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SARS-CoV-2 Infection After Vaccination: Kidney Transplant Recipient Profile and Disease Evolution in a Single Center

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ABSTRACT

Background. SARS-CoV-2 infection has had a major impact on kidney transplant patients. Recent evidence suggests that solid organ transplant recipients who received mRNA vaccines reach low immunization rates. There are only few reports about the risk factors and severity of COVID-19 in these patients. Our single center experience describes the patient profile and disease evolution observed in this vulnerable group after inoculation.

Material and Methods. Retrospective cohort study with kidney transplant patients who received a COVID-19 vaccine before testing positive for SARS-CoV-19 using polymerase chain reaction. Demographic characteristics and clinical information are described and compared with our previous series of patients who were infected before the initiation of the vaccination rollout.

Results. Sixteen kidney transplant recipients diagnosed with COVID-19 after being vaccinated were included and compared with our previous series of 76 unvaccinated patients who were positive for COVID-19. No differences were found among risk factors such as age, time after transplant, hypertension, and obesity between groups (P value > .05). After COVID-19 diagnosis among inoculated patients, 10 patients were hospitalized, and 4 of who met the criteria for admission to the intensive care unit. Three patients died of COVID-19 complications. Despite this, the incidence of infections has decreased after vaccination rollout (P value < .05).

Conclusions. Patients’ risk profiles remain constant among recipients who were positive for COVID-19 between waves. We did not find significant differences in hospitalization and severity rates in this reduced group of patients. However, the overall incidence in our kidney transplant population has decreased.

Since the declaration of the COVID-19 pandemic situation in March 2020, all countries around the world have registered a large number of cases in different waves that have brought their health-care systems to the limit of saturation.

Several factors such as advanced age, obesity, diabetes mellitus, hypertension, and cardiovascular pathology have been associated with disease severity in the general population. Against this backdrop, solid organ transplant patients are a major risk group given the high prevalence of these factors in addition to their chronic immunosuppressive state [1,2]. The mortality rates among kidney transplant patients vary in different reports, but are high, especially in the elderly and in the early post-transplant period [3,4]. A report of the Spanish Registry shows differences in overall mortality between the first (March-June) and second (July-December) wave (27.4% vs 15.1%) but similar rates in critical patients [5].

After initiation of the vaccination rollout in kidney transplant patients, several reports have indicated an impaired anti-SARS-CoV-2 antibody response in the context of maintenance immunosuppression [6]. This situation raised concerns about their

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protection and the susceptibility and severity of the disease after vaccination in these patients.

The aim of this communication is to describe, and provide a first approach to, the profile of the kidney transplant recipient diagnosed with SARS-CoV-2 after vaccination in our unit looking into their evolution, severity of the disease, and differences with respect to unvaccinated patients of the previous COVID-19 waves.

MATERIALS AND METHODS

Study Design and Participants

Retrospective cohort study that included all adult kidney transplant recipients with a functioning allograft who tested positive for SARS-CoV-2 between March 16, 2020 and September 6, 2021. For the purpose of analysis, data was divided into 2 groups: our previous series of 76 patients, infected between March 16, 2020 and February 11, 2021 before the vaccination rollout, and the 16 recipients who tested positive between May 18, 2021 and September 6, 2021 after receiving the vaccine at our center.

Our first goal was to describe and compare the characteristics and evolution of these patients. Because the recipients in the first group completely differ from those in the second group, we treated them as independent measures. Second, in order to know if the proportion of contagions had decreased between waves in our overall population of functioning allografts after vaccination rollout, data was treated as paired.

Data Collection

The information about demographic, clinical, laboratory and comorbidity data was extracted from electronic medical records at our center. SARS-CoV-2 diagnosis was based on the polymerase chain reaction test by means of a nasopharyngeal swab.

Table 1. Demographic and Baseline Characteristics Among Vaccinated and Unvaccinated Recipients Who Tested Positive for SARS-CoV-2

|                        | Unvaccinated (n = 76) | Vaccinated (n = 16) |
|------------------------|-----------------------|---------------------|
| Demographic information|                       |                     |
| Sex, no. (%)           |                       |                     |
| Male                   | 49 (64.47)            | 12 (75)             |
| Female                 | 27 (35.52)            | 4 (25)              |
| Age (mean ± SD, y)     | 57.5 ± 13.9           | 55.4 ± 12.4         |
| Cause of CKD, no. (%)  |                       |                     |
| Glomerular             | 22 (28.95)            | 3 (18.75)           |
| ADPKD                  | 13 (17.10)            | 1 (6.25)            |
| Hypertensive nephropathy| 11 (14.47)            | 1 (6.25)            |
| Interstitial           | 10 (13.16)            | 3 (18.75)           |
| Unknown                | 10 (13.16)            | 5 (31.25)           |
| Other                  | 10 (13.16)            | 3 (18.75)           |
| Comorbidities, no. (%) |                       |                     |
| Hypertension           | 63 (82.89)            | 13 (81.25)          |
| Overweight/obesity     | 36 (47.36)            | 7 (43.75)           |
| Diabetes mellitus      | 29 (38.15)            | 6 (37.50)           |
| Cardiovascular disease | 22 (28.94)            | 2 (12.50)           |
| Post-transplant time to diagnosis, median (IQR 25-75), months | 90 (40.3-162) | 85.5 (37.5-210.8) |

ADPKD, autosomal dominant polycystic kidney disease; CKD, chronic kidney disease; IQR, interquartile range.

RESULTS

Demographic and Clinical Characteristics

Since the outbreak of the pandemic in March 2020 until February 2021, 76 kidney transplant recipients were diagnosed with COVID-19 before the vaccine rollout started (Table 1). Between April and May 2021, the patients at our center received a COVID-19 vaccine. As of May 18, 16 patients developed SARS-CoV-2 infection after vaccination. Thus, a total of 92 patients out of 1,500 functioning allografts (6.13%) at our center were infected since the start of the pandemic. Fig 1 shows the overall COVID-19 case evolution in kidney transplant patients at the transplant unit of La Fe Hospital in Valencia between waves, where a downward trend was observed in the last months.

Among the 16 patients who tested positive for COVID-19 after inoculation, 14 (87.50%) had received Moderna, one (6.25%) Pfizer-BioNTech, and one (6.25%) was inoculated with AstraZeneca/Vaxzevria. Regarding vaccination schedule, 14 patients had completed a 2-dose mRNA series, one received...
both doses of Oxford-AstraZeneca (Vaxzevria), and the remaining recipient had received only one dose of Moderna at the time of infection. This last patient developed SARS-CoV-2 infection 29 days after first dose of inoculation. Those who had completed the vaccine schedule developed infection 39 to 115 days after vaccination (median 67, IQR 53.5-84.5). It is noteworthy that at least 6 of the contagions (37.50%) occurred because of contact with a family member positive for SARS-CoV-2.

For several reasons, we were unable to obtain the results regarding antibodies in all of our functioning allografts (a total of 1500). Thus, only a small percentage of patients infected with SARS-CoV-2 after vaccination had this parameter tested, making it unfeasible to draw any type of correlation and therefore this information was not included. This is the reason why we adopted a conservative attitude regarding the effectiveness of the vaccine, focusing instead on the patient’s profile and possible differences among risk profile between waves.

Out of 16 patients, 75% were men, and the remaining 25% were women between 36 and 75 years of age, with a mean of 55.4. Regarding blood type, 9 (56.25%) were type A, 6 (37.50%) were type O, and one (6.25%) belonged to type AB. The most common cause of chronic kidney disease was non-fililated (n = 5 [31.25%]), followed by glomerular (n = 3 [18.75%]) and interstitial disease (n = 3 [18.75%]) and other causes (n = 5 [31.25%]). Hypertension was the most common comorbidity affecting 13 (81.25%) patients, followed by overweight/obesity (n = 7 [43.75%]), diabetes (n = 6 [37.50%]), and cardiovascular disease (n = 2 [12.50%]). Time to SARS-CoV-2 diagnosis after transplantation ranged from 3 to 330 months (27.5 years) with a median of 85.5 and IQR (37.5-210.8), and most patients (n = 10 [62.50%]) were diagnosed during the first decade after transplantation. Maintenance immunosuppression therapy consisted of a standard guideline, including steroids, tacrolimus, and antimetabolite (mycophenolate mofetil or mycophenolic acid) for most of the patients (n = 15 [93.75%]), and only one received mTOR inhibitor treatment. Table 1 shows baseline characteristics of the patients according to their vaccination status.

Clinical Outcome and Laboratory Results

The most common symptoms were cough (n = 12 [75%]), fever (n = 11 [68.75%]), gastrointestinal symptoms (n = 4 [25%]), asthenia (n = 4 [25%]), dyspnea (n = 3 [18.75%]), anosmia (n = 3 [18.75%]), and odynophagia (n = 3 [18.75%]). None of the other patients remained completely asymptomatic, presenting mild symptoms. Nine patients (56.25%) developed pneumonia and 10 (62.50%) needed hospitalization. Henceforth, data will refer to these 10 recipients.

Time from COVID-19 diagnosis to hospitalization ranged from zero (being diagnosed the same day of admission) to 16 days. The patients’ main symptoms at admission were cough (n = 9 [90%]), fever (n = 7 [70%]), and gastrointestinal symptoms (n = 4 [40%]), followed by asthenia (n = 3 [30%]) and dyspnea (n = 3 [30%]). Three patients needed oxygen support on admission, of which 2 had a blood oxygen saturation level (SpO2) rate ≤ 92%. Hospitalization time ranged from 4 days to 35 days.

Regarding laboratory parameters on admission, creatinine (mg/dL), C-reactive protein (mg/L), lymphocyte (×10³/µL), leucocyte (×10⁹/µL), and D-dimer (ng/mL) were recorded. Thus, creatinine levels for vaccinated patients showed a median of 1.9 mg/dL and IQR (1.6-3.7 mg/dL), and leukocyte presented a median of 6.5 × 10⁹/µL and IQR (5.2-7.7 × 10⁹/µL). Ninety percent of the patients had lymphopenia (<1 × 10⁹/µL), with the median for all patients being 0.7 × 10⁹/µL and IQR (0.5-0.7 × 10⁹/µL). Median and IQR for C-reactive protein and D-dimer

![Fig 1. COVID-19 case evolution.](image-url)
were 67.9 mg/L (35.8-103.4 mg/L) and 600 ng/mL (360-657 ng/mL), respectively. Table 2 shows clinical and laboratory characteristics among vaccinated and unvaccinated recipients who required hospitalization. It is noteworthy that originally, and among nonvaccinated patients, a total of 48 were hospitalized. However, laboratory and clinical information during admission for 2 of them could not be obtained. Therefore, information in Table 2 will refer to the 46 remaining subjects. Significant differences were not found between both groups regarding laboratory results (P value > .05).

Seven patients (70%) experienced acute renal failure, and 4 of whom required hemodialysis. These 4 also met the criteria for admission to the intensive care unit (ICU), followed by a torpid evolution, after which 3 died. None of the patients experienced acute rejection or allograft loss.

### Treatment of COVID-19 and Oxygen Therapy

Treatment changed between the waves with more frequent use of ritonavir/lopinavir, hydroxychloroquine, and azithromycin in the first wave and with more frequent use of remdesivir and steroids in the second wave. Patients with cytokine storm received tocilizumab in the initial stages but not in the next waves. High steroid doses were used as treatment for pneumonia and hyper-inflammatory state mainly in the last wave. Asymptomatic patients did not receive specific drugs against COVID-19 and did not require immunosuppression adjustment. In patients with pneumonia, the reduction of immunosuppressive treatment was made according to the published recommendations of the DESCARTES Group [7].

According to the protocol established, ventilatory support via nasal cannula with reservoir was provided to patients whose SpO2 rate was ≤92%, aiming at a SpO2 rate toward 96%. If this was insufficient, a high flow nasal cannula or Venturi Mask was provided. Noninvasive mechanical ventilation was the next step in order to consider whether respiratory failure continued, unless immediate intubation criteria existed. Thus, 5 patients (50%) needed oxygen support throughout the hospitalization period, 4 of whom required intubation. Table 3 shows detailed clinical information regarding vaccinated patients.

### Vaccinated Kidney Transplant Recipient Profile of Infected Patients

Based on the results of the analysis of our previous series through Lasso selection and multivariate logistic regression in which age, time after transplant, hypertension, overweight/obesity, and the need of supplementary oxygen at admission were shown as risk factors related to hospitalization and poor disease evolution, we studied these factors in the group of infected patients after immunization. No significant differences were found between unvaccinated and vaccinated patients among these variables (P value > .05). Thus, the profile of the infected kidney transplant recipient regarding risk factors remains constant between waves: a patient with a mean age above 55 years, hypertensive, with a similar percentage of overweight and obesity, and with a median post-transplant time of around 90 months. Regarding the need for supplementary oxygen at admission, with SpO2 ≤ 92%, although the percentage has decreased from 28.3% among the nonvaccinated to 20% among the vaccinated, these differences were not significant (P value > .05).

On the other hand, we observed that the risk factors related to a worse disease evolution in our previous series present among the 4 vaccinated recipients who required ICU admission. These patients were elderly, between 59 and 75 years (mean = 65.25) of age, and all were hypertensive and with overweight/obesity. Two (50%) needed oxygen support on admission. Although

### Table 2. Clinical Manifestation and Laboratory Results Among Unvaccinated and Vaccinated Recipients Who Needed Hospitalization Owing to SARS-CoV-2 Infection

|                                      | Hospitalized Without Vaccine (n = 46) | Hospitalized With Vaccine (n = 10) |
|--------------------------------------|-------------------------------------|-----------------------------------|
| **Clinical information**             |                                     |                                   |
| Symptoms on admission, no. (%)       |                                     |                                   |
| Cough                                | 30 (65.21)                          | 9 (90)                            |
| Fever                                | 29 (63.04)                          | 7 (70)                            |
| Dyspnea                              | 15 (32.60)                          | 3 (30)                            |
| Asthenia                             | 13 (28.26)                          | 3 (30)                            |
| Gastrointestinal                     | 9 (19.56)                           | 4 (40)                            |
| Need of oxygen support on admission, no. (%) | 19 (41.30)                          | 3 (30)                            |
| SpO2 ≤ 92%, no. (%)                 | 13 (28.26)                          | 2 (20)                            |
| **Laboratory results, median (IQR 25-75)** |                                     |                                   |
| Creatinine (mg/dL)                   | 1.6 (1.2-2.5)                       | 1.9 (1.6-3.7)                     |
| Lymphocyte (*10^3/μL)                | 0.8 (0.5-1.2)                       | 0.7 (0.5-0.7)                     |
| Leucocyte (*10^3/μL)                 | 5.9 (4.5-7)                         | 6.5 (5.2-7.7)                     |
| C-reactive protein (mg/L)            | 55.5 (19.4-91.1)                    | 67.9 (35.8-103.4)                 |
| D-dimer (ng/mL)                      | 600 (383-838.2)                     | 600 (360-657)                     |

IQR, interquartile range.
Table 3. Detailed Clinical Information Regarding Vaccinated Patients

| Patient | Vaccine   | Symptoms                                      | Immunosuppression Adjustment | COVID-19 Treatment                                      | Oxygen Therapy | RRT | Outcome      |
|---------|-----------|-----------------------------------------------|------------------------------|---------------------------------------------------------|----------------|-----|--------------|
| 1       | Moderna   | Cough, asthenia, pneumonia                    | Not modified                 | Ceftriaxone                                             | No             | No  | Cured        |
| 2       | Moderna   | Cough, fever, dyspnea, odynophagia, gastrointestinal, pneumonia | Completely withdrawn | Ceftriaxone, steroids, tocilizumab, azithromycin | Yes            | Yes | ICU-Exitus   |
| 3       | Moderna   | Cough, fever, dyspnea, gastrointestinal, pneumonia | Completely withdrawn | Ceftriaxone, steroids, azithromycin, remdesivir         | Yes            | Yes | ICU-Exitus   |
| 4       | Moderna   | Cough, fever, odynophagia                     | Not modified                 | No                                                       | No             | No  | Cured        |
| 5       | Moderna   | Cough, fever, gastrointestinal, pneumonia     | Antimetabolite discontinued Tacrolimus reduced | No                                                        | No             | No  | Cured        |
| 6       | Moderna   | Cough, fever, dyspnea, odynophagia, anosmia, pneumonia | Antimetabolite discontinued Tacrolimus reduced | Ceftriaxone, steroids, azithromycin                    | No             | No  | Cured        |
| 7       | Moderna   | Cough                                          | Not modified                 | No                                                       | No             | No  | Cured        |
| 8       | Vaxzevria | Cough, asthenia, gastrointestinal, pneumonia | Antimetabolite discontinued Tacrolimus reduced | Ceftriaxone, steroids                                   | No             | No  | Cured        |
| 9       | Moderna   | Cough, fever, anosmia                         | Not modified                 | No                                                       | No             | No  | Cured        |
| 10      | Moderna   | Asthenia                                      | Not modified                 | No                                                       | No             | No  | Cured        |
| 11      | Moderna   | Cough, fever, anosmia                         | Not modified                 | Piperacillin/tazobactam                                 | No             | No  | Cured        |
| 12      | Pfizer    | Cough, fever, asthenia, pneumonia             | Completely withdrawn         | Steroids, tocilizumab                                   | Yes            | Yes | ICU-Cured    |
| 13      | Moderna   | Cough, pneumonia                              | Antimetabolite discontinued  | Ceftriaxone, steroids, azithromycin                     | Yes            | No  | Cured        |
| 14      | Moderna   | Fever                                         | Not modified                 | No                                                       | No             | No  | Cured        |
| 15      | Moderna   | Fever                                         | Not modified                 | No                                                       | No             | No  | Cured        |
| 16      | Moderna   | Fever, pneumonia                              | Completely withdrawn         | Steroids                                                | Yes            | Yes | ICU-Exitus   |

ICU, intensive care unit; RRT, renal replacement therapy.
diabetes did not reach significance as a risk factor for severe disease in our previous series, we observed that 3 out of 4 patients (75%) admitted to the ICU and who died were diabetic.

From our current series of 16 vaccinated and infected patients, 10 required hospital admission (62.5%) and 3 of them died of COVID-19 complications. Differences between the hospitalization rate and severity of evolution between both groups of patients could not be found ($P$ value $> .05$). However, the proportion of contagions among our 1500 kidney transplant recipients decreased significantly from 5% during the first waves to 1% after vaccination rollout ($P$ value $< .05$).

Thus, the profile of the infected patient remains similar between series. We observed that all the significant risk factors regarding hospitalization and poor disease evolution in our previous series were found among the 4 patients who required ICU admission after vaccination rollout.

**DISCUSSION**

This is a retrospective cohort study that reflects the experience of a single center faced with the impact of COVID-19 infection in their kidney transplant vaccinated patients.

When we analyze the evolution of COVID-19 affected patients in the prevaccination periods, the need for hospitalization was 63.5% of all affected patients in our series. The mortality rate was 14.5%, a lower percentage with respect to other published series which is above 25% [8,9]. Only 12 diagnosed patients (15.8%) remained asymptomatic. In the overall series, symptoms like fever, cough and dyspnea are the most common at presentation, and hospital admission percentages are similar in previous reports [9,10].

Among unvaccinated COVID-19 positive patients, old age and hypertension are the main risk factors for hospitalization, and the probability of being hospitalized decreases with time after transplantation. It should be highlighted that 67.1% of our patients were diagnosed after the first post-transplant decade. Advanced age and COVID-19 infection in the first months were associated with severe disease and high mortality in previous series [2,11]. We also analyzed in our hospitalized patients which factors at admission could be related to a worse evolution and severe pneumonia. Among all of them, only SpO2 $\leq 92\%$ on admission (OR 8.954, $P$ value $= 0.026$) and overweight/obesity (OR 13.453, $P$ value $= 0.001$) were predictors of a worse evolution. These observations are similar to the published results from a registry series [5,12].

After having received the COVID-19 vaccine, 16 patients developed infection. When we analyze the disease evolution in this group of patients and we compare it with the previous non-immunized infected patients, no significant differences were seen in patient risk profile and disease evolution. It should be noted that among the patients who died, an elevated prevalence of diabetes was the case, which underlines the fact that diabetes plays an important role as a risk factor of severe disease, as described in previous reports [13].

Our results are similar to other published reports that analyze COVID-19 infection after vaccination [14,15], whereas in other series a lower rate for hospital and ICU admission [16] in immunized patients was found. Probably all the reports reflect the impaired capacity of achieving an adequate protective immune response in transplant patients. Therefore, it is essential to keep strict protective measures in this population, and at the same time the convenience of a third vaccine dose has to be emphasized to enhance immunization in this vulnerable group of patients.

This retrospective cohort study has some limitations. This is a preliminary study of a single center series with a small sample size. But on the other hand, our own control series group provides the advantage of a follow-up and homogeneous treatment criteria, which can be considered a study strength. Thus, our findings, far from offering definitive conclusions, probably reflect the low immunization rate in this group of patients, especially those with a higher risk, and reinforce the need to improve it. Larger studies are needed to shed more light on this matter.

**DATA AVAILABILITY**

The data that has been used is confidential.

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