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CLINICAL EFFICACY AND OPTIMAL REGIMEN OF BNT162B2 VACCINE IN CHRONIC DIALYSIS PATIENTS

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Background and Aims: Highly effective vaccines against severe acute respiratory syndrome virus 2 (SARS-CoV-2) have been developed and administered worldwide. Protection from coronavirus disease 2019 (COVID-19), however, is not absolute, and optimal vaccination regimens need to be established. Concerns regarding breakthrough COVID-19 disease in vaccinated patients are increasing, as vaccine efficacy appears to gradually decline in the months following vaccination. The emergence of highly infective variants, escalates these issues. This study assessed the clinical efficacy of the BNT162b2 vaccine and all-cause mortality among dialysis patients receiving varying numbers of vaccine doses.

Method: This study was conducted using the electronic database of Clalit Health Services in Israel. Patients receiving chronic hemodialysis or peritoneal dialysis during COVID-19 pandemic were included in the analysis. The control group consisted of age-and sex-matched individuals, in a 4:1 ratio to the dialysis group. The study included the pre- and post-vaccination periods.

Results: A total of 14,230 people were included; 2,846 on chronic dialysis and 11,384 controls. Mean age was 66.2±14.3 years (range 18-97). Before the vaccine was available in Israel, 223 dialysis patients were infected with SARS-CoV2. Their mortality rate was 18.4% compared to 10.8% among uninfected, unvaccinated patients in the same period ($p = 0.001$). On post-vaccination period, we compared the clinical efficacy of a fourth dose to patients who received only 3 doses of BNT162b2 vaccine. SARS-CoV-2 infection rates, hospitalizations due to severe COVID-19, COVID-19–related mortality and all-cause mortality rates were lower among chronic dialysis patients who received a fourth dose of vaccine as compared to those who received only 3 doses (after adjusting for age, sex and comorbidities). Despite lower mortality rates observed with the Omicron variant, an additional booster dose was associated with reduced COVID-19–related mortality (1.7% vs. 3.8%, $p = 0.04$, HR 0.44 (95% CI 0.2–0.98) in patients who received 4 doses compared to 3 doses.

Conclusion: As seen in the general population, and with previous vaccine boosters, the fourth dose of the BNT162b2 vaccine reduced rates of severe COVID-19 hospitalization and mortality among chronic dialysis patients. This study strengthens the recommendation to administer a fourth booster dose of vaccine to dialysis patients. Further studies are needed to establish the exact dose and schedule of the COVID-19 vaccine in the vulnerable population patients on chronic maintenance dialysis.

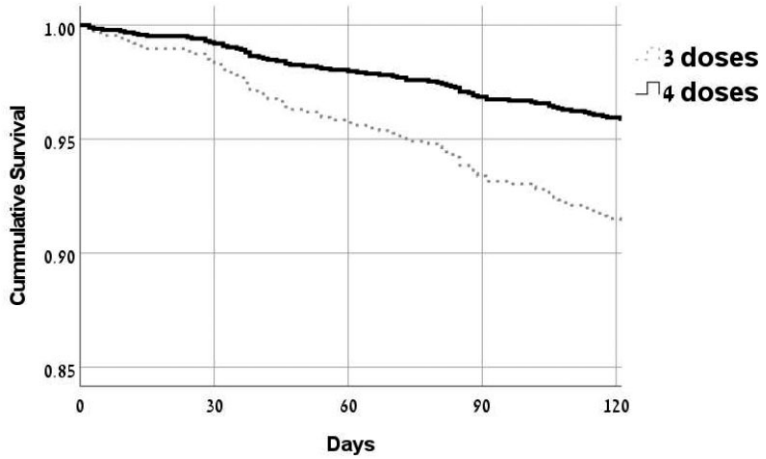

Figure 1: Adjusted Cox survival curves for dialysis patients who received 4 vs. 3 vaccine doses; p = 0.001 (HR = 0.5 95% CI: 0.3-0.7).