FREQUENCY OF ADVERSE EVENTS ASSOCIATED WITH THE SARS-COV2 VACCINATION AMONG PATIENTS WITH GLOMERULAR DISEASES

SOPHIA LIONAKI[1], PELAGIA KRIKI[2], SMARAGDI MARINAKI[3], DIMITRA GALITSIOU[4], EVAGGELIA DOUNOUSI[5], SOPHIA FLOUDA[6], IOANNIS BELLOS[3], VASILEIOS LIAKOPOULOS[7], VASILEIOS VAIOS[7], AGGELIKI SARDELI[1], ZOI KLEINAKI[3], DIMITRA PETROU[1], PETROS KALOGEROPOULOS[1], LOUIZA GKIKA-ZERVOU[5], MARIOS PAPASOTIRIOU[8], DIMITRIOS GOUMENOS[8], ALIKI VENETSANOPOULOU[9], PARASKEVI VOULGARI[9], EIRINI GRAPSA[10], KONSTANTINOS STYLIANOU[11], STYLIANOS PANAGOUTSOS[2], IOANNIS N. BOLETIS[3]

1 Department of Nephrology, 2nd Propaedeutic Internal Medicine, Attikon University Hospital, National and Kapodistrian University of Athens, Greece
2 Department of Nephrology, University of Thrace, Alexandroupolis
3 Nephrology and Transplantation clinic, Laiko Hospital, National and Kapodistrian University of Athens, Greece
4 Department of Nephrology, Gennimatas Hospital
5 Department of Nephrology, University of Ioannina
6 Rheumatology and clinical immunology Unit, Attikon University Hospital, National and Kapodistrian University of Athens, Greece
7 Division of Nephrology and Hypertension, 1st Department of Internal Medicine, AHEPA Hospital, Aristotle University of Thessaloniki, Thessaloniki, Greece.
8 Department of Nephrology and Renal Transplantation, Patras University Hospital, Patras, Greece.
9 Rheumatology Department, University of Ioannina, Ioannina, Greece.
10 Department of Nephrology, Aretaieio Hospital, National and Kapodistrian University of Athens, Athens, Greece.
11 Department of Nephrology, University Hospital of Heraklion, Heraklion, Greece.

SARS-CoV-2 vaccination

ADVERSE EVENTS (AE)

LOCAL

- Pain
- Swelling
- Tenderness
- Itching
- Skin Rash
- Allergic Reaction

SYSTEMIC

- Headache
- Myalgias
- Arthralgias
- Fever
- Chills
- Fatigue
- Diarrhea
- Nausea
- Lymphadenopathy

Aim of the study

- Evaluate the frequency of AE from the SARS-CoV-2 vaccination in patients with diagnosed glomerular disease (GD)
- Evaluate the most common AE in this group
- A possible effect of vaccination on kidney function of these patients
- Incidence of a GD relapse after vaccination
- The difference in relapse rate by histopathological diagnosis

Methods

Retrospective Study

Inclusive criteria:

- History of GN diagnosis
- Histologically confirmed GN
- At least one dose of SARS-CoV-2 vaccination

Exclusive criteria:

- Patients with first GN diagnosis after vaccination
- Patiens in ESKD before vaccination

GLOMERULAR DISEASES: DEFINITIONS

ANCA-GN

Complete remission: no evidence of active disease – negative urine sendiment – no more need for dialysis

Partial remission: consistent hematuria despite improved renal function (cr_s)

Relapse: proof of activity in any system

Lupus-GN

Remission: proteinuria <0.5g/24h, stabilization of cr_s and improved haematuria

Relapse: Reapperance of hematuria, with or without red blood cells casts, wbc in urine sediment without evidence of infection, increased proteinuria, with or without impaired renal function (increase of serum creatinine)

Minimal Change Disease (MCD)

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

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

Relapse: proteinuria > 3.5 g/d

Membranous nephropathy (MN)

Complete remission : proteinuria <300mg/d and Alb_s ≥3.5 g/dL

Partial remission: decrease of proteinuria ≥50 % and proteinuria between 0.3 and 3.5 g/d

Relapse: proteinuria > 3.5 g/d

Focal segmental glomerulosclerosis (FSGS)

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

Partial remission: decrease of proteinuria>50 %, with values between 300 mg and 3.5 g/d, with or without improvement in Alb_s

Relapse: proteinuria > 3.5 g/d in patients with complete remission, or an increased proteinuria >50% in patients with partial remission

IgA nephropathy

Remission proteinuria <1g/24h, no hematuria

Relapse: proteinuria >1g/24h, eGFR impairment

Methods

Retrospective, multicenter study

- Demographics
- Histopathological diagnosis
- Immunosuppressive Regiments
  - Induction therapy
  - Maintenance therapy
- Outcomes (of GN)
- Vaccination type, number of doses and timing
- Adverse Events of vaccination

  (local or systemic)

- Potential effect on the clinical course of GN
- Laboratory tests before and after vaccination
- Kidney function before and after vaccination

Vaccinated patients' characteristics

Parameter	Number of patients (N=315)
Age at diagnosis	51 [36-63]
Male sex	142 (45.1%)
Histological diagnosis	
ANCA-GN	66 (20.9%)
Lupus-GN	69 (21.9%)
IgA nephropathy	41 (13.0%)
Minimal Change Disease (MCD)	29 (9.2%)
Membranous nephropathy (MN)	63 (0.2%)
Fibrillary GN	1 (0.3%)
C3 GN	1 (0.3%)
Focal segmental glomerulosclerosis (FSGS)	38 (12.1%)
IgA vasculitis	3 (0.9%)
Other	4 (1.3%)

Vaccinated patients' characteristics

Immunosupression	Number of patients (N=315)
Induction therapy	
Cyclophosphamide	121 (38.4%)
Corticosteroids	256 (81.3%)
Mycophenolate mofetil	17 (5.4%)
Calcineurin inhibitor	43 (13.7%)
Rituximab	23 (7.3%)
Maintenance therapy	
Cyclophosphamide	9 (2.9%)
Corticosteroids	49 (15.65)
Mycophenolate mofetil	68 (21.6%)
Azathioprine	36 (11.4%)
Rituximab	24 (7.6%)
First outcome	301
Remission	267 (88.7%)
Treatment resistant	34 (11.3%)

Vaccination type	Number (N=315)
BNT162b2 (Pfizer)	303 (96.2%)
mRNA-1273 (Moderna)	9 (2.9%)
Janssen (Johnson & Johnson)	1 (0.3%)
ChAdOx1 nCoV-19 (Astra-Zeneca)	2 (0.6%)
Number of vaccine doses	3 [3-4]
Time from GN diagnosis to 1st vaccine dose (months)	48.9 [19.8-106.2]

Vaccination AE - Systemic

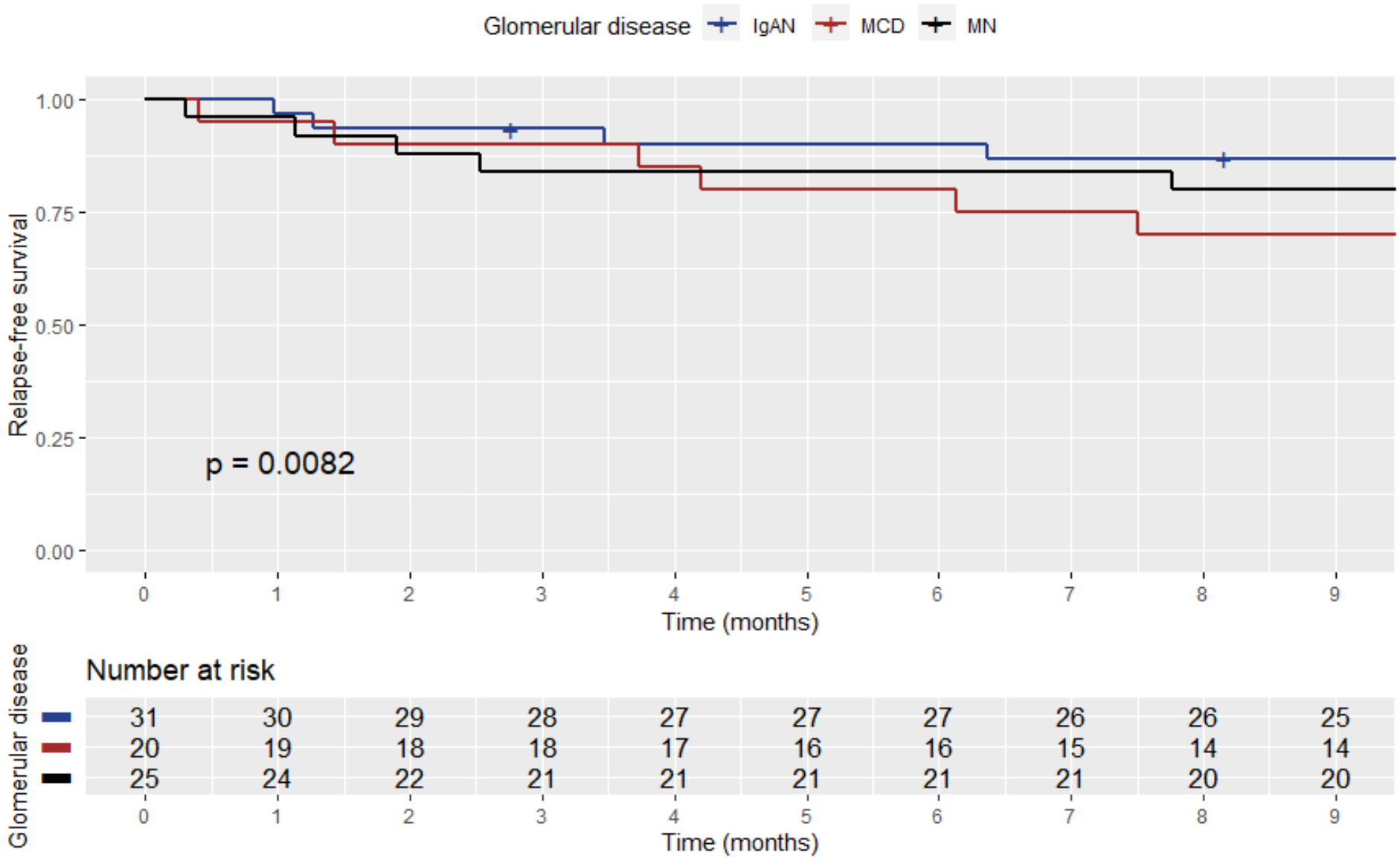
Systemic AE, N=315	N=66 (21.0%)
Headache	33 (10.5%)
Myalgias	43 (13.7%)
Arthralgias	17 (5.4%)
Fever	24 (9.5%)
Chills	9 (3.5%)
Fatigue	26 (8.3%)
Diarrhea	1 (0.3%)
Nausea	1 (0.3%)
Lymphadenopathy	5 (2.0%)
AE from kidney	3 (1,0%)
Acute renal injury	2 (0,6%)

Vaccination AE - local

Local AE	N=122 (38.7%)
Pain	41 (13.0%)
Itching	4 (1.3%)
Allergic reaction	1 (0.3%)
Rash	2 (0.6%)

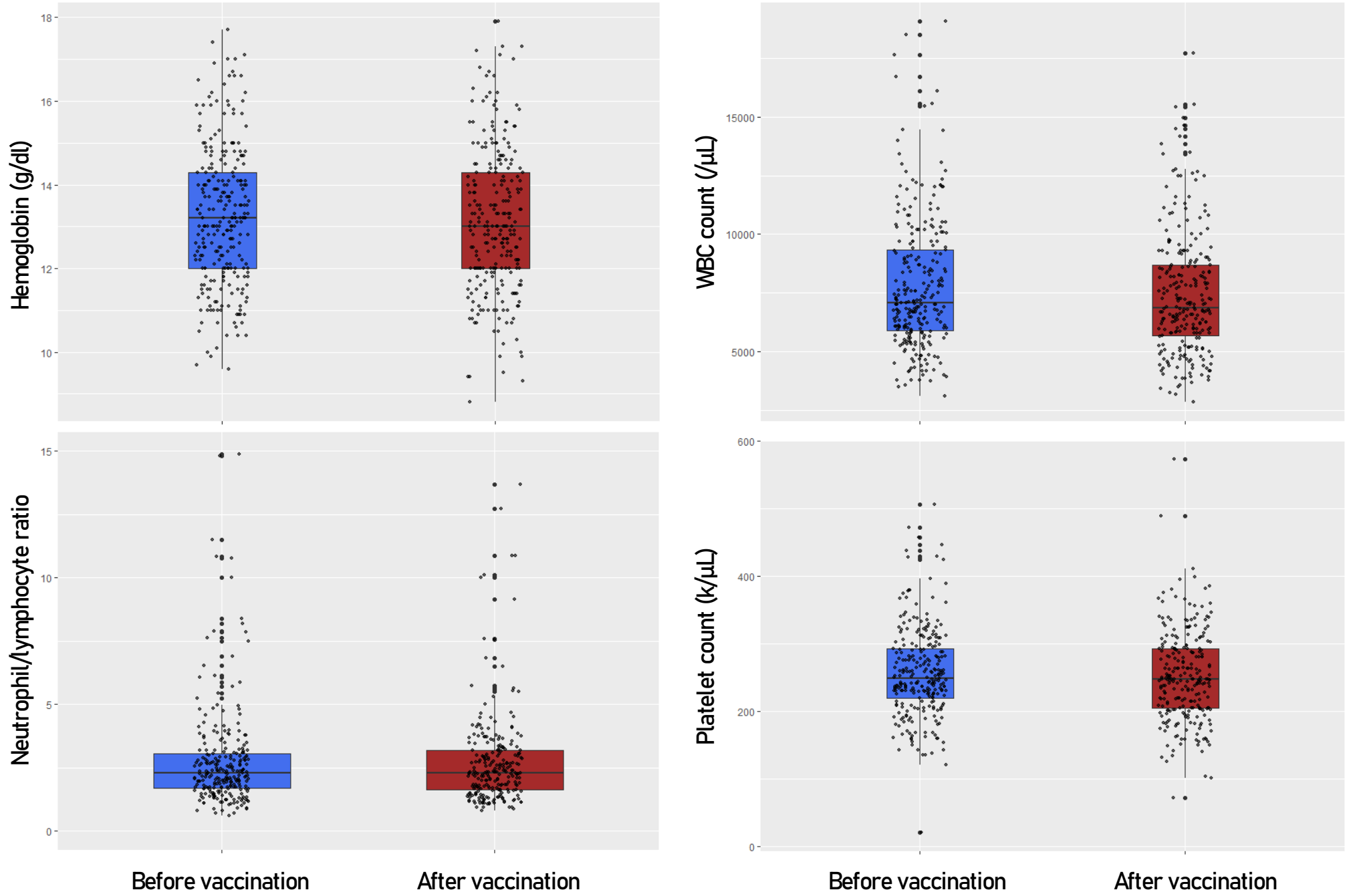
GN relapse after vaccination

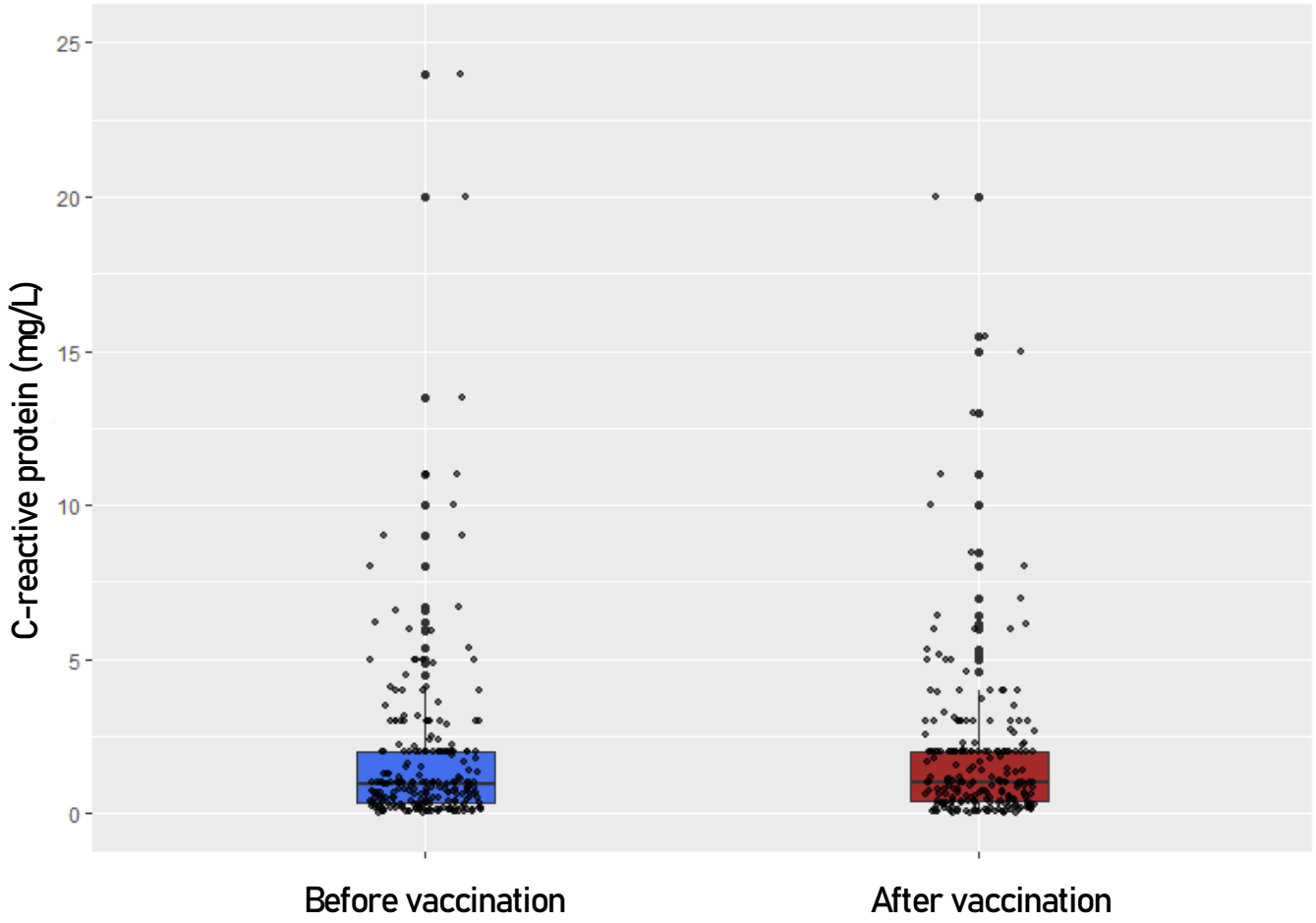
Parameter	Vaccinated (N=255)
GN at vaccination	
Remission	224 (87.8%)
Relapse GN after vaccination	23 (9.0%)
Histological diagnosis	
ANCA-GN	2 (8.7%)
IgA nephropathy	7 (30.4%)
Minimal Change Disease (MCD)	6 (26.1%)
Membranous nephropathy (MN)	5 (21.7%)
Lupus-GN	1 (4.3%)
Focal segmental glomerulosclerosis (FSGS)	2 (8.7%)
Time from vaccination to relapse (months)	2.5 [1.2-6.4]
Follow up time (months)	18.2 (15.5-20.1)


Glomerular disease
IgAN
MCD
MN
1.00
0.75
0.50
0.25
0.00
Relapse-free survival
p = 0.0082
0
1
2
3
4
5
6
7
8
9
Time (months)
Number at risk
Glomerular disease
31 30 29 28 27 27 27 26 26 25
20 19 18 18 17 16 16 15 14 14
25 24 22 21 21 21 21 21 20 20
0
1
2
3
4
5
6
7
8
9
Time (months)

Laboratory tests before and after vaccination

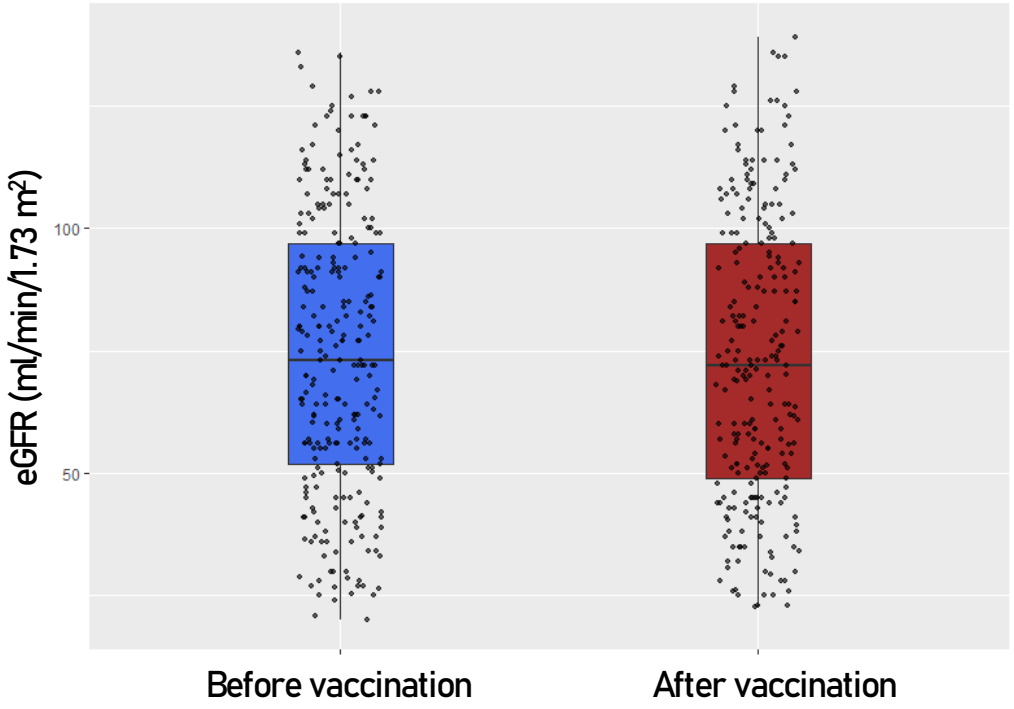
Parameter	Before vaccination	After vaccination	P-value
Hemoglobin (g/dl)	13.2±1.6	13.1±1.7	0.426
WBC count (/μL)	7100 [5908-9338]	6870 [5680-8700]	0.162
Neutrophil count (/μL)	4300 [3358-6100]	4144 [3188-5849]	0.168
Lymphocyte count (/μL)	2000 [1540-2520]	1886 [1411-2371]	0.094
Neutrophil-to-lymphocyte ratio	2.29 [1.69-3.08]	2.32 [1.65-3.20]	0.941
Serum lactate dehydrogenase (U/L)	211.9±56.5	216.8±70.0	0.451
C-reactive protein (mg/L)	0.98 [0.36-2.00]	1.00 [0.40-2.00]	0.368

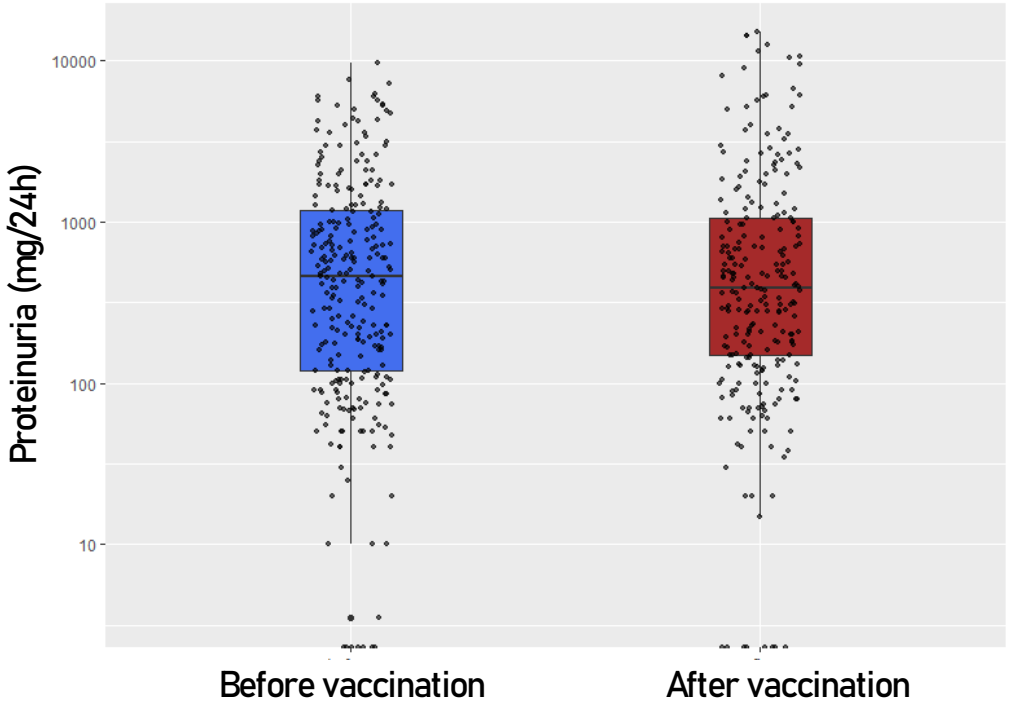

Hemoglobin (g/dl)
18
16
14
12
10
WBC count (/μL)
15000
10000
5000
Neutrophil/lymphocyte ratio
15
10
5
0
Platelet count (k/μL)
600
400
200
0
Before vaccination
After vaccination
Before vaccination
After vaccination


C-reactive protein (mg/L)
25
20
15
10
5
0
Before vaccination
After vaccination

Kidney function before and after vaccination

Parameter	Before vaccination	After vaccination	P-value
Serum creatinine (mg/dl)	1.06 [0.80-1.50]	1.09 [0.80-1.47]	0.812
eGFR (ml/min/1.73 m^2)	72.9±29.7	71.5±30.4	0.595
24h urinary protein excretion (mg)	432.5 [110-1154]	372 [132-1038]	0.883
Max urine RBC per high power field	2 [1-4]	2 [1-3]	0.077


eGFR (ml/min/1.73 m²)
100
50
Before vaccination
After vaccination


Proteinuria (mg/24h)
10000
1000
100
10
Before vaccination
After vaccination

Conclusions

- AE of SARS-CoV-2 vaccination in patients with GN were mostly local and didn’t differ from those of the general population
- Possibility of relapse after vaccination was 9%, with a median time of relapse 2,5 months
- No alteration in laboratory tests before and after vaccination
- No change in kidney function before and after vaccination

Thank you

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