

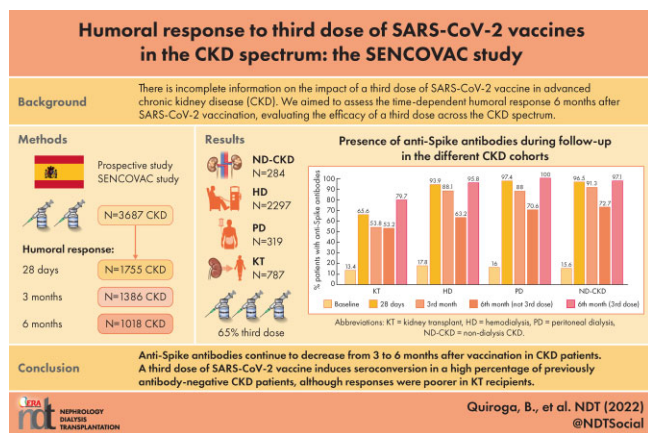
COVID-19 IN 2021

FC 001 HUMORAL RESPONSE TO THIRD DOSE OF SARS-COV-2 VACCINES IN THE CKD SPECTRUM: THE SENCOVAC STUDY

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GRAPHICAL ABSTRACT



BACKGROUND AND AIMS: There is incomplete information on the impact of a third dose of the SARS-CoV-2 vaccine in advanced chronic kidney disease (CKD). The aim of the present analysis was to evaluate the kinetics of humoral response in the CKD spectrum (KT, HD, PD and ND-CKD) 6 months after completing the initial

vaccine schedule. Some patients of each group received a third dose before 6 months, providing a pragmatic insight into real-world responses to different vaccine schedules in patients with advanced CKD not on dialysis, on dialysis or in KT recipients.

METHOD: The SENCOVAC study describes the humoral response and safety of different SARS-CoV-2 vaccines in a real-world setting in 3687 CKD patients: 787 kidney transplant (KT), 319 peritoneal dialysis (PD), 2297 haemodialysis (HD) and 284 non-dialysis-CKD (ND-CKD) patients. Anti-Spike antibodies were assessed in an efficacy analysis at 28 days ($n = 1755$), 3 months ($n = 1386$), and 6 months ($n = 1018$), of whom 628 had received a third vaccine dose. Adverse events (AEs) were registered during follow-up, including SARS-CoV-2 infections in the safety analysis.

RESULTS: Among the patients included in the efficacy analysis, KT recipients presented lower anti-Spike antibody titers than other CKD cohorts at 28 days and 3 months ($P < .001$ for all). A total of 943 patients [249 (26%) KT, 108 (11%) PD, 511 (54%) HD and 75 (8%) ND-CKD] had negative baseline anti-Spike antibodies. Again, at 28 days or 3 months, KT recipients developed lower anti-Spike antibody titers than PD ($P < .001$), HD ($P < .001$) and ND-CKD ($P < .001$) patients. At 6 months, patients that had received a third vaccine dose had higher anti-Spike antibody titers than those without the third dose [1837 (507–9726) UI/mL versus 80 (19–409) ml/UI; $P < .001$] and this was evident in all CKD cohorts. Anti-Spike titers after the third dose were higher in patients boosted with mRNA-1273 than with BNT162b2 [1710 (322–9615) versus 472 (34–2094); $P < .001$]. At 6 months, in patients that had received a third dose, a positive humoral response (anti-Spike antibodies > 36 UI/mL) was achieved in 584 (93%): 94 (80%) of 118 KT recipients, 20 (100%) of 20 patients on PD, 436 (96%) of 455 patients on HD and 34 (97%) of 35 patients with ND-CKD (Fig. 1). Among patients without humoral response 3 months after completing the initial vaccination schedule, 72 (69%) seroconverted after the third dose (62% KT, 76% HD, 100% ND-CKD, all PD patients had a positive humoral response at 3 months). Independent predictors of a positive humoral response at 6 months were not-KT (HR for KT 0.26, $P = .011$), third dose (HR 22.9, $P < .001$), initial mRNA-1273 (HR 1.78, $P = .017$) and humoral response at 3 months (HR 26.2, $P < .001$). Breakthrough SARS-CoV-2 infections occurred in 1.1% of patients, and mortality was 14.6%, none after the third dose.

CONCLUSION: In the CKD spectrum, anti-Spike antibody titers continued to decrease from 3 to 6 months after complete vaccination, and KT recipients presented higher rates of negative humoral response at 6 months. A third dose of mRNA vaccine increased anti-Spike antibody titers but was still insufficient to spur a humoral immune response in at least 38% of KT recipients and 24% of patients on HD that lacked anti-SARS-CoV-2 antibodies 3 months post-initial vaccination. New strategies are urgently needed to protect CKD patients that remain negative for anti-SARS-CoV-2 antibodies, given the high mortality of breakthrough SARS-CoV-2 infections.

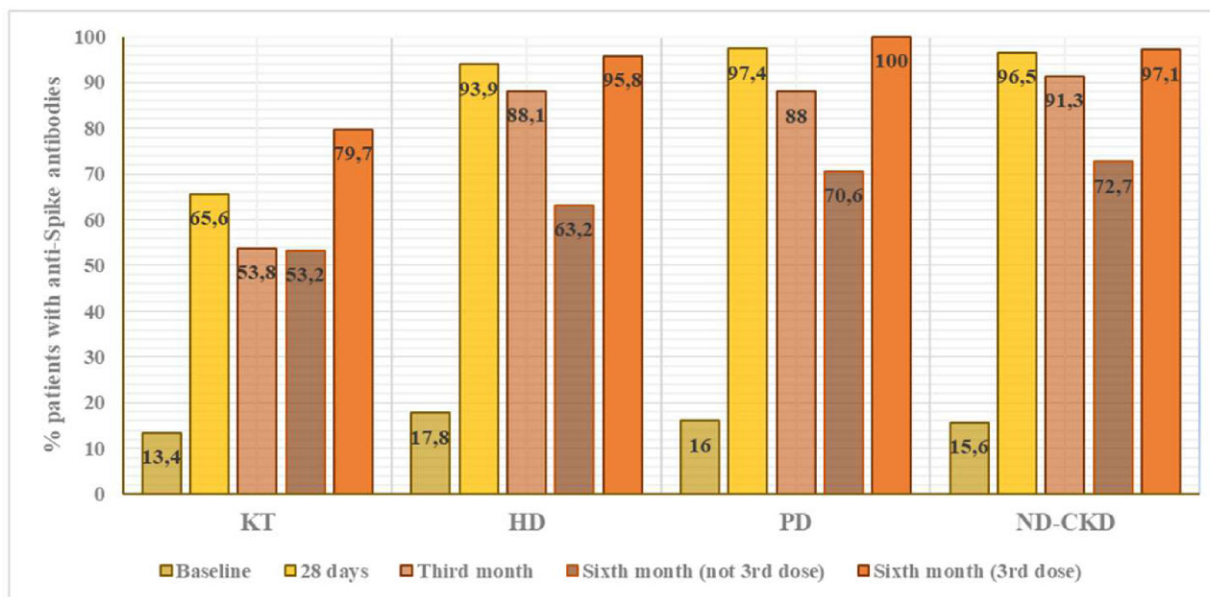
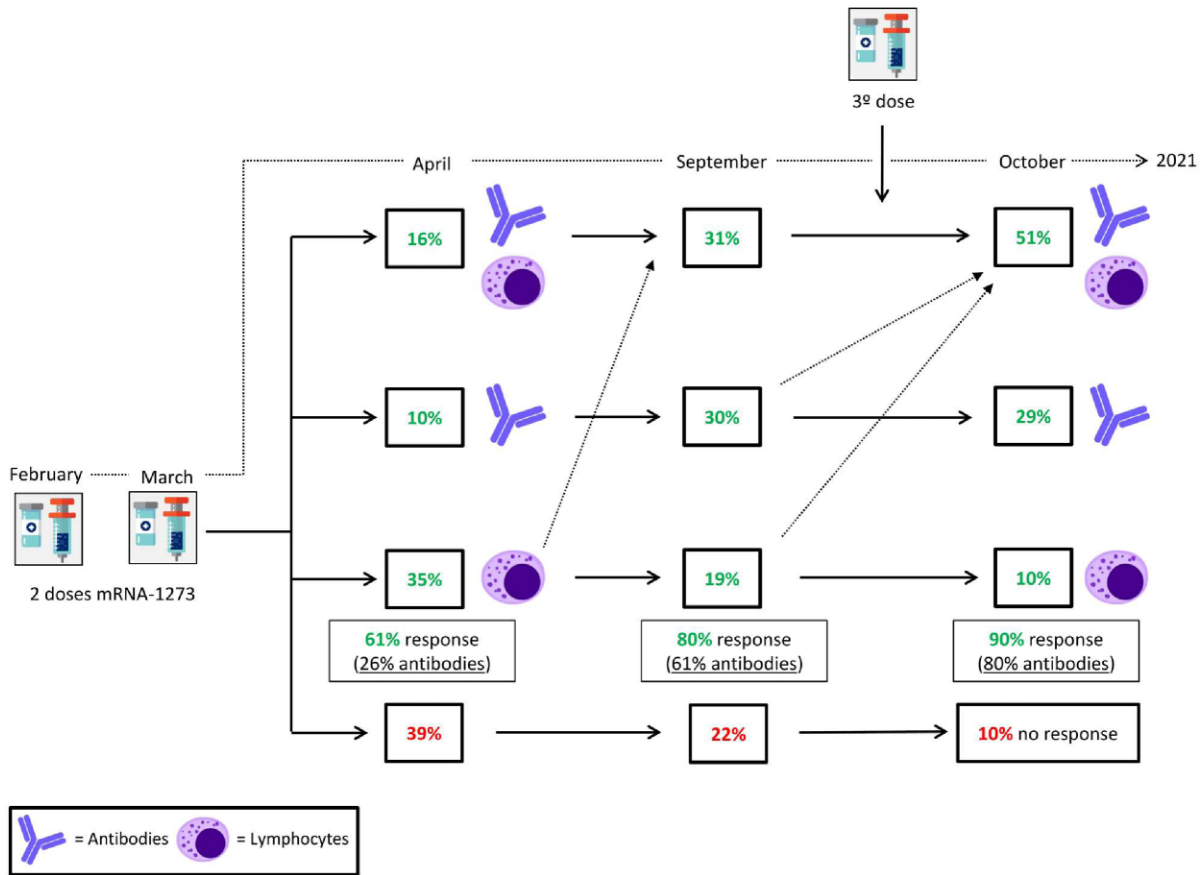


FIGURE 1: Presence of anti-Spike antibodies during follow-up in the different CKD cohorts. Data expressed as % of patients with presence of anti-Spike antibodies (i.e. titer > 36 IU/mL).



FC 002 HUMORAL AND CELLULAR IMMUNE RESPONSES AFTER A THREE-DOSE COURSE OF MRNA-1273 COVID-19 VACCINE IN KIDNEY TRANSPLANT RECIPIENTS: A PROSPECTIVE COHORT STUDY

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BACKGROUND AND AIMS: Seroconversion after a two-dose course of mRNA COVID-19 vaccination in kidney transplant recipients ranges between 30% and 50% in different series. We previously demonstrated that a substantial proportion of patients (35%) without a humoral response, develop a cellular response after the second dose assessed by the ELISpot technique. We aim to study the evolution of both humoral and cellular responses in the same cohort before and 1 month after the administration of the third dose of 100 mcg of mRNA-1273 COVID-19 vaccine.

METHOD: Final population included 129 KTRs studied at four time-points: at baseline before the first dose, after the second dose (median 42 days) and before (203 days) and after (232 days) the third dose. At all the time-points, IgG and IgM were assessed as well as N- and S-protein specific ELISpot. The main outcome was seroconversion after the third dose.

RESULTS: After the second dose, 26.7% of naïve cases experienced seroconversion. Before the third dose and in the absence of clinically evident COVID-19, this percentage increased to 61.9%. After the third dose, seroconversion was observed in 80.0% of patients. S-ELISpot positivity after the second dose was significantly associated with final seroconversion [OR (95% CI) 3.14 (1.10–8.96); P = .032], while transplantation < 1 year and previous kidney transplant were negatively associated with [OR (95% CI) 0.23 (0.07–0.80); P = .021 and OR (95% CI) 0.22 (0.06–0.78); P = .020, respectively]. IgG after third dose were significantly higher (P < .001) in patients who maintained S-ELISpot positivity throughout the study (34.3%) and were correlated with S-spots after the second dose (r = 0.344, P < .001).

CONCLUSION: A substantial proportion of KTRs vaccinated with mRNA-1273 develops a late seroconversion after two doses and only a fifth remained seronegative

after a third. Cellular immunity seems to play a major role in the development of a final strong humoral response.

FC 003 ASSOCIATION BETWEEN METABOLIC DYSFUNCTION-ASSOCIATED FATTY LIVER DISEASE AND HYPERFILTRATION IN SUBJECTS WITH PREDIABETES AND ABDOMINAL OBESITY WITHOUT EVIDENCE OF CHRONIC KIDNEY DISEASE

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BACKGROUND AND AIMS: The newly defined metabolic dysfunction-associated fatty liver disease (MAFLD) [1] is a multifactorial state that could influence multiple extra-hepatic diseases. Glomerular hyperfiltration (GHF) is an important early determinant of diabetic kidney disease onset and progression in a subgroup of patients, and recently it was reported that prediabetes stage is an independent risk for incident GHF [2]. Currently, no data are available on the association between MAFLD and GHF. The aim of the study was to determine the prevalence of MAFLD and whether and to which extent it is associated with GHF in prediabetic subjects with abdominal obesity and without evidence of chronic kidney disease (CKD).

METHOD: Data from a total of 6697 civil servants, aged 18–65 years, with prediabetes (fasting plasma glucose $\geq 100 \leq 125$ mg/dL, American Diabetes Association criteria), abdominal obesity (waist circumference ≥ 94 cm for men and ≥ 80 cm for women, International Diabetes Federation criteria) and an estimated glomerular filtration rate