained from all the individual participants included in the study.

Conflict of interest: Nil

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