

Multicenter Study to Evaluate the Frequency of Adverse Reactions associated with Vaccination Against SARS-CoV-2 in Patients with Podocytopathies

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Aim of the study

To evaluate:

- The frequency of adverse events (AE) from SARS-CoV-2 vaccination in patients with podocytopathy
- The most common AE in this group
- The incidence of relapse after vaccination
- The difference in relapse rate by histopathological diagnosis

Methods I

Multicentre, retrospective study

Inclusion criteria:

- 1. Biopsy-proven MCD/FSGS
- 2. >1 vaccine dose against SARS-CoV-2

and/or

3. SARS-CoV-2 infection

Exclusion criteria

- ESKD prior to vaccination/infection
- Patients with first podocytopathy diagnosis after vaccination

Methods II

Records:

- Demographics
- Histopathological diagnosis
- Immunosuppressive Regiments
 - Induction therapy
 - Maintenance therapy
- Outcome of podocytopathy
- Vaccination type, number of doses and timing
- Adverse Events of vaccination
- Potential effect on the clinical course of podocytopathy

Podocytopathies: definitions

<u>Complete remission:</u> reduction of proteinuria to <300 mg/d, stable value of cr_s and Alb_s >3.5 g/dL

<u>Partial remission</u>: decrease of proteinuria >50%, with values between 300 mg and 3.5 g/d

<u>Relapse</u>: proteinuria >3.5 g/d after complete remission has been achieved

Cohort characteristics I

Parameter	N =77 patients
Age at diagnosis, years (SD)	46.1 (17.8)
Gender, male	38 (49.3%)
Time from diagnosis, months (SD)	91.2 (81.7)
Histological diagnosis	
FSGS	41 (53,2%)
MCD	36 (46,7%)
Induction therapy	68 (88,3%)
Glucocorticoids	47 (69,1%)
Calcineurin Inhibitors and glucocorticoids	14 (20,6%)
Other (CYC, RTX, MMF)	7 (10,3%)
1 st Outcome of podocytopathy	
Complete remission	62 (80,5%)
Relapse	10 (12,9%)

Cohort characteristics II

Parameter	N = 77 patients
Vaccination against SARS-CoV-2	67 (87%)
COVID-19	56 (72%)
Number of doses received, mean (SD)	2.9 (0,76)
Time from diagnosis to vaccination, months (SD)	69.2 (75.8)
Immunosuppressive therapy at vaccination	25 (37.3%)
Glucocorticoids	9 (36%)
Calcineurin Inhibitors	9 (36%)
Calcineurin Inhibitors+ Glucocorticoids	4 (16%)
Other	4 (16%)

Results – Post vaccination adverse events

Adverse events	N = 67
Systematic - Headache - Myalgias - Fever - Other (Arthralgias, Fatigue, Lymphadenopathy)	17 (25.3%) 9 (13.4%) 9 (13.4%) 5 (7.4%) 7 (10.2)
Local (Pain, pruritus, other)	21 (31.3%)
Disease relapse after vaccination - MCD - Time to relapse from 1 st dose, months (SD)	7 (10.4%)* 5 (71.4%)** 3.5 (2.7)

* Odds ratio: 1.02 (0.05, 21.36)

** Odds ratio: 4.5 (0.8, 25.3)

Statistically **non**-significant!

Conclusions

- Vaccines against SARS-CoV-2 has a good safety profile
- 7 (10.4%) patients who had archived remission experienced relapse of nephrotic syndrome with a median time of 3,5 months since first dose of vaccination
 - ☐ 5 of relapsers had MCD
- Disease relapse after vaccination was not statistically significant in the cohort