

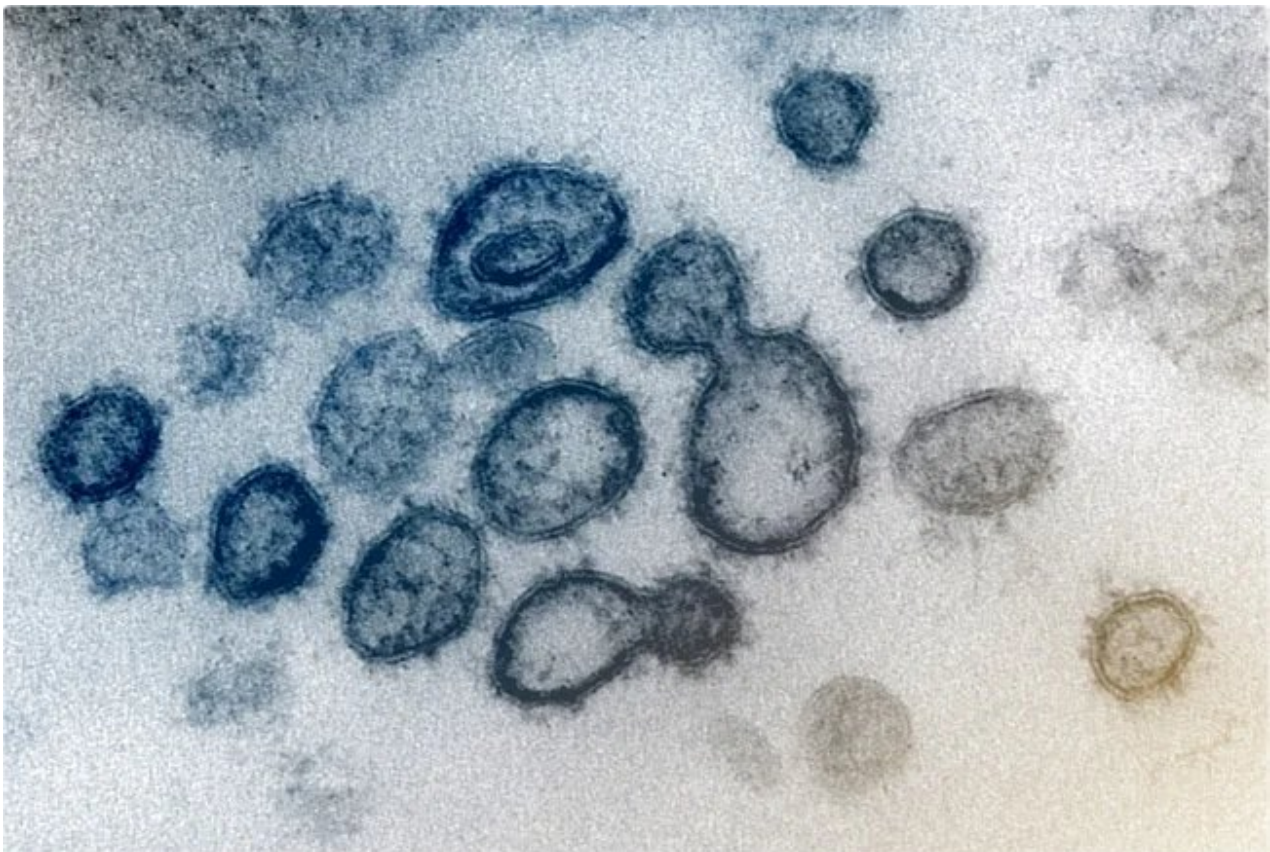
Israeli study of breakthrough infections following full BNT-Pfizer vaccination, 40% immunocompromised



By Dr. Tomislav Meštrović, MD, Ph.D.

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Severe forms of coronavirus disease (COVID-19) linked to high mortality rates might arise in a minority of fully-vaccinated individuals with many co-occurring medical conditions, finds a recent study by Israeli researchers published in the journal *Clinical Microbiology and Infection*.



Study: BNT162b2 vaccine breakthrough: clinical characteristics of 152 fully-vaccinated hospitalized COVID-19 patients in Israel. Image Credit: NIAID

In Phase III clinical trials, two mRNA COVID-19 vaccines (Pfizer/BioNTech's BNT162b2 and Moderna's mRNA-1273) were shown to be 94-95% effective in preventing symptomatic forms of the disease. Moreover, similar efficacy was observed in different age groups, as well as in those older than 75 and those with comorbidities.

Israel's vaccination campaign was swift, effective, and had a significant impact on the local COVID-19 dynamics. Factors that played a huge role here were small geographical and population size, advanced informatization, as well as effective cooperation between the government and the community-based health funds.

However, there is not enough data on the nature of breakthrough infections with COVID-19 vaccines that we started to observe even in highly vaccinated populations like Israel. Furthermore, we lack data on the clinical traits and serologic correlates of protection of individuals hospitalized with COVID-19 after they have received their jabs.

According to the Israeli Ministry of Health registry, by the end of April 2021, a total of 397 fully vaccinated patients were hospitalized with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) after their second vaccine dose – with 234 of them suffering severe COVID-19 and 90 of them succumbing to the disease.

By using a subset of hospitalized patients, a research group led by Dr. Tal Brosh-Nissimov from the Samson Assuta Ashdod University Hospital in Israel aimed to characterize vaccinated and hospitalized patients with breakthrough COVID-19 infection, but also to define principal risk factors linked to poor outcomes in this group.

A multi-center cohort study

This study used a cohort approach to study patients in seventeen different hospitals. Individuals that were included in the study have received two doses of Pfizer/BioNTech vaccine, they were positive for SARS-CoV-2 on PCR test and were hospitalized in a COVID-19 unit.

Furthermore, clinical data has been retrieved from patients' medical records in accordance with a predefined questionnaire. Alongside PCR testing, even viral genomic sequencing has been pursued in order to identify variants of concern in the samples.

A mixture of either mechanical ventilation or in-hospital death has been considered as a poor outcome, which was the main interest of this study. On the other hand, a favorable outcome has been defined as patient discharge or

hospitalization without the need for ventilation.

Breakthrough infections linked to comorbidities

From a total of 152 patients included in the study, poor outcome was observed in 38 of them and mortality rate reached 22%. The clinical profile of these individuals resembled other COVID-19 hospitalized patients, which means they were primarily older men with a plethora of comorbidities associated with COVID-19 severity.

Nonetheless, comorbidities were more frequent in patients with vaccine breakthrough infections in comparison to a large case series on unvaccinated hospitalized patients – including hypertension, diabetes, heart failure, chronic kidney diseases, chronic lung diseases, dementia and cancer. Moreover, 40% of the patients were immunocompromised.

Higher SARS-CoV-2 viral load was linked to a substantially higher risk of poor outcome, which was also increased (albeit not significantly) in patients receiving a specific treatment regimen with anti-CD20 monoclonal antibodies, as well as in patients with low titers of protective antibodies.

Implications for high-risk individuals

The results of this study clearly imply that a small minority of individuals fully vaccinated with Pfizer/BioNTech vaccine might still present with a severe SARS-CoV-2 infection and the need for in-patient care – despite the vaccine's high effectiveness. More specifically, the outcome of patients included in the study was comparable to that of non-vaccinated hospitalized COVID-19 patients.

“Additional prospective longitudinal studies are urgently needed to identify predictors for vaccine breakthrough infection and simple correlates of vaccine protection, to enable identification of individuals at higher risk, who would require continued strict precautions, and possibly repeated active vaccination or other prophylactic measures, such as passive vaccination”, say study authors.

Such research endeavors will aid in developing guidance to improve the protection of such patients. In the meantime, we should be cognizant that mass vaccination (leading to herd immunity) is an optimal way to indirectly protect vulnerable individuals.

Journal reference:

- Brosh-Nissimov, T. et al. (2021). BNT162b2 vaccine breakthrough: clinical characteristics of 152 fully-vaccinated hospitalized COVID-19 patients in Israel. *Clinical Microbiology and Infection*. <https://doi.org/10.1016/j.cmi.2021.06.036>, [https://www.clinicalmicrobiologyandinfection.com/article/S1198-743X\(21\)00367-0/fulltext](https://www.clinicalmicrobiologyandinfection.com/article/S1198-743X(21)00367-0/fulltext)



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