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Loss of humoral response 3 months after SARS-CoV-2 vaccination in the CKD spectrum: the multicentric SENCOVAC study

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SENCOVAC is a prospective multicentric study promoted by the Spanish Society of Nephrology (S.E.N.), which included four cohorts of adults with chronic kidney disease (CKD): kidney transplant recipients (KTRs), haemodialysis (HD), peritoneal dialysis (PD) and non-dialysis (ND)-CKD patients [glomerular filtration rate (GFR) <30 mL/min/1.73 m²] [1]. Participants were immunized with locally available vaccines [BNT162b2 (Pfizer-BioNTech[®]), mRNA-1273 (Moderna[®]), ChAdOx1-S (AstraZeneca[®]) or Ad26.COV.2 (Janssen[®])]

prescribed by regional health authorities unrelated to the study investigators. The present analysis (20 September 2021) predates booster doses. The primary objective was seroconversion after vaccination. Preliminary data showed lower anti-Spike antibody development after vaccination in KTRs than in other CKD patients [1] (Supplementary Material and methods).

SENCOVAC included 3439 patients and analysed 28-day humoral immunity in 1061 patients and 3-month humoral immunity in 567 patients. Baseline characteristics of patients

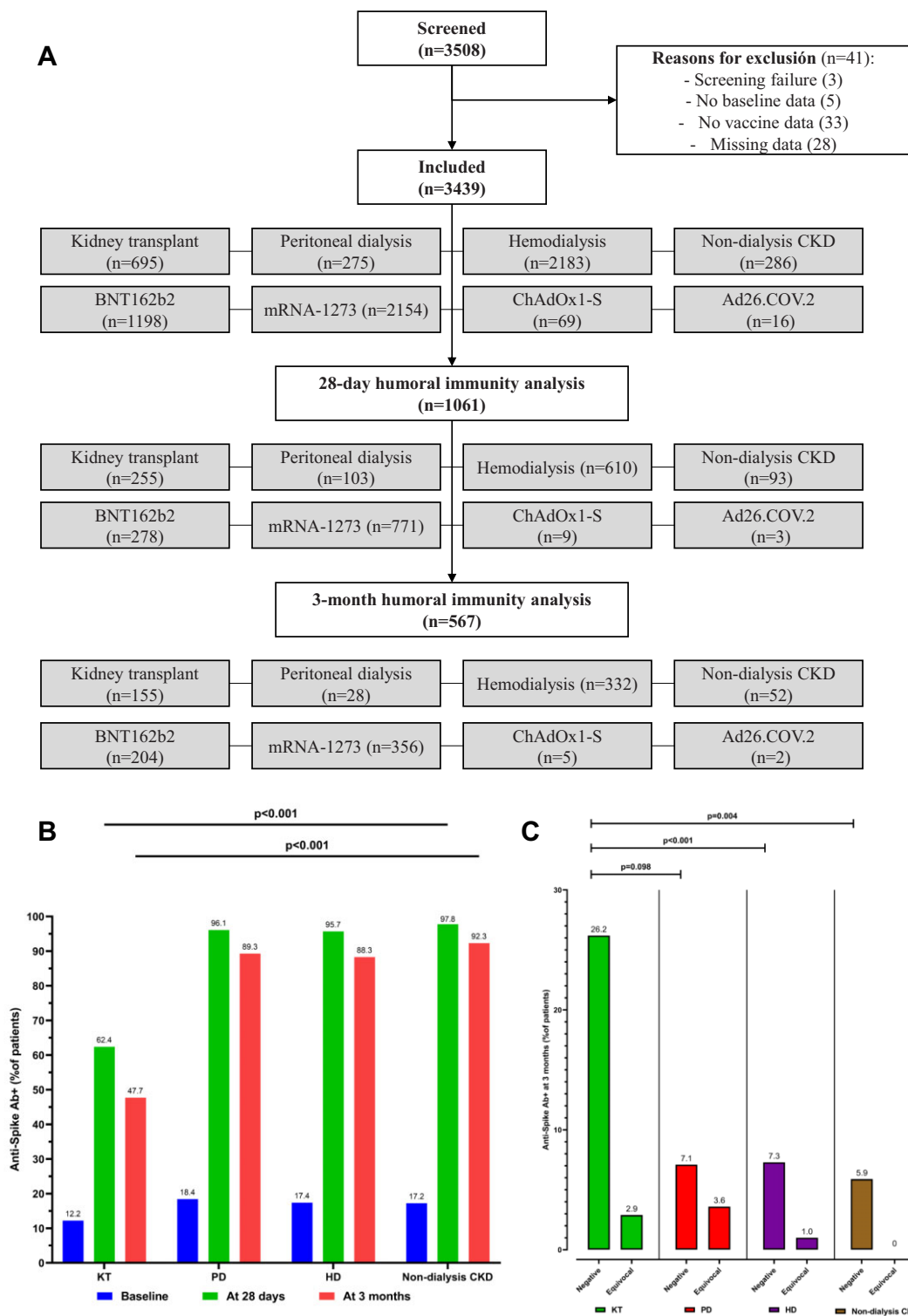


FIGURE 1: (A) Flow chart of the SENCovac study. (B) Proportion of patients with positive humoral response at baseline, 28 days and 3 months. (C) Negative and equivocal humoral response 3 months after completing vaccine schedule among patients with positive humoral response at 28 days. Data expressed as percentage of those who were positive at 28 days.

analysed 28 days and 3 months after vaccine completion are summarized in Supplementary data, Tables S1 and S2. At 28 days, 255 (24%) were KT, 103 (10%) PD, 610 (57%) HD and 93 (9%) ND-CKD patients (Figure 1A). At 3 months, 155 were KT (27%), 28 (5%) PD, 332 (59%) HD and 52 (9%) ND-CKD patients (Figure 1A).

The humoral response at 28 days differed between groups. Among the 255 KTRs, 159 (62.4%) presented humoral immunity, which was lower than the 91 (97.8%) of 93 ND-CKD patients, 100 (97%) of 103 PD patients and 584 (95.7%) of 610 HD patients ($P < 0.001$). At 3 months, the rate of humoral response in KTRs was even lower (47.7%)

($P < 0.001$) (Figure 1B). Anti-Spike antibody titres differed between cohorts, being lower in KTRs ($P < 0.001$) at 28 days and at 3 months (Supplementary data, Figures S1 and S2). A strong correlation was found between 3-month and 28-day anti-Spike titres ($\rho 0.858$, $P < 0.001$) (Supplementary data, Figure S3).

When assessing differences between the most common vaccines, BNT162b2 and mRNA-1273, at 3 months, anti-Spike antibody titres were higher for mRNA-1273 ($P < 0.0001$) (Supplementary data, Figure S4). mRNA-1273 was associated with higher antibody titres in PD ($P = 0.005$) and HD patients ($P < 0.001$) (Supplementary data, Figure S5). Among patients with negative baseline anti-Spike antibodies, mRNA-1273 was also associated with higher antibody titres 3 months after vaccination ($P = 0.009$) (Supplementary data, Figure S4). Among these patients, mRNA-1273 was associated with higher antibody titres in PD ($P = 0.009$) and HD patients ($P < 0.001$) (Supplementary data, Figure S6). Interestingly, in a preprint study from Florida, the risk of infection after full vaccination with mRNA-1273 was about 60% lower than after full vaccination with BNT162b2 [Incidence rate ratio (IRR): 0.39 [95% confidence interval (CI): 0.24–0.62]], indicating a higher protection with mRNA-1273 [2]. Similar results were reported in immunocompromised adults [3].

Factors associated with a lack of humoral response 28 days after completing vaccination were female sex ($P = 0.02$), negative baseline anti-Spike antibodies ($P < 0.001$), previous influenza vaccine ($P = 0.02$) and KTR ($P < 0.0001$). Independent predictors for negative humoral response were older age [hazard ratio (HR): 1.02 (95% CI: 1.00–1.04); $P = 0.031$], female sex [HR: 1.97 (95% CI: 1.26–3.10); $P = 0.003$], negative baseline anti-Spike antibodies [HR: 10.42 (95% CI: 3.15–34.89); $P < 0.001$], KTRs [HR: 21.62 (95% CI: 12.74–36.70); $P < 0.001$] and BNT162b2 [HR: 2.25 (95% CI: 1.32–3.81); $P = 0.003$] (Supplementary data, Table S3). Older age has been associated with less antibody response and worse coronavirus disease 2019 (COVID-19) outcomes [4, 5]. In contrast to our results regarding sex differences, in healthy people, humoral responses were lower in males [6]. Moreover, factors associated with negative humoral responses 3 months after completing vaccination were negative baseline anti-Spike antibodies ($P < 0.001$), lower anti-Spike antibody titres at 28 days ($P < 0.001$) and KTR ($P < 0.0001$). In the multivariate model, KTRs [HR: 5.39 (95% CI: 2.50–11.58); $P < 0.001$] and anti-Spike antibody titres at 28 days [HR: 0.99 (95% CI: 0.99–0.99); $P < 0.001$] maintained their independent predictor value for negative humoral response (Supplementary data, Table S3). Multivariate assessment using the same predictive model but excluding 28-day anti-Spike titres showed that age [HR: 1.03 (95% CI: 1.01–1.06); $P = 0.003$], negative baseline anti-Spike antibodies [HR: 13.6 (95% CI: 4.43–41.79); $P < 0.001$], KTRs [HR: 23.14 (95% CI: 12.12–44.18); $P < 0.001$] and BNT162b2 [HR: 3.09 (95% CI: 1.71–5.61); $P < 0.001$] were associated with negative humoral response 3 months after completing vaccination (Supplementary data, Table S4).

Among the 496 patients with a positive humoral response at 28 days, 55 (11%) had become anti-Spike antibody negative

at 3 months. KTRs lost the humoral response more frequently (26%) than the other cohorts ($P < 0.001$) (Figure 1C). Factors associated with the loss of the humoral response were KTRs ($P < 0.0001$), negative baseline anti-Spike antibodies ($P = 0.04$) and lower antibody titres at 28 days ($P < 0.001$). An adjusted multivariate logistic regression showed that KTRs [HR: 2.72 (95% CI: 1.38–5.37); $P = 0.004$] and lower 28-day antibody titres [HR: 0.99 (95% CI: 0.99–0.99); $P < 0.001$] were predictors for losing humoral response 3 months after vaccination. Among KTRs, losing humoral immunity was associated with negative baseline anti-Spike antibodies ($P = 0.002$), lower 28-day antibody titres ($P < 0.001$), steroids prescription ($P = 0.017$) and a trend was observed for shorter transplantation vintage ($P = 0.08$). In HD patients, losing humoral immunity was associated with BNT162b2 ($P = 0.015$) and lower 28-day antibody titres ($P < 0.001$). The response rate, anti-Spike antibody titres and rate of loss of anti-Spike antibodies were similar for PD, HD and ND-CKD patients. However, antibody titres were lower at 3 months than at 28 days. A recent small report of 41 chronic HD patients reached similar conclusions and alerts about the decline in humoral immunity [7].

During follow-up [median 3.9 (3.6–4.4) months] and after completing the vaccine schedule, 26 patients (0.8%) were infected by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and 5 patients (<0.1% of vaccinated patients, 19% of breakthrough SARS-CoV-2 infections) died from COVID-19 (Supplementary data, Tables S5 and S6). Overall, 59 patients (1.7%) died during follow-up. One patient, registered as a possible-probable vaccine-related death, developed a haemorrhagic stroke 21 days after the first dose of mRNA-1273 (Supplementary data, Tables S5 and S6).

Issues for further exploration include the relevance of cellular immunity after vaccination or the impact of a third dose in CKD patients.

In conclusion, KTRs developed lower vaccine response rates and anti-Spike antibody titres and lost antibodies faster than other CKD cohorts, and BNT162b2 was associated with lower anti-Spike antibody titres than mRNA-1273. Identifying predictors for loss of antibodies should help in prioritizing patients at higher risk for booster doses or the prophylactic use of anti-SARS-Cov-2 monoclonal antibodies [8], as breakthrough infections were uncommon but had high mortality. Anti-Spike antibody titres 28 days after completing the vaccine schedule predicted the loss of humoral responses. To our knowledge, this is the first report including the whole spectrum of CKD patients, with a 3-month follow-up and a considerable sample size.

SUPPLEMENTARY DATA

Supplementary data are available at *ndt* online.

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CONFLICT OF INTEREST STATEMENT

B.Q. has received honoraria for conferences, consulting fees and advisory boards from Vifor-Pharma, Astellas, Amgen, Bial, Ferrer, Novartis, AstraZeneca, Sandoz, Laboratorios Bial, Esteve, Sanofi-Genzyme and Otsuka. M.J.S. reports honorarium for conferences, consulting fees and advisory boards from AstraZeneca, NovoNordisk, Esteve, Vifor, Bayer, Mundipharma, Ingelheim Lilly, Jansen, ICU Medical and Boehringer. A.O. has received consultancy or speaker fees or travel support from Astellas, AstraZeneca, Amicus, Amgen, Fresenius Medical Care, Bayer, Sanofi-Genzyme, Menarini, Kyowa Kirin, Alexion, Otsuka and Vifor Fresenius Medical Care Renal Pharma, and is Director of the Catedra Mundipharma-UAM of diabetic kidney disease and the Catedra Astrazeneca-UAM of CKD and electrolytes. A.B. has received honoraria for conferences from Vifor-Pharma and Shire. C.J.J.M. has received honoraria for one conference from Vifor-Pharma. C.C.G. has received honoraria for conferences, consulting fees and advisory boards from Fresenius and AstraZeneca. A.M. has received honoraria for conferences, consulting fees and advisory boards from Astellas, Novartis, Chiesi, GSK and Sanofi-Genzyme. She is a member of the Board of the S.E.N. and the Spanish Society of Transplantation (S.E.T.). J.C.R.S.M. has received honoraria for conferences, consulting fees and advisory boards from Novartis, Alexion, Astellas, Chiesi and Sandoz. J.M.C. has received honoraria for conferences from Astellas and AstraZeneca. S.C. has received honoraria for conferences, consulting fees and Advisory Boards from: Vifor-Pharma, Astellas, Amgen, Novartis, Novo Nordisk, Chiesi, AstraZeneca, Sanofi-Genzyme, Otsuka, Chemo-Centrix, Boheringher and Rovi. M.Crespo has received honoraria for conferences, consulting fees and advisory boards from Astellas, Sanofi, Novartis and Chiesi. S.S. reports an honorarium for conferences and Advisory Boards from Vifor-Pharma, Astellas and Baxter. P.d.S. reports an honorarium for conferences, consulting fees and advisory boards from Amgen, Astellas, AstraZeneca, Baxter, Braun, Fresenius, Nipro and Vifor-Pharma. She is the present president of the S.E.N.

A.B.M.D., V.O.G.P., M.Cervienka, M.O.D., R.L.V., M.C.D.R., S.M., M.G.S.M., M.G., P.M.R., N.M.C., N.T., C.L.N., M.T.R.D.T., D.G.F., B.V.L., E.G.P., C.G.-I., R.S.E., M.C.A.C., M.I.J.M., M.S.P.S., L.R.-O.J., A.Y., A.L., J.R. and R.T.G. do not present conflict of interests.

AUTHORS' CONTRIBUTIONS

Research idea and study design was by B.Q., M.J.S., A.O., R.T.G. and P.d.S. Data acquisition was performed by A.B., A.B.M.D., C.J.J.M., V.O.G.P., C.C.G., M.Crespo, A.M., J.M.C., M.C.D.R., S.M., M.O.D., R.L., M.G.S.M., C.L.N., E.G.P., C.G.-I., M.T.R.D.T., M.C.A.C., M.G., P.M.R., N.M.C., N.T., J.C.R.S.M., R.S.E., M.Cervienka, B.V.L., M.I.J.M., L.R.-O.J.,

S.C., S.S., D.G.F., M.S.P.S. and A.Y. Data analysis/interpretation was carried out by B.Q., M.J.S., A.O., A.L., J.R., R.T.G. and P.d.S. Statistical analysis was performed by B.Q. and A.O. Supervision or mentorship was provided by B.Q., M.J.S., A.O., S.M., R.T.G., A.L., J.R., R.T.G. and P.d.S.

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