ID POSTER 1251

Intravenous cyclophosphamide versus mycophenolate mofetil for induction therapy in incident lupus nephritis: **Data from a multi-ethnic, multinational Latin American cohort (GLADEL 2.0)**

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PANLAR 2026 28 CONGRESO PANAMERICANO DE REUMATOLOGÍA PAN-AMERICAN CONGRESS OF RHEUMATOLOGY CONGRESSO PANAMERICANO DE REUMATOLOGIA

*Victor Pimentel-Quiroz**, *Guillermina B. Harvey, Marina Scolnik, Carmen Funes Soaje, Carla Andrea Gobbi, Verónica Saurit, Valeria Arturi, Leonel Berbotto, Rosana Quintana, Luciana Gonzalez Lucero, Eduardo Mario Kerzberg, Nicolás Perez, Cecilia Nora Pisoni, Vicente Juárez, Joaquín Martinez Serventi, Ana Carolina O. S. Montandon, Andrese Aline Gasparin, Henrique Ataide Mariz, Evandro Mendes Klumb, Eduardo F. Borba, Eloisa Bonfa, Edgard Torres dos Reis-Neto, Iris Guerra Herrera, Milena Mimica, Gustavo Aroca Martínez, Antonio iglesias Gamarra, Carlos Alberto Cañas, Gerardo Quintana-Lopez, Carlos Enrique Toro Gutiérrez, Mario Javier Moreno Alvarez, Reyna Elizabeth Sánchez-Briones, Margarita Portela Hernández, Fragoso-Loyo Hilda, Luis M. Amezcua-Guerra, YelitzaC.González-Bello, Jorge A. Esquivel Valerio, Isabel Acosta Colman, Jhonatan Losanto, Claudia Mora-Trujillo, Manuel F. Ugarte-Gil, Armando Calvo Quiroz, Roberto Muñoz Louis, Martín Rebella, Álvaro Danza, Federico Zazzetti, Ashley Orillion, Bernardo A. Pons-Estel, Luis Catoggio.*

**Presenting author*

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BACKGROUND

Lupus nephritis (LN) is one of the most severe complications of patients with systemic lupus erythematosus. As induction treatment, cyclophosphamide (CYC) or mycophenolate mofetil (MMF) are used; however, comparative outcome data in Latin American populations remain limited.

METHODS

Patients from the *Grupo Latin oAmericano De Estudio de Lupus* (GLADEL) cohort 2.0 with incident LN were evaluated. LN diagnosis was based on kidney biopsy and/or 24-hour proteinuria (24-HP) or urine protein-creatinine ratio (UPCR)>0.5g. All patients included had to have data on 24-HP/UPCR, serum creatinine level and estimated glomerular filtration rate (eGFR) at baseline, 6th and 12th month. Complete renal response (CRR) was defined as 24-HP or UPCR≤0.7g combined with eGFR≥ 60ml/min/1.73m^2 or absence of a confirmed eGFR decrease greater than 20% from baseline, whereas partial renal response (PRR) was defined as ≥50% reduction of 24-HP or UPCR. Both CRR and PRR were evaluated at 6th and 12th month from baseline. Sociodemographic features (sex, age, ethnicity, socioeconomic status, educational level), tobacco use, cumulative dose of glucocorticoid (GC), antimalarial use, antiproteinuric drugs use, disease activity, and type of induction treatment (CYC or MMF) were recorded. Univariable (UV) and multivariable (MV) logistic regression models were used to evaluate the association between induction therapy (MMF or CYC) and CRR, adjusting for relevant baseline confounders.

RESULTS

Seventy-six patients were included. Female sex and Mestizo ethnicity were more frequent [66 (86.8%) and 55 (72.4%), respectively]. At 6th month, 44 (57.9%) and 8 (10.5%) patients achieved CRR and PRR, respectively, whereas at 12th month, 39 (56.5%) and 5 (7.3%) achieved CRR and PRR, respectively (Table 1). In both UV and MV analyses, no baseline variables were significantly associated with CRR at 6th and 12th month (Table 2). Although not statistically significant, a numerically higher proportion of CYC users achieved CRR compared with MMF users in both time points [6th month: 25 (56.8%) vs 19 (43.2%), p=0.660; 12th month: 30 (61.2%) vs19 (38.8%), p=0.613] (Table 1). At 12th month, there was only one death in CYC group and there was no difference in infections and serious infections rates between CYC and MMF users (data not shown).

TABLE 1.
Sociodemographic features of incident LN patients at baseline and according to renal response on the 6th and 12th month.

VARIABLES[a]	ALL PATIENTS (N=76)	CRR (N=44)	PRR (N=8)	NO RESPONSE (N=24)	p[b]
Sex					0.471
Female	66 (86.8)	38 (86.4)	6 (75.0)	22 (91.7)	
Male	10 (13.2)	6 (13.6)	2 (25.0)	2 (8.3)	
Age at diagnosis (years)[c]	26.0 (20.8-32.2)	27.0 (22.0-35.2)	30.5 (26.5-35.0)	21.5 (19.0-27.5)	**0.031**
Ethnicity					**0.014**
White	18 (23.7)	12 (27.3)	0	0	
Mestizo	55 (72.4)	32 (72.7)	4 (50)	19 (79.2)	
ALA	3 (3.9)	0	0	3 (12.5)	
Socio-economic status					0.336
High/Middle-high	13 (17.6)	7 (16.7)	2 (25.0)	4 (16.7)	
Middle	26 (35.1)	18 (42.9)	3 (37.5)	5 (20.8)	0.429
Middle-low/Low	35 (47.3)	17 (40.5)	3 (37.5)	15 (62.5)	
Educational level (years)[c]	13.0 (11.0-15.0)	13.0 (11.0-16.0)	14.5 (13.2-15.5)	12.0 (11.5-14.5)	**0.001**
Tabacco use					0.229
Never	64 (91.4)	38 (92.7)	4 (80.0)	22 (91.7)	
Past	3 (4.3)	1 (2.4)	0	2 (8.3)	
Current	3 (4.3)	2 (4.9)	1 (20.0)	0	
LN Class					0.427
I	1 (1.4)	0	1 (12.5)	0	
Proliferative + membranous	42 (58.3)	23 (56.1)	3 (37.5)	16 (69.6)	
V	7 (9.7)	4 (9.8)	1 (12.5)	2 (8.7)	
II	3 (4.2)	2 (4.9)	0	1 (4.3)	
III	19 (26.4)	12 (29.3)	3 (37.5)	4 (17.4)	
Proteinuria (g)[c]	2.4 (1.2-4.5)	2.2 (0.9-4.4)	6.4 (4.1-7.9)	1.9 (1.5-3.2)	**0.008**
Nephrotic proteinuria	28 (36.8)	16 (36.4)	6 (75.0)	6 (25.0)	
Creatinine level (mg/dl)[c]	0.8 (0.7-1.1)	0.8 (0.7-1.1)	0.7 (0.5-0.8)	0.8 (0.7-1.1)	0.235
Severe disease[d]	14 (19.2)	4 (9.8)	1 (12.5)	9 (37.5)	**0.022**
6TH MONTH					
Proteinuria (g)[c]	0.6 (0.3-2.1)	0.3 (0.2-0.5)	1.2 (0.9-2.2)	2.6 (1.2-3.2)	**0.001**
Creatinine level (mg/dl)[c]	0.7 (0.6-0.9)	0.7 (0.6-0.9)	0.7 (0.6-0.7)	0.8 (0.6-1.1)	0.189
Cumulative dose of GC (mg/d)[c]	2710.0 (1800.0-4537.5)	3007.5 (1800.0-4537.5)	2325.0 (1700.0-3076.2)	2710.0 (1980.0-5062.5)	0.723
Antimalarial use	24 (31.6)	17 (38.6)	3 (37.5)	4 (16.7)	0.178
Antiproteinuric drug use	52 (86.7)	30 (83.3)	5 (83.3)	17 (94.4)	0.515
Induction treatment					0.660
Cyclophosphamide	45 (59.2)	25 (56.8)	4 (50.0)	16 (66.7)	
Mycophenolate mofetil	31 (40.8)	19 (43.2)	4 (50.0)	8 (33.3)	
12TH MONTH					
Proteinuria (g)[c]	0.5 (0.3-1.2)	0.4 (0.2-0.7)	3.0 (2.5-5.6)	1.7 (0.7-3.5)	0.001
Creatinine level (mg/dl)[c]	0.8 (0.6-0.9)	0.8 (0.5-0.9)	0.8 (0.7-0.8)	0.7 (0.6-1.0)	0.969
Cumulative dose of GC (mg/d)[c]	2700.0 (1365.0-4150.0)	3075.0 (1620.0-4500.0)	3035.0 (2400.0-3795.0)	2325.0 (400.0-2669.0)	0.147
Antimalarial use	24 (34.8)	16 (32.7)	2 (40.0)	6 (40.0)	0.840
Antiproteinuric drug use	41 (87.2)	29 (87.9)	4 (100.0)	8 (80.0)	0.779
Induction treatment					0.613
Cyclophosphamide	40 (58.0)	30 (61.2)	2 (40.0)	8 (53.3)	
Mycophenolate mofetil	29 (42.0)	19 (38.8)	3 (60.0)	7 (46.7)	

***HDL-c**=high-density lipopraaaaa*
***CRR**: Complete renal response. **PRR**: Partial renal response. **ALA**: African Latin American. **LN**: Lupus nephritis. **GC**: glucocorticoids.*
[a] *All data are shown in numbers and percentages, except where otherwise indicated.*
[b] *Chi-Square test, Fisher's exact test and Wilcoxon test as appropriate.*
[c] *Values are median and interquartile range (IQR).*
[d] *Severe disease was defined by the Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) > 12.*

TABLE 2.
Univariable and multivariable analyses of achieving CRR on the 6th and 12th months.

VARIABLE	UNIVARIABLE ANALYSIS OR (95% CI)	p	MULTIVARIABLE ANALYSIS OR (95% CI)	p
6TH MONTH				
Sex				
Female	Ref		Ref	
Male	1.01 (0.26, 3.96)	0.985	0.70 (0.16, 3.13)	0.641
Age at diagnosis	1.03 (0.98, 1.08)	0.302	1.03 (0.97, 1.08)	0.337
Ethnicity				
White	Ref		Ref	
Mestizo	0.70 (0.23, 2.13)	0.524	1.06 (0.29, 3.88)	0.925
Educational level	1.06 (0.93, 1.20)	0.370	1.05 (0.91, 1.21)	0.508
Proteinuria	0.89 (0.74, 1.07)	0.215	0.91 (0.74, 1.11)	0.354
Antimalarial use	1.98 (0.70, 5.63)	0.200	1.89 (0.57, 6.23)	0.294
Severe disease[a]	0.34 (0.09, 1.29)	0.114	0.44 (0.09, 2.03)	0.290
Induction treament				
Cyclophosphamide	Ref		Ref	
Mycophenolate mofetil	1.69 (0.63, 4.53)	0.298	1.9 (0.67, 5.38)	0.226
12TH MONTH				
Sex				
Female	Ref		Ref	
Male	0.38 (0.08, 1.92)	0.243	0.38 (0.06, 2.31)	0.294
Age at diagnosis	1.01 (0.96, 1.06)	0.716	1.00 (0.94, 1.05)	0.946
Ethnicity				
White	Ref		Ref	
Mestizo	0.24 (0.05, 1.19)	0.08	0.31 (0.05, 1.73)	0.18
African Latin American	0.13 (0.01, 1.45)	0.096	0.22 (0.02, 3.18)	0.266
Educational level	0.98 (0.86, 1.13)	0.799	0.98 (0.84, 1.15)	0.832
Proteinuria	0.81 (0.66, 0.99)	0.038	0.83 (0.66, 1.05)	0.117
Antimalarial use	0.73 (0.25, 2.13)	0.562	0.72 (0.19, 2.83)	0.643
Severe disease[a]	0.35 (0.08, 1.64)	0.183	0.20 (0.03, 1.65)	0.136
Induction treament				
Cyclophosphamide	Ref		Ref	
Mycophenolate mofetil	0.63 (0.22, 1.81)	0.393	0.77 (0.21, 2.79)	0.692

***OR**: Odds ratio.*
[a] *Severe disease was defined by the Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) > 12.*

CONCLUSIONS

Contrary to reports from other populations indicating superior efficacy of MMF, this study found no evidence of MMF superiority over CYC as induction therapy in achieving CRR among patients with incident LN in this multi-ethnic Latin American cohort. Although a numerically higher response was observed with CYC, these findings should be interpreted cautiously given the sample size.