Medical Xpress

Bivalent COVID-19 booster vaccine shown to be highly effective in reducing deaths and hospitalizations

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Since September, 2022, bivalent mRNA vaccines—which contain elements from both the original wild type COVID strain and an updated

component from the omicron strain—have replaced older style monovalent boosters in the U.S., Israel, and other countries. These vaccines were designed to help improve vaccine-induced immunity against the omicron variant and subsequent subvariants.

A new study published in *The Lancet Infectious Diseases* and presented at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID 2023, Copenhagen April 15-18) is one of first the assess the effectiveness of this new type of COVID-19 vaccine in vulnerable people aged 65 years and over.

The study assessed the Pfizer bivalent vaccine, since Pfizer is the main supplier of COVID vaccines to Israel. The study shows that, compared to people in this age group eligible to receive this bivalent booster yet who did not, those receiving it had a 72% lower risk of COVID-19 related hospitalization and a 68% lower risk of COVID-19 related death.

"Bivalent mRNA booster vaccination in adults aged 65 years or older is an effective and essential tool to reduce their risk of hospitalization and death due to COVID-19. Vaccination remains the primary tool for avoiding severe COVID-19," explains study co-author Dr. Ronen Arbel, Community Medical Services Division, Clalit Health Services, Tel Aviv, and the Maximizing Health outcomes Research Lab, Sapir College, Sderot, Israel. "Our findings highlight the importance of new types of vaccines containing different variants of SARS-CoV-2, which are likely to induce broader immune responses and provide enhanced protection against severe outcomes."

To date, randomized controlled trials evaluating the clinical efficacy of a bivalent mRNA booster vaccine are unavailable. The bivalent mRNA booster vaccines are currently prioritized in Israel for people at high risk of severe COVID-19, primarily those aged 65 years or older. This made it possible for the authors to do a retrospective cohort study to evaluate

the effectiveness of a bivalent mRNA vaccine booster dose to prevent hospitalizations and deaths due to COVID-19.

Between Sept 27, 2022, and Jan 25, 2023, 569,519 eligible participants were identified. Of those, 134,215 (24%) participants received a bivalent mRNA booster vaccination during the study period. Hospitalization due to COVID-19 occurred in 32 participants who received a bivalent mRNA booster vaccination and 541 who did not receive a bivalent booster vaccination (with analysis showing this to mean a 72% reduction in the risk of hospitalization for those receiving the bivalent booster).

The adjusted risk for COVID-19 hospitalizations in the bivalent mRNA booster recipients was 0.035% versus 0.124% in the non-recipients. Therefore the absolute risk reduction for hospitalizations due to COVID-19 was 0.089%, and accordingly, one hospitalization due to COVID-19 was avoided for every 1,118 people vaccinated.

The adjusted risk for COVID-19 death was 0.013% in the bivalent mRNA booster recipients versus 0.040% in the non-recipients, meaning a 68% relative risk reduction death for the bivalent vaccine recipients. The absolute risk reduction of death was 0.027%, and accordingly, one death due to COVID-19 was avoided for every 3,722 people vaccinated.

The authors note some limitations of their study, including the low numbers of hospitalizations and deaths, and that use of only the Pfizer bivalent vaccine means that generalization of the results to other bivalent vaccines should be done with caution. Also, the study was not a direct comparison between bivalent and monovalent vaccines, since both were not administered at the same time in Israel during the study period.

They also note adverse events are outside the scope of the study, but note that "preliminary short-term safety results published by the CDC have

shown a comprehensive safety profile for the bivalent booster and reassured that adverse events reported after a bivalent booster dose are consistent with those reported after monovalent doses."

The authors conclude, "Our results suggest that the bivalent mRNA vaccine booster dose is associated with a reduced risk of severe COVID-19 outcomes in adults aged 65 years or older. Our findings highlight the importance of bivalent booster vaccination in populations at high risk of severe COVID-19 and the necessity to increase efforts to encourage eligible people to be vaccinated."

More information: Effectiveness of a bivalent mRNA vaccine booster dose to prevent severe COVID-19 outcomes: a retrospective cohort study, *The Lancet Infectious Diseases* (2023). DOI: 10.1016/S1473-3099(23)00122-6. www.thelancet.com/journals/lan … (23)00122-6/fulltext

Comment: Effectiveness of bivalent mRNA booster vaccines against COVID-19: methodological and public health considerations, *The Lancet Infectious Diseases* (2023). DOI: 10.1016/S1473-3099(23)00187-1. www.thelancet.com/journals/lan … (23)00187-1/fulltext

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