Sesión bibliográfica

Glucococorticoides

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Daniel Martín Iglesias

Clinical science

Methylprednisolone plus MTX-based regime vs prednisone-based standard of care for GCA: a propensity score study

Adriana Soto-Peleteiro [1,†], José Hernández-Rodríguez [2,†], Fátima Raad [2], Borja de Miguel [3], Leonor Acha [1], Marina Torio [1], Halbert Hernandez-Negrin [1], Verónica Gómez-Caverzaschi [2], Ioana Ruiz-Arruza [1,4], Olga Araujo [2], Sergio Prieto-González [2], Georgina Espígol-Frigolé [2], Maria C. Cid [2], Guillermo Ruiz-Irastorza [1,4,*]

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[†]A.S.-P. and J.H.-R. contributed equally.

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- Estudio observacional
- 3 centros nacionales (Cruces, Clínic, 12 Oct)
- Comparar pauta de tratamiento
  - Estándar (1mg/kg máximo 40-60mg y pauta descendente)
  - Pauta alternativa: uso de pulsos de MP + GC a dosis bajas + metotrexato de inicio
- Resultados
  - 1ª Remisión
  - 2ª tiempo a pred < 5mg, dosis acumulada de GC y toxicidad asociada a GC

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- Pautas de tratamiento
  - Pauta 1 (Clínic+12 Oct): Estándar→ *"**prednisone 40– 60 mg/d** (or equivalent) during **4 weeks** were followed by a progressive tapering until achieving a maintenance dose of 5– 2.5 mg/d. In this SOC group, **pulses of IVMP** at doses ranging from 125 to 1000 mg/d during 3 days were reserved only for patients **with severe ischaemic manifestations**"*
  - Pauta 2 (Cruces+12 Oct): Pauta alternativa→ *"**three initial pulses of IVMP 125, 250 or 500 mg/d** (125 or 250 mg/d depending on the severity of systemic symptoms and 500 mg/d pulses being reserved for patients with severe ischaemic manifestations, like visual loss or stroke) and **MTX**. IVMP pulses were followed by **prednisone at initial doses of 20–30 mg/d with a fixed tapering scheme: weekly** reductions to 20 and 15 mg/d; once 15 mg/d were reached, prednisone was reduced within **2 weeks to 10 mg/d** and then every 2–4 weeks to 10/7.5, 7.5 and 7.5/5 mg/d, reaching a maintenance dose of **5 mg/d in 12–16 weeks**"*
- Análisis estadístico: Propensity Score → *"individual PS expresses the probability of being treated with the SOC prednisone vs IVMP/MTX-based protocols"*

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†A.S.-P. and J.H.-R. contributed equally.

Table 1. Baseline data of the whole GCA cohort and each treatment group

Variable	Total GCA cohort ($n = 151$)	SOC prednisone ($n = 79$)	IVMP/MTX ($n = 72$)	P
Centre				
H. Clínic, n (%)	72 (48%)	72 (91%)	0	<0.001
H. Cruces, n (%)	59 (39%)	0	59 (82%)	
H. 12 Octubre, n (%)	20 (13%)	7 (9%)	13 (18%)	
Age; mean (S.D.)	74.6 (8)	75 (8.3)	74 (7.8)	0.391
Female; n (%)	107 (71%)	58 (73.4%)	49 (68%)	0.469
Fever; n (%)	57 (37.7%)	31 (39%)	26 (36%)	0.692
Weight loss; n (%)	59 (39%)	34 (43%)	25 (34.7%)	0.296
PMR; n (%)	52 (34.4%)	31 (39%)	21 (29%)	0.193
Headache; n (%)	121 (80%)	61 (77%)	60 (83%)	0.347
Jaw claudication; n (%)	56 (37%)	33 (42%)	23 (32%)	0.212
Ischaemic manifestations; n (%)	60 (39.7%)	26 (33%)	34 (47%)	0.073
ESR (mm/1st h); mean (S.D.)	92 (29)	93 (26)	90 (32)	0.505
CRP (mg/dl); mean (S.D.)	10.8 (13.7)	9.8 (7)	11.8 (18.5)	0.377
Haemoglobin (g/l); mean (S.D.)	11.4 (1.5)	11.2 (1.4)	11.7 (1.7)	0.099
Weak/strong SIR; n (%)	107 (71%)/44 (29%)	55 (70%)/24 (30%)	52 (72%)/20 (28%)	0.725

SOC: standard of care; IVMP/MTX: methylprednisolone/MTX; SIR: systemic inflammatory response.

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Table 2. Characteristics of the treatment used in the entire cohort and each treatment group

Characteristics	Total GCA cohort ($n = 151$)	SOC prednisone ($n = 79$)	IVMP/MTX ($n = 72$)	P
IVMP; n (%)	85 (56%)	13 (16.5%)	72 (100%)	<0.001
IVMP dose; n (%)				
0 mg	66 (43.7%)	66 (83.5%)	0 (0%)	<0.001
125 mg	32 (21%)	1 (1.3%)[a]	31 (43%)	
250 mg	33 (22%)	4 (5%)[a]	29 (40%)	
500 mg	15 (10%)	3 (4%)[a]	12 (17%)	
1000 mg	5 (3.3%)	5 (6.2%)[a]	0 (0%)	
MTX; n (%)	71 (47.7%)	0 (0%)	71 (98.6%)	<0.001
CYC; n (%)	6 (4%)	0 (0%)	6 (8%)	0.009
Initial prednisone dose (mg/d)	40.1 (19)	56.3 (9.6)	22.3 (5.6)	<0.001
Cumulative prednisone dose (g); mean (S.D.)				
At 3 months	2.133 (1.224)	3.151 (0.770)	1.015 (0.307)	<0.001
At 6 months	2.842 (1.502)	4.090 (0.917)	1.455 (0.398)	<0.001
At 12 months	3.824 (1.917)	5.456 (1.074)	2.034 (0.533)	<0.001
At 24 months	5.205 (2.373)	7.181 (1.450)	3.038 (0.691)	<0.001
Weeks to prednisone 5 mg/d; mean (S.D.)	36.2 (27.6)	56.6 (23.4)	13.9 (6.5)	<0.001

[a] All patients receiving initial IVMP in the group treated with the SOC prednisone-based scheme suffered visual/neurological ischaemic complications.
SOC: standard of care; IVMP/MTX: methylprednisolone/MTX.

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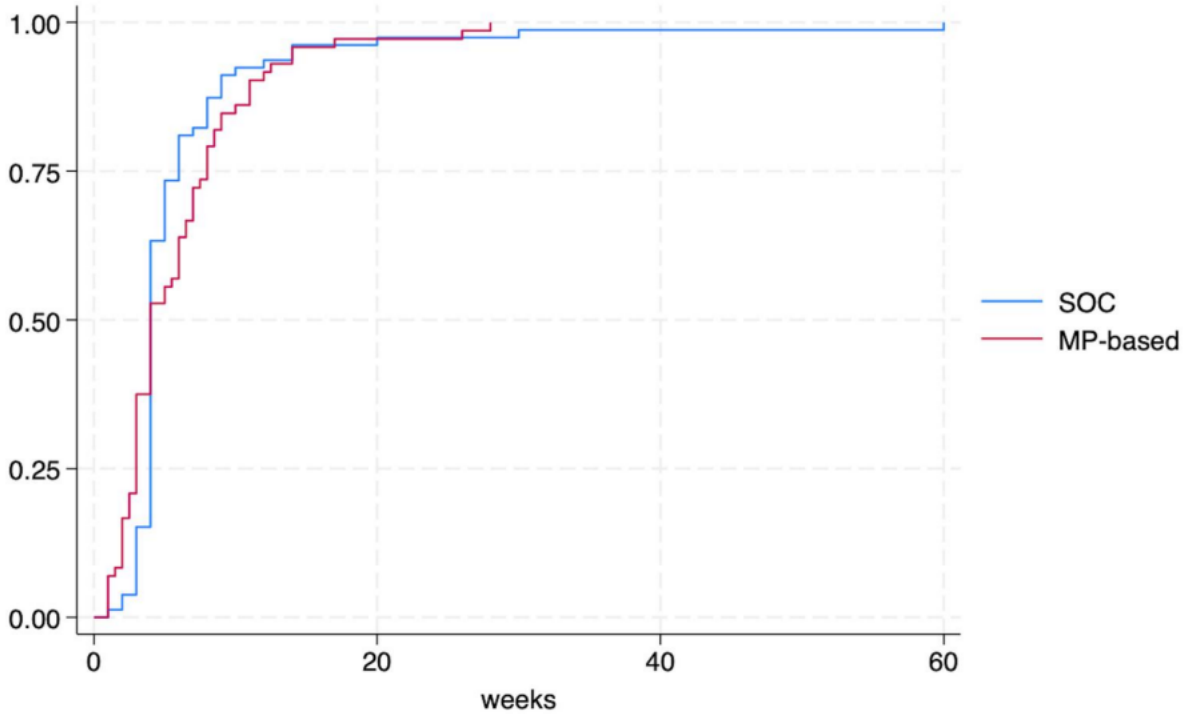

Figure 1. Kaplan–Meier curves for remission of patients with GCA in both therapeutic regimens. SOC: standard of care; MP-based: methylprednisolone/MTX

REMISIÓN

Soto-Peleteiro A, Hernández-Rodríguez J, Raad F, de Miguel B, Acha L, Torio M, Hernandez-Negrin H, Gómez-Caverzaschi V, Ruiz-Arruza I, Araujo O, Prieto-González S, Espígol-Frigolé G, Cid MC, Ruiz-Irastorza G. Methyl-prednisolone plus methotrexate-based regime vs prednisone-based standard of care for giant cell arteritis: a propensity score study. Rheumatology (Oxford). 2025 Sep 16:keaf499.

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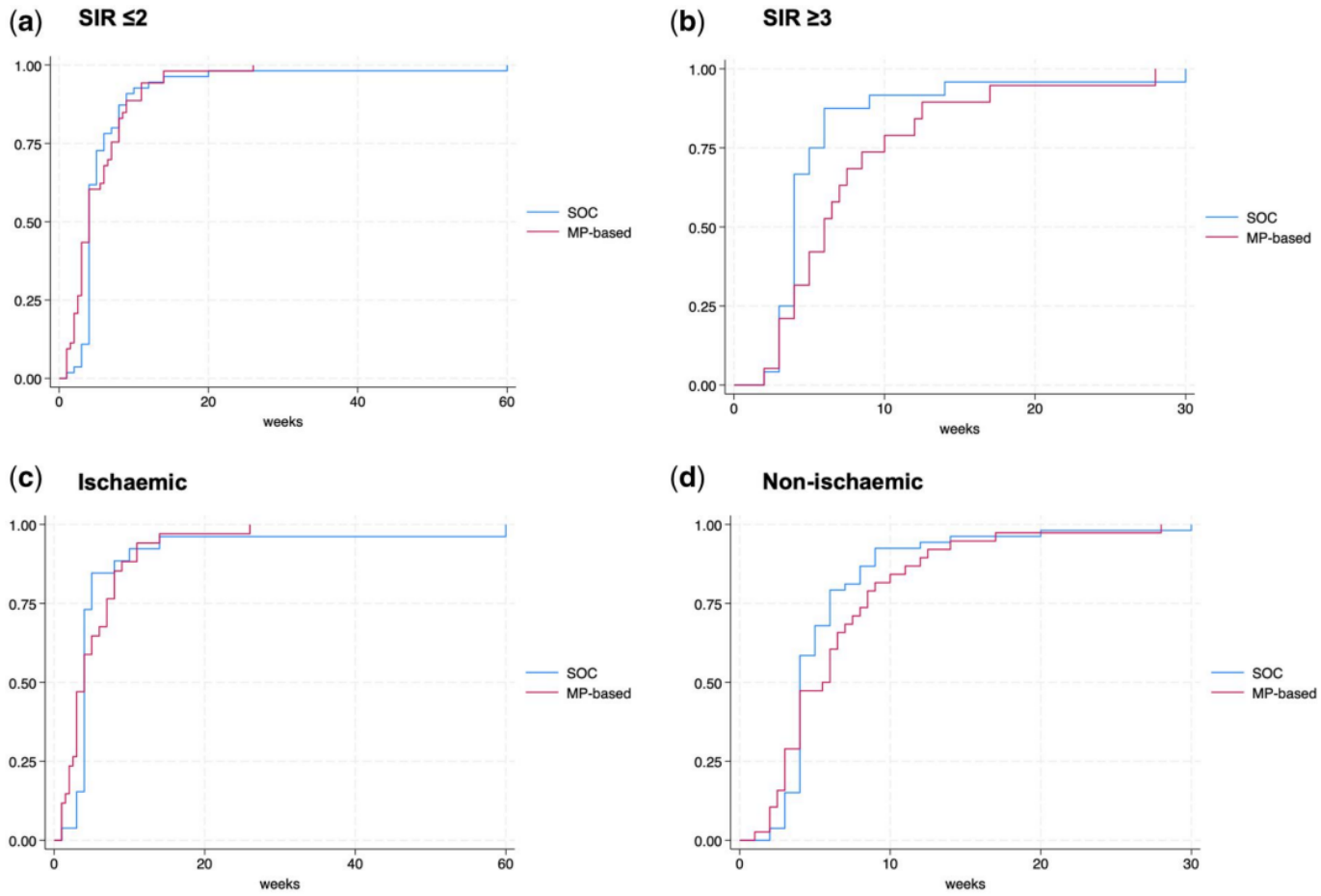

Figure 2. Kaplan–Meier curves for remission of patients with GCA in both therapeutic regimens according to the intensity of the systemic inflammatory response and the development of ischaemic complications at disease onset, among patients with a SIR ≤2 (a) or a SIR ≥3 (b), and with (c) or without ischaemic manifestations (d). SIR: systemic inflammatory response score; SOC: standard of care; MP-based: methylprednisolone/MTX

Remisión por subgrupos

Soto-Peleteiro A, Hernández-Rodríguez J, Raad F, de Miguel B, Acha L, Torio M, Hernandez-Negrin H, Gómez-Caverzaschi V, Ruiz-Arruza I, Araujo O, Prieto-González S, Espígol-Frigolé G, Cid MC, Ruiz-Irastorza G. Methyl-prednisolone plus methotrexate-based regime vs prednisone-based standard of care for giant cell arteritis: a propensity score study. Rheumatology (Oxford). 2025 Sep 16:keaf499.

Resultados – ef adversos

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Table 4. Potential glucocorticoid-related complications

Characteristics	Total GCA cohort ($n = 151$)	SOC prednisone ($n = 79$)	IVMP/MTX ($n = 72$)	*P*
New or worsening hypercholesterolemia; *n* (%)	23 (15%)	16 (20%)	7 (9.7%)	0.072
New diabetes mellitus; *n* (%)	9 (6%)	5 (6.3%)	4 (5.6%)	0.841
New cataracts; *n* (%)	7 (4.6%)	6 (7.6%)	1 (1.4%)	0.070
New symptomatic osteoporotic fractures; *n* (%)	6 (4%)	3 (3.8%)	3 (4.2%)	0.908
Infections requiring admission; *n* (%)	6 (4%)	6 (7.6%)	0 (0%)	0.029
Patients with any GC-related complication; *n* (%)	43 (28.5%)	29 (37%)	14 (20%)	0.019

SOC: standard of care; IVMP/MTX: methylprednisolone/MTX; GC: glucocorticoid.

Menos dosis acumulada de GC
Menos tiempo en llegar a pred<5mg/día

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Conclusiones

Clinical science

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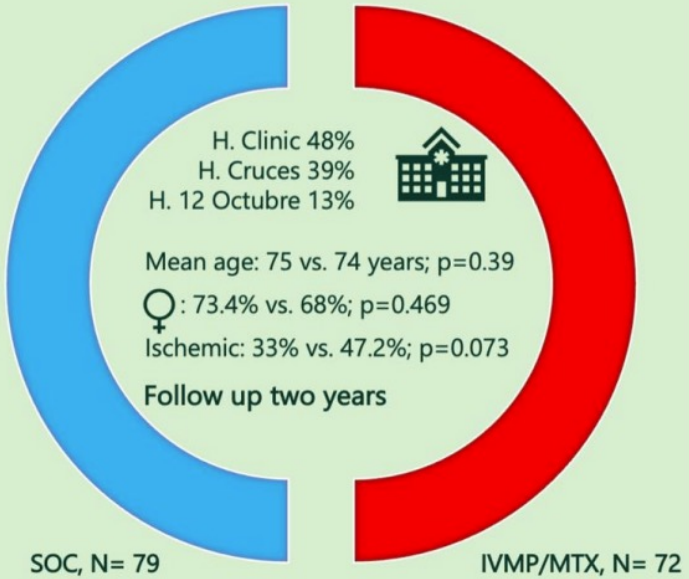
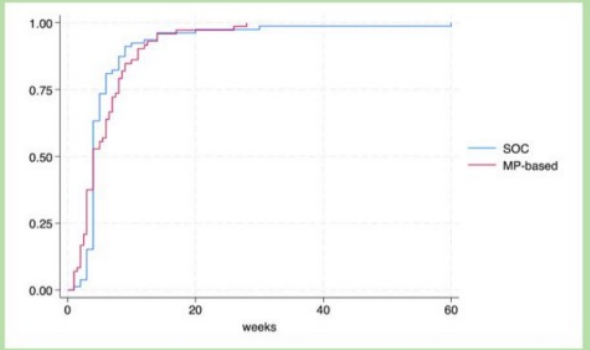
An alternative scheme based on Methyl-prednisolone pulses (IVMP), followed by lower doses of Prednisone (Pred) and Methotrexate (MTX), was compared with high-dose Pred-based standard of care (SOC) in a Spanish multicentric, observational, propensity score-controlled study.



Methods

- Therapy with IVMP/MTX was as effective as SOC in inducing remission in GCA.



- IVMP/MTX patients had a significant reduction >60% in cumulative Pred doses and reached Pred ≤5 mg/d faster than SOC patients (13.8 vs. 56.5 weeks; p<0.001).
- Patients in the IVMP/MTX group were less likely to suffer any GC-related adverse effect (adjusted OR 0.35, 95%CI 0.14-0.85; p=0.021).

Key findings

Soto-Peleteiro A, Hernández-Rodríguez J, Raad F, de Miguel B, Acha L, Torio M, Hernandez-Negrin H, Gómez-Caverzaschi V, Ruiz-Arruza I, Araujo O, Prieto-González S, Espígol-Frigolé G, Cid MC, Ruiz-Irastorza G. Methyl-prednisolone plus methotrexate-based regime vs prednisone-based standard of care for giant cell arteritis: a propensity score study. Rheumatology (Oxford). 2025 Sep 16:keaf499.

Glucocorticoides

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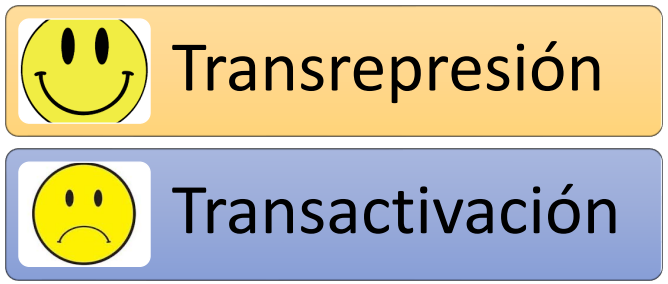
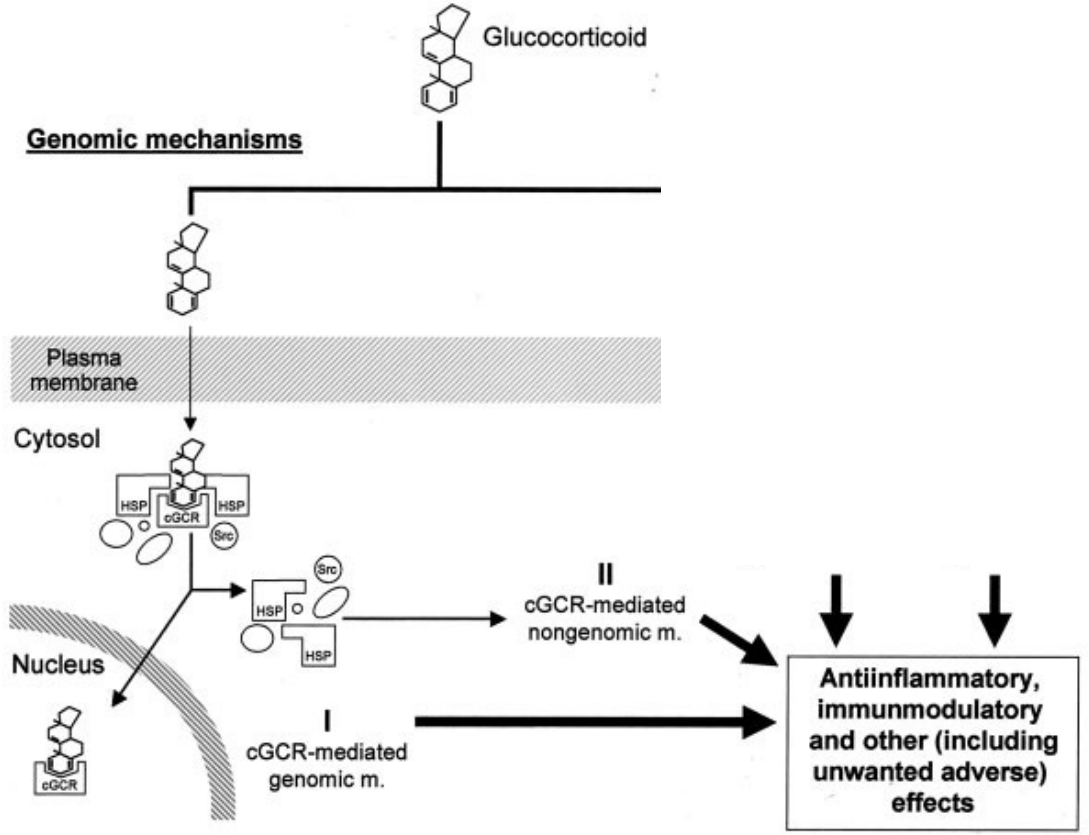
Mecanismo de acción





Buttgereit F, Straub RH, Wehling M, Burmester GR. Glucocorticoids in the treatment of rheumatic diseases: an update on the mechanisms of action. Arthritis Rheum. 2004;50(11):3408-17

Glucocorticoides

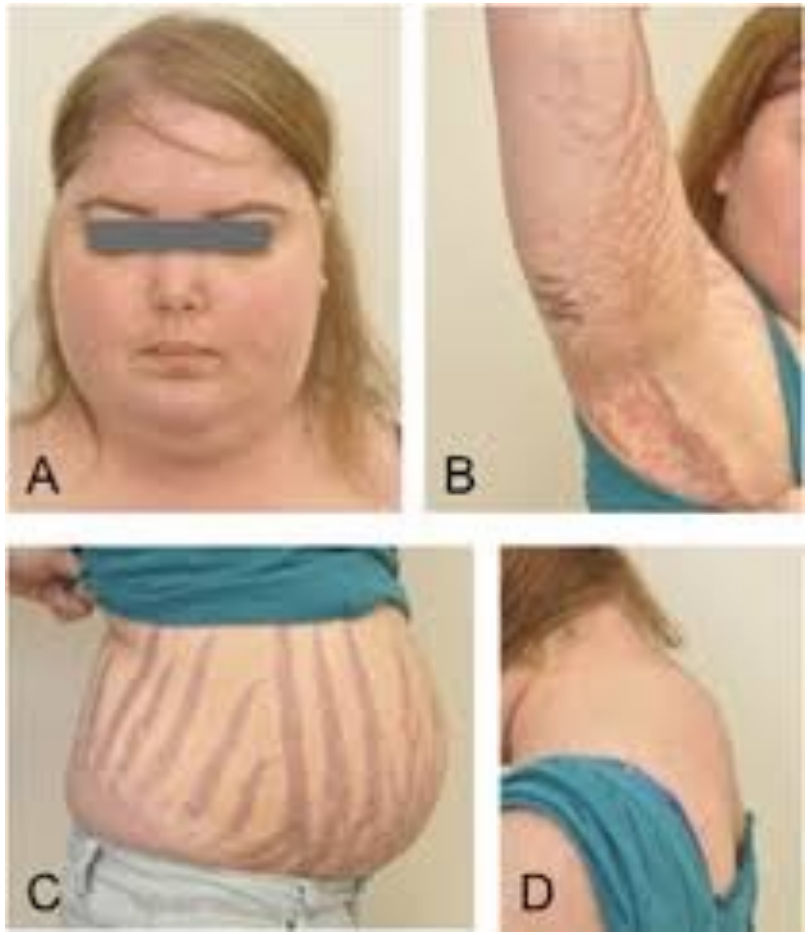
TABLE 2 Adverse effects of GCs—time and dose relationship

Adverse effect	Time dependent	Dose dependent	Minimum dose of occurrence[a], mg
Osteoporosis [17, 19]	Yes (early)	Yes (maximum at 6 months)	5
Hyperglycaemia [24]	Yes (early)	Yes	2.5
Cushing syndrome [17]	Yes (at least 1 month)	Yes	5
Cardiovascular disease [25]	Yes	Yes	7.5
Increased risk of infections [27, 28, 56]	Yes	Yes	5–7.5
Dermatological [17]	Yes	Yes	Undefined
Glaucoma [16]	Yes	Yes	7.5
Cataracts [17]	Yes (delayed)	Yes	6
Psychological and behavioural [30, 31]	Yes (early)	Yes	Undefined

[a]Expressed as prednisone-equivalent daily doses.

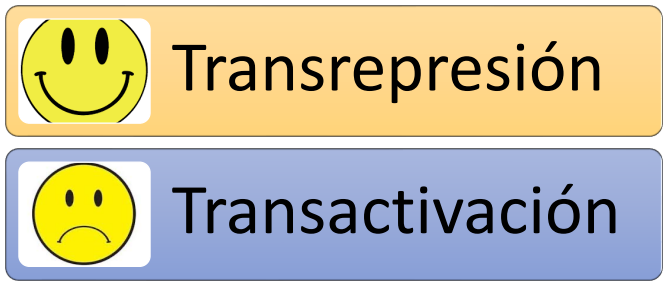
Ruiz-Irastorza G, Danza A, Khamashta M. Glucocorticoid use and abuse in SLE. Rheumatology (Oxford). 2012;51(7):1145-53. doi: 10.1093/rheumatology/ker410.

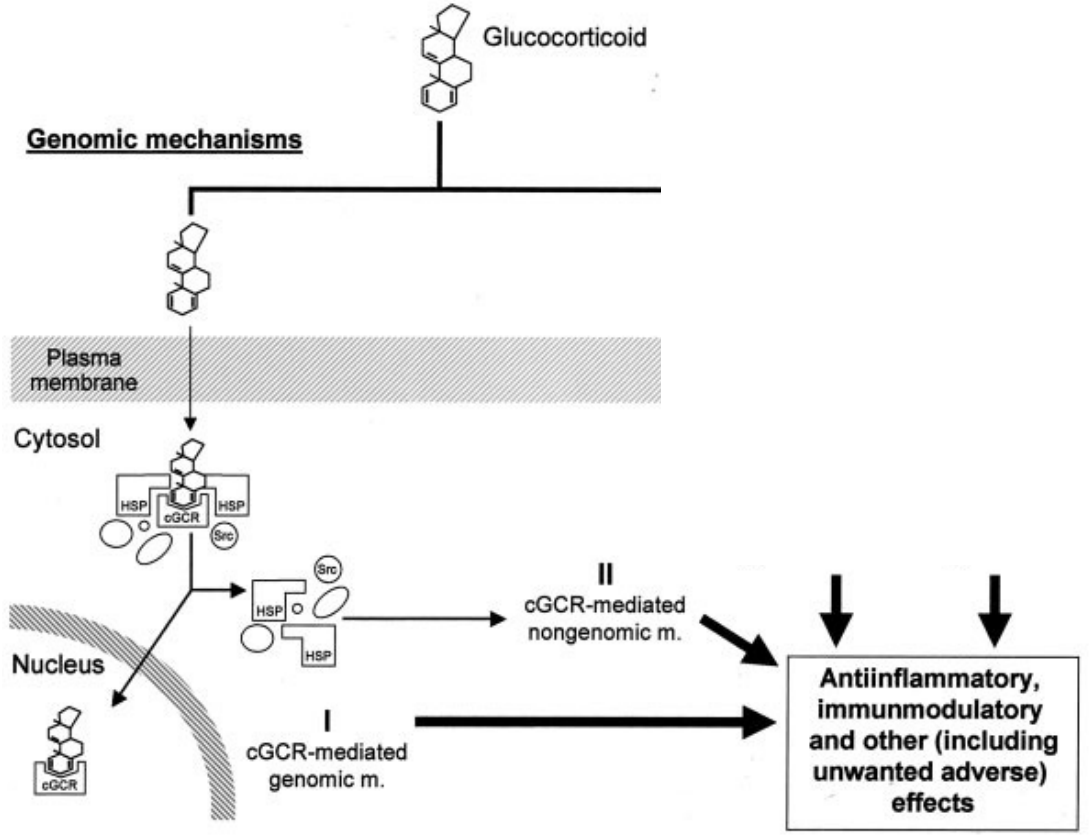
Glucocorticoides



Glucocorticoides

Mecanismo de acción





Buttgereit F, Straub RH, Wehling M, Burmester GR. Glucocorticoids in the treatment of rheumatic diseases: an update on the mechanisms of action. Arthritis Rheum. 2004 Nov;50(11):3408-17

Glucocorticoides

Table 1. Current knowledge on the relationship between clinical dosing and cellular actions of glucocorticoids

Terminology*	Clinical application†	Genomic actions (receptor saturation)‡§	Nongenomic actions§	
			Nonspecific	cGCR-mediated
Low dose (≤7.5 mg/day)	Maintenance therapy for many rheumatic diseases	+ (<50%)	–	?
Medium dose (>7.5 to ≤30 mg/day)	Initial treatment for primary chronic rheumatic diseases	++ (>50 to <100%)	(+)	(+)
High dose (>30 to ≤100 mg/day)	Initial treatment for subacute rheumatic diseases	++(+) (almost 100%)	+	+
Very high dose (>100 mg/day)	Initial treatment for acute and/or potentially life-threatening exacerbations of rheumatic diseases	+++ (almost 100%)	++	+(+?)
Pulse therapy (≥250 mg for 1 or a few days)	For particularly severe and/or potentially life-threatening forms of rheumatic diseases	+++ (100%)	+++	+(++?)

Table 1. Anti-inflammatory potency and toxicity of different doses of prednisone according to the activation of the genomic and non-genomic ways.

Dose	Potency	Toxicity
Up to 7.5 mg/day	+	+
7.5–30 mg/day	++	++
30–100 mg/day	+++	+++
≥100 mg/day*	++++	–/+
≥250 mg/day*	++++++	+

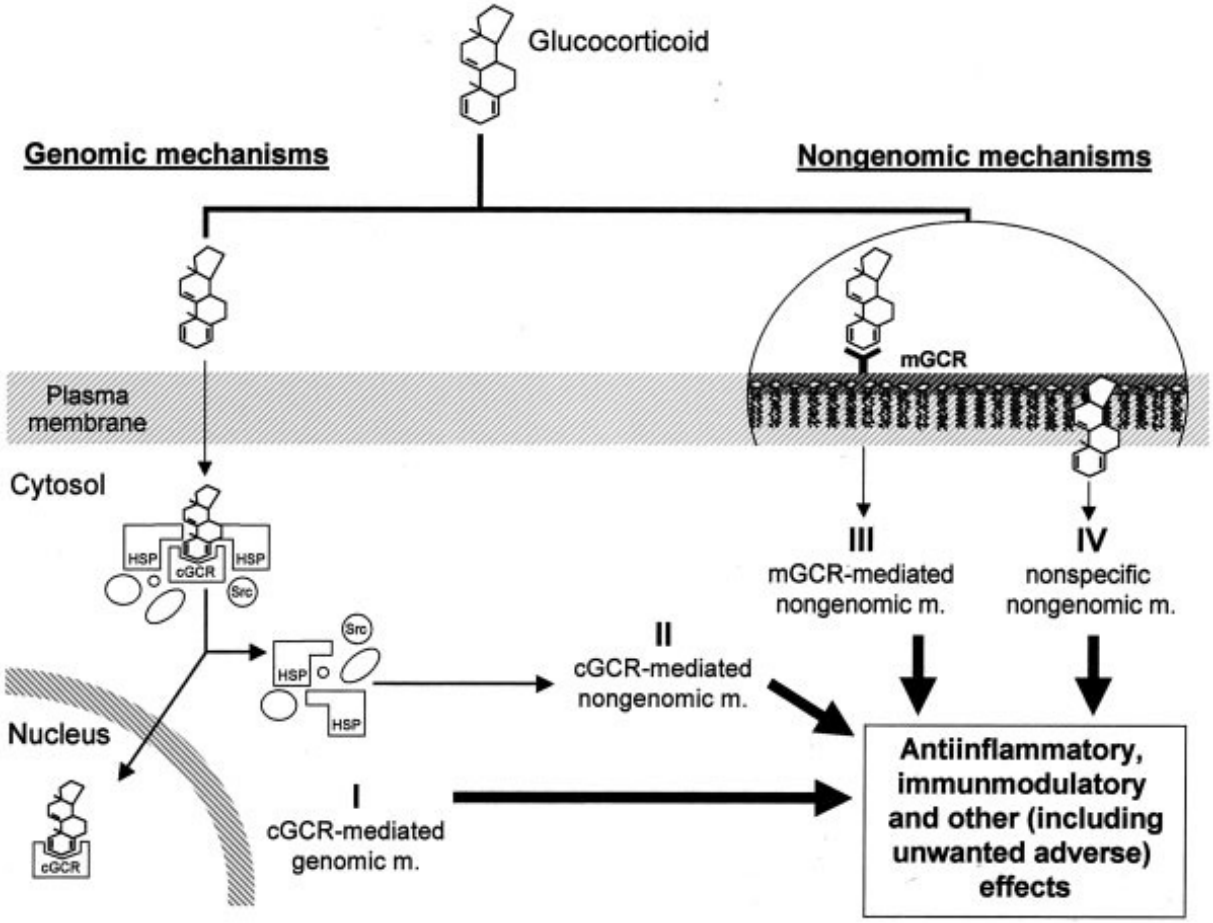
*Pulse therapy during 1–3 days.

Buttgereit F, Straub RH, Wehling M, Burmester GR. Glucocorticoids in the treatment of rheumatic diseases: an update on the mechanisms of action. Arthritis Rheum. 2004;50(11):3408-17
Ruiz-Irastorza G, Ugarte A, Ruiz-Arruza I, Khamashta M. Seventy years after Hench's Nobel prize: revisiting the use of glucocorticoids in systemic lupus erythematosus. Lupus. 2020;29(10):1155-1167

Glucocorticoides

Prednisona 20-30mg

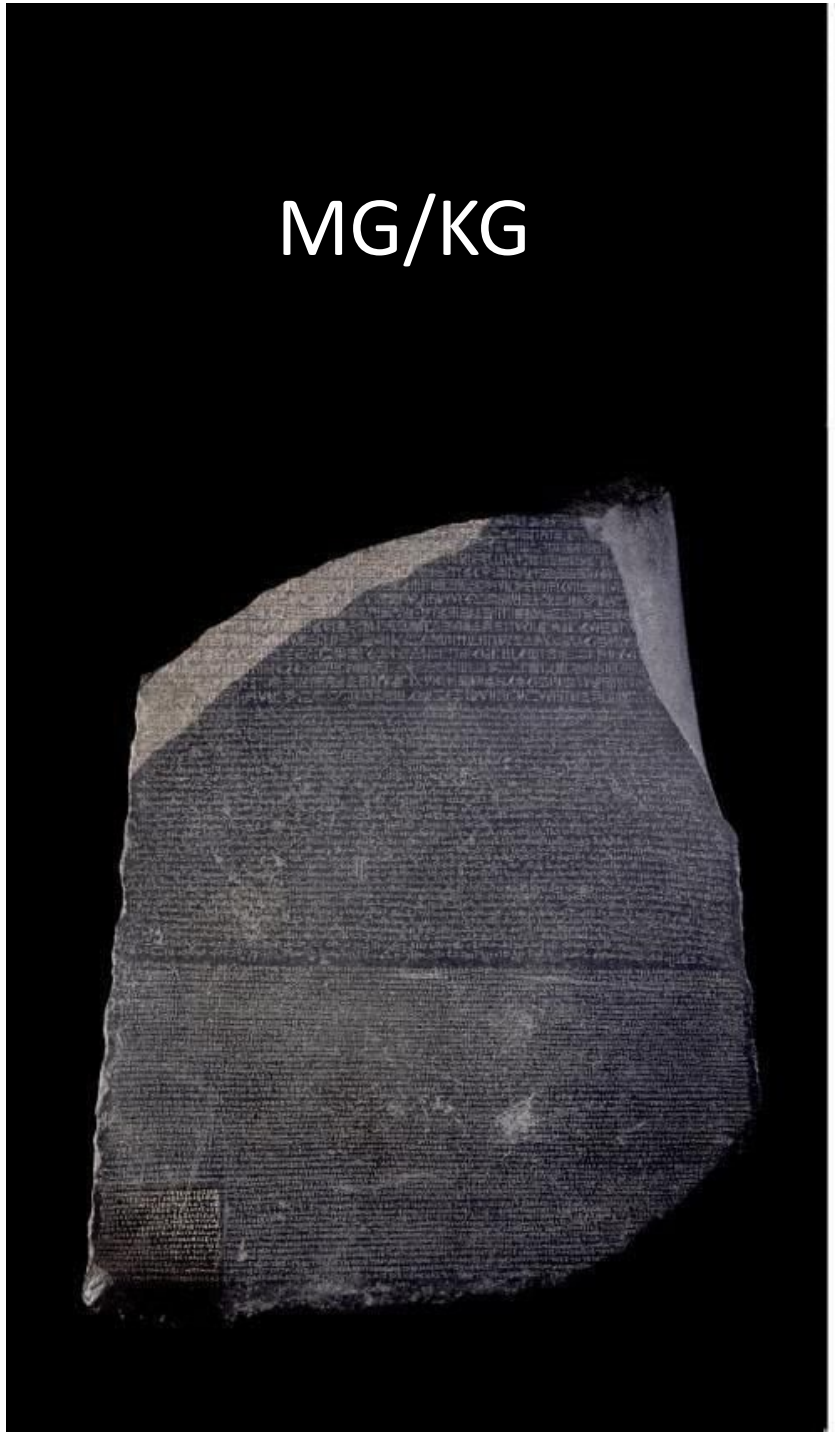
Dosis de mantenimiento: Prednisona 5mg



Pulsos de metilprednisolona iv 125-250-500mg 3 días consecutivos

Buttgereit F, Straub RH, Wehling M, Burmester GR. Glucocorticoids in the treatment of rheumatic diseases: an update on the mechanisms of action. Arthritis Rheum. 2004 Nov;50(11):3408-17

MG/KG



Glucocorticoides

Table 2. Clinical studies on the efficacy of different doses of glucocorticoids in SLE.

Author, year (ref)	Study design and characteristics	Main results
Zeher, 2011[44]	Randomized equivalence clinical trial. 81 patients with biopsy-confirmed class III or IV LN. All patients received 3 boluses of 500 mg methyl-prednisolone followed by mycophenolate sodium up to 2160 mg/day. Then randomized to two different doses of prednisone: Standard-dose glucocorticoids: starting 1 mg/kg/day, then tapered down to 5 mg/day (patient's weight ≤65 kg) or 10 mg/day (patient's weight >65 kg). Reduced dose glucocorticoids: half the dose of the standard dose.	Similar complete (19% vs. 20.5%) and partial response rates (47.6 vs. 35.9%) of the standard and reduced dose groups, respectively, after 24 weeks. Similar decrease in both groups in BILAG and SLEDAI scores. Infections in 57.1% vs. 35.9%, respectively ($P = 0.056$). Herpes zoster in 16.7% vs. 0% ($P = 0.012$).
Fischer-Betz, 2012[45]	Observational study. 38 with LN class III, IV and V and 2 with no biopsy. All patients received 12 i.v. cyclophosphamide pulses (NIH-like regime). No methyl-prednisolone was given to any patient. Prednisone was given according to extra-renal activity. Post-hoc analysis of patients treated with prednisone ≥20 mg/day (low-glucocorticoid, $n = 21$) and <20 mg/day (high-glucocorticoid, $n = 19$).	CR 52.6% vs. 71.4%, respectively, in the high and low-glucocorticoid groups ($P = 0.37$). PR in 26.3% vs. 14.3% ($P = 0.58$). The HR for renal flares during the follow-up in the low-glucocorticoid group vs. high-glucocorticoid group was 0.73 (95% CI 0.25–2.12).
Ruiz-Irastorza, 2014[14]	Observational study. 45 patients with class III, IV or V LN. 15 treated with reduced oral glucocorticoid regime. 30 historic controls. Patients in the reduced glucocorticoid group received lower initial doses of prednisone (median 20 vs. 50 mg/day), lower cumulative doses of prednisone (median 1.65 vs. 4.2 g), more hydroxychloroquine (100% vs. 33%) and more pulses of methyl-prednisolone (median 8 vs. 0 pulses per patient).	At 6 months, CR was achieved by 40% patients of the reduced glucocorticoid group vs. 10% controls ($P = 0.08$). At 12 months, the respective CR rates were 47% vs. 30% ($P = 0.04$). CR or PR was achieved by 87% vs. 63% of patients, respectively ($P = 0.055$). Glucocorticoid-related toxicity was seen in 7% of the reduced glucocorticoid patients vs. 67% controls ($P < 0.001$). Osteoporotic fractures were predicted by the number of weeks on prednisone >5 mg/day. Osteonecrosis was independently predicted by the initial prednisone dose. The total dose of methyl-prednisolone was inversely related with global glucocorticoid toxicity.
Condon, 2013[46]	Observational study. 50 patients with class III, IV or V LN, treated with a regime consistent on rituximab 1000 mg and methyl-prednisolone 500 mg, on days 1 and 15, mycophenolate mofetil up to 1500 mg/12 hours and no oral glucocorticoids.	90% of patients achieved CR (72%) or PR (18%) after a median time of 37 weeks. 22% patients relapsed.
Ruiz-Arruza, 2015[47]	Observational study. 30 patients included in the Lupus-Cruces cohort without or with mild forms of LN, presenting with SLEDAI ≥6, treated with prednisone doses ≤30 mg/day (mean 11 mg/day) compared to 30 patients from the historic cohort treated with prednisone doses >30 mg/day (mean 63.4 mg/day). Follow-up 5 years.	Among patients in the low-dose prednisone group, hydroxychloroquine was used in 100% vs. 33% of patients and methyl-prednisolone pulses were given to 34% vs. 10%, respectively. Patients in the low-dose prednisone group had similar control of activity at 1 year and accrued less damage at 5 years.

(continued)

Table 2. Continued

Author, year (ref)	Study design and characteristics	Main results
Ruiz-Irastorza, 2016[48]	Observational study. 223 Spanish lupus patients from the multicentric inception cohort RELES. Follow-up 1 year.	Prednisone doses in the first month predicted doses during the following 11 months. Those treated with higher initial doses had less chance to be with average doses ≤7.5 mg/day at month 12. Methyl-prednisolone pulses reduced the likelihood to be treated with average medium-high doses of prednisone at month 12.
Ruiz-Irastorza, 2017[49]	Observational study. 29 patients with biopsy-confirmec class III, IV and V LN included in the Lupus-Cruces cohort (CC) compared to 44 lupus nephritis patients from the Bordeaux Hospital cohort (BC). Maximum doses of prednisone, number of weeks until 5 mg/day maintenance doses and mean doses at 6 months were lower in the CC. The number of pulses of methyl-prednisolone was higher in the CC, but not the cumulative dose.	Patients in the CC achieved more CR at 6 months (69% vs. 30%, $P = 0.001$) and 12 months (86% vs. 43%, $P < 0.001$). The reduction of proteinuria was higher in the CC. The only treatment independently associated with a CR was the number of methyl- prednisolone pulses. There was a significantly lower risk of developing glucocorticoid-related toxicity in the CC.
Ruiz-Arruza, 2018[27]	Observational study. 74 inception patients in the inception Lupus-Cruces cohort were compared to 213 historic controls. The study compared a protocolized scheme with restrictive use of glucocorticoids vs. a traditional scheme. Mean follow-up 8.2 vs. 9.6 years.	Fewer patients accrued damage in the first year and at the end of the follow-up in the inception cohort compared to the historic cohort. Cardiovascular and glucocorticoid-related damage was less likely to occur in the inception cohort. Lupus-related damage was similar in both groups.
Rovin, 2019[50]	Randomized phase 2 controlled trial. 265 patients with class III, IV or V LN. All patients were treated with mycophenolate mofetil and were randomized to receive placebo, low-dose voclosporin or high-dose voclosporin. All three arms received 2 pulses of 500 mg of methyl-prednisolone followed by prednisone 20–25 mg/day, with rapid tapering to 2.5 mg/day at week 16 (achieved by 75% of participants).	CR at 24 weeks was achieved by 19.3% placebo group, 32.6% low-dose voclosporin group and 27.3% high-dose voclosporin group. CR at week 48 was achieved, respectively, by 23.9%, 49.4% and 39.8%.
Ruiz-Irastorza, 2019[51]	Observational study. 92 unselected inception patients from the Lupus-Cruces cohort (CC) compared to 81 patients from the Bordeaux Hospital cohort (BC). Patients in the CC received lower doses of prednisone (men 4.4 vs. 15.9 mg/day during the first year), more methyl-prednisolone pulses (42% vs. 26%), more hydroxychloroquine (57.3 vs. 43.6 cumulative months of treatment), and more methotrexate (21% vs. 11%) than patients from the BC. The proportion of patients on clinical remission on treatment (ClinROnT) at years 1, 2, 3, 4 and 5 after the diagnosis was compared between both cohorts.	The reduction in the SLEDAI score was similar in both cohorts ($P > 0.05$ at every yearly comparison). ClinROnT was achieved by 84% CC vs. 43% BC patients at year 1, 87% vs. 70% at year 2, 88% vs. 73% at year 3, 92% vs. 73 at year four and 89% vs. 78% at year 5. Prolonged ClinROnT from year 1 to year 5 was achieved by 70% CC vs. 28% BC patients ($P < 0.001$).
Mathian, 2020[52]	Randomized controlled trial. 124 patients with clinically quiescent SLE (SELENA-SLEDAI ≤4; D or E scores in all BILAG systems leucopenia, lymphopenia or isolated positive	4/61 (7%) patients in the maintenance group versus 17/63 (27%) in the withdrawal group suffered a flare during the follow-up (RR 0.2, 95% CI 0.1 to 0.7).

(continued)

Ruiz-Irastorza G, Ugarte A, Ruiz-Arruza I, Khamashta M. Seventy years after Hench's Nobel prize: revisiting the use of glucocorticoids in systemic lupus erythematosus. Lupus. 2020;29(10):1155-1167

Glucocorticoides

PEXIVAS

Table S3. Dosing for oral Glucocorticoids in the standard and reduced-dose limbs from trial start.

Week	Standard			Reduced-dose		
	<50 kg	50-75 kg	>75 kg	<50 kg	50-75 kg	>75 kg
	pulse	pulse	pulse	pulse	pulse	pulse
1	50	60	75	50	60	75
2	50	60	75	25	30	40
3-4	40	50	60	20	25	30
5-6	30	40	50	15	20	25
7-8	25	30	40	12.5	15	20
9-10	20	25	30	10	12.5	15
11-12	15	20	25	7.5	10	12.5
13-14	12.5	15	20	6	7.5	10
15-16	10	10	15	5	5	7.5
17-18	10	10	15	5	5	7.5
19-20	7.5	7.5	10	5	5	5
21-22	7.5	7.5	7.5	5	5	5
23-52	5	5	5	5	5	5
>52	Investigators' Local Practice			Investigators' Local Practice		

AURORA

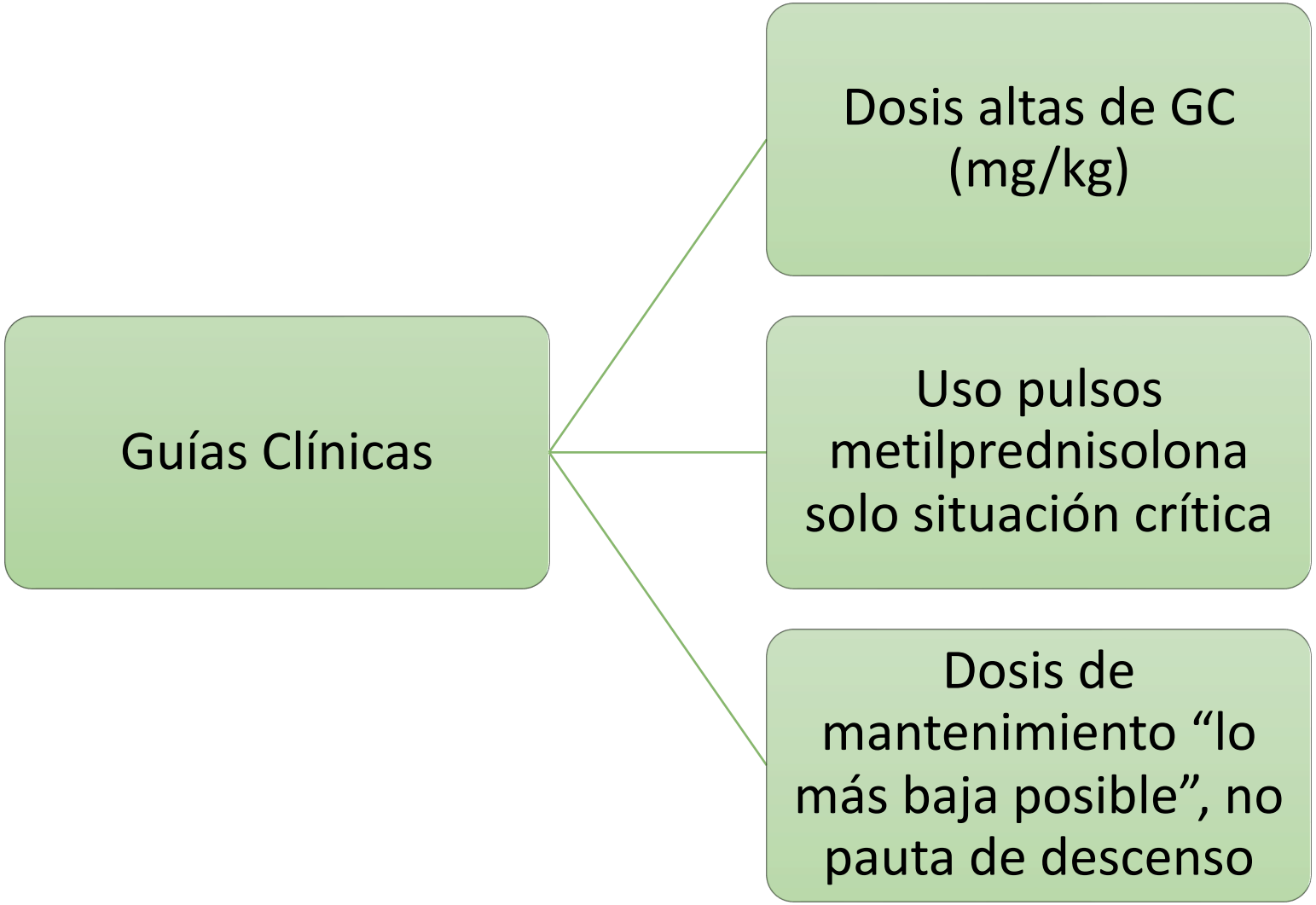
Table S3 Dosing Schedule for IV Methylprednisolone and Daily Oral Prednisone

	Patients <45 kg	Patients ≥45 kg	In Case of Prior IV Steroids During Screening (pre-randomisation)
Weeks 1-2*			
Days 1-2†	0·25 g (IV)	0·5 g (IV)	1 g minus prior IV steroids mg or 0·5 g minus prior IV steroids mg for patients who weigh <45 kg‡
Days 3-13	20 mg (oral)	25 mg (oral)	
Week 2 (Day 14)	15 mg (oral)	20 mg (oral)	
Week 4 (Day 28)	10 mg (oral)	15 mg (oral)	
Week 6 (Day 42)	10 mg (oral)	10 mg (oral)	
Week 8 (Day 56)	5 mg (oral)	5 mg (oral)	
Week 12 (Day 84)	5 mg (oral)	5 mg (oral)	
Week 16 (Day 112)	2·5 mg (oral)	2·5 mg (oral)	

*Day 0-13: Oral steroids dosed according to patient weight and then tapered beginning at Day 14.
†Oral corticosteroids were to be commenced on Days 1 or 2 if corticosteroids were administered during screening.
‡It was recognised that dosing with IV methylprednisolone may not be in the patient's best interest if they had already received therapy within the 3 months prior to screening. In this case, the Investigator was permitted to omit the administration of further IV methylprednisolone after discussion with the Medical Monitor.
Notes: Oral prednisone taper should have been done within ±3 days of specified timeframe. When clinically indicated, patients were allowed to be completely titrated off of oral corticosteroids.
IV, Intravenous; MMF, mycophenolate mofetil.

Walsh M, Merkel PA, Peh CA, Szpirt WM, Puéchal X, Fujimoto S, Hawley CM, Khalidi N, Floßmann O, Wald R, Girard LP, Levin A, Gregorini G, Harper L, Clark WF, Pagnoux C, Specks U, Smyth L, Tesar V, Ito-Ihara T, de Zoysa JR, Szczeklik W, Flores-Suárez LF, Carette S, Guillevin L, Pusey CD, Casian AL, Brezina B, Mazzetti A, McAlear CA, Broadhurst E, Reidlinger D, Mehta S, Ives N, Jayne DRW; PEXIVAS Investigators. Plasma Exchange and Glucocorticoids in Severe ANCA-Associated Vasculitis. N Engl J Med. 2020;382(7):622-631.
Rovin BH, Teng YKO, Ginzler EM, Arriens C, Caster DJ, Romero-Diaz J, Gibson K, Kaplan J, Lisk L, Navarra S, Parikh SV, Randhawa S, Solomons N, Huizinga RB. Efficacy and safety of voclosporin versus placebo for lupus nephritis (AURORA 1): a double-blind, randomised, multicentre, placebo-controlled, phase 3 trial. Lancet. 2021;397(10289):2070-2080.

Glucocorticoides



Martin-Iglesias D, Paredes-Ruiz D, Ruiz-Irastorza G. Use of Glucocorticoids in SLE: A Clinical Approach. Mediterr J Rheumatol. 2024;35(Suppl 2):342-353.

Glucocorticoides

Table 1. Recommendations for the use of glucocorticoids in Systemic Lupus Erythematosus practice guidelines.

Guideline (year) [ref]	Clinical setting	Pulse therapy	Initial dose of prednisone	Tapering scheme	Maintenance dose	Discontinuation scheme
ACR (2012)[9]	LN III- IV	500-1000 mg/day methylprednisolone for 1-3 days	0.5-1 mg/kg/d	Not specified. "For a few weeks"	Not specified. "To lowest effective dose"	Not specified
	LN V	NO	Prednisone 0.5 mg/kg/d	Not specified. Maintain initial dose by for 6 months	Not specified.	Not specified
BSR (2018)[9]	Mild activity	Not indicated	≤20 mg/day	Not specified. Maintain initial dose for 4 weeks. Taper over several weeks	≤7.5 mg/day	Immunosuppression for at least 3 years, in combination with low dose prednisone. Gradual drug withdrawal, GCs first.
	Moderate activity	MP ≤250 mg/day for 1-3 days	≤0.5 mg/kg/ day if no MP	Not specified		
	Severe activity	MP 500-750 mg/day for 1-3 days	≤0.75-1 mg/ kg/day if no MP OR ≤0.5 mg/kg/ day + MP	Not specified		
GLADEL/ PANLAR (2019)[10]	LN	Not indicated	1–2 mg/ kg/ day, maximum 60 mg/day for paediatric patients. No scheme proposed for adult patients	Not specified Lowest doses for the shortest period	≤7.5 mg/day	Not specified
	Diffuse alveolar haemorrhage	Indicated, no specific scheme proposed	Not specified			
EULAR (2019)[11]	Mild-moderate flare	Not indicated	≤0.5 mg/kg/d	Not specified Gradual tapering recommended	≤7.5 mg/d	Not specified Discontinue when possible Prompt initiation of immunomodulatory agents can expedite the discontinuation of GC
	Severe/organ-threatening disease:	Consider MP 250-1000 mg/d for 1-3 days	0.5-0.7 mg/ kg/d	Not specified Gradual tapering recommended		
EULAR/ERA-EDTA (2020)[12]	LN III-IV	MP total dose 500–2500 mg/day, depending on disease severity	Prednisone 0.3–0.5 mg/ kg/day	Prednisone 0.3–0.5 mg/kg/ day for up to 4 weeks, tapered to ≤7.5 mg/day by 3 to 6 months	≤7.5 mg/day	Not specified. Gradual withdrawal of treatment (GC first, then IS), when at least 3-5 years in complete clinical response.
	LN V	Prednisone 20 mg/day	Prednisone tapered to ≤5 mg/day by 3 months	≤5 mg/ day		

continued on next page

Table 1. Recommendations for the use of glucocorticoids in Systemic Lupus Erythematosus practice guidelines.

continued from previous page

Guideline (year) [ref]	Clinical setting	Pulse therapy	Initial dose of prednisone	Tapering scheme	Maintenance dose	Discontinuation scheme
KDIGO (2021)[13]	LN III-IV	MP 250-500 mg/day for 3 days	Prednisone 0.8–1 mg/kg/ day OR Prednisone 0.6-0.7 mg/ kg/day OR Prednisone 0.5-0.6 mg/kg/ day (max 40 mg/day)	Prednisone tapered to 5 mg/ day at week 21 OR Prednisone tapered to 5 mg/ day at week 17 OR Prednisone tapered to 5 mg/ day at week 11	≤7.5 mg/day	Not specified. May be considered after complete clinical response for about a year and with no extrarenal disease.
	LN V	No specified GCs scheme				
EULAR (2023)[1]	Mild-moderate flare	Not indicated	≤0.5 mg/kg/ day	Not specified Gradual tapering recommended	≤5 mg/day	Not specified. Discontinue "when possible". Prompt initiation of immunomodulatory agents. can expedite the discontinuation of GCs.
	Severe/organ-threatening disease	Consider MP 250-1000 mg/day for 1-3 days	0.5-0.7 mg/ kg/day	Not specified Gradual tapering recommended		
KDIGO (2024)[14]	LN class III-IV-V	MP 250-500 mg/day for 3 days	0.5–0.6 mg/ kg (max 40 mg)	Tapering scheme detailed in week-by-week bases reaching 2.5 mg/day by week 13	Low-dose prednisone (2.5 mg/day)	Consider GC complete withdrawal after at least 12 months after clinical remission

LN: Lupus nephritis; SLE: systemic lupus erythematosus; MP: methyl-prednisolone pulses; HCQ: hydroxychloroquine; GCs: glucocorticoids; CNS: central nervous system.

Martin-Iglesias D, Paredes-Ruiz D, Ruiz-Irastorza G. Use of Glucocorticoids in SLE: A Clinical Approach. Mediterr J Rheumatol. 2024;35(Suppl 2):342-353.

Glucocorticoides

Table 2. Proposal for the treatment of Systemic Lupus Erythematosus according to clinical scenarios.

Long-term HCQ 200 mg/d with ophthalmological survey					
Clinical setting	**Pulse therapy**	**Initial dose of prednisone**	**Tapering scheme***	**Maintenance dose**	**Discontinuation scheme**
Mild flares (Polyarthralgia, small joint mono-oligoarthritis, limited skin lesions)	Not needed initially	≤7.5 mg/d		2.5-5 mg/d	Clinical remission for at least 3-5 years on prednisone ≤5 mg/d, then Previous gradual withdrawal of immunosuppressive drugs, then Slow tapering (≤3-6 months) by 2.5 mg/d on alternate days until discontinuation
Moderate flares (Polyarthritis, moderate thrombocytopenia (20,000 50,000/mm3), haemolytic anaemia with a low rate of haemolysis, widespread skin lupus lesions, non-severe pericardial effusion/pericarditis, pleural effusion, **mild flares non responding to treatment**)	MP 125-250 mg/d for 3 days	Prednisone ≤10-15 mg/d	Reduced 1-2 weekly (10-7.5) to 5 mg/d		
Severe flares (Lupus nephritis, pneumonitis, severe thrombocytopenia (<20,000/mm3), haemolytic anaemia with a high rate of haemolysis, severe pericardial effusion, refractory pleural effusion, severe neuropsychiatric manifestations, **moderate flares non responding to treatment**)	MP 250-500 mg/d for 3 days or dexamethasone 40 mg for 4 days Repeat pulses if persistent activity MP 125 mg added to each fortnightly dose of iv cyclophosphamide, if used	Prednisone 20-30 mg/d	2-4 weekly reduced (20-15-10-7.5) to 5 mg/d (in 12 weeks)		

MP: methylprednisolone pulses; HCQ: hydroxychloroquine.
*If the clinical course does not allow a reduction of prednisone in moderate disease, additional therapy should be added depending on specific organ involvement: mepacrine and/or methotrexate in skin, articular, or serosal diseases, azathioprine in immune cytopenias and in women with forthcoming pregnancy plans, belimumab in refractory disease despite immunosuppressive therapy. In severe flares, potent immunosuppressive drugs should be added from the beginning: cyclophosphamide in renal, CNS, lung disease, mycophenolate +/- calcineurin inhibitors in renal disease, rituximab in life-threatening disease or in severe disease without rapid response to therapy.

Martin-Iglesias D, Paredes-Ruiz D, Ruiz-Irastorza G. Use of Glucocorticoids in SLE: A Clinical Approach. Mediterr J Rheumatol. 2024;35(Suppl 2):342-353.

Glucocorticoides - Conclusiones

Table 3. Do's and Don'ts in the management of glucocorticoids in patients with Systemic Lupus Erythematosus.

Do's
✓ Maintain long-term HCQ unless toxicity is confirmed.
✓ Adjust induction therapy to the severity of the disease.
✓ Restrict maintenance dose of prednisone to ≤5 mg/day (preferably ≤2.5 mg/day).
✓ Use MP (125-500 mg/day for 3 days) to treat moderate to severe flares.
✓ Use immunosuppressive drugs form the beginning to treat moderate to severe flares.
✓ Consider MP to treat mild flares that do not respond to prednisone up to 7.5-10 mg/day within one week.
✓ Use immunosuppressive drugs to treat mild flares that do not respond to antimalarials and prednisone up to 5 mg/day.
✓ Consider the discontinuation of prednisone after clinical remission for at least 3-5 years.
✓ Start prednisone withdrawal after immunosuppressive drugs discontinuation, and slowly taper for at least 3-6 months until definitive discontinuation.
Don'ts
✗ Ever start prednisone at doses higher than 30 mg/day.
✗ Ever use maintenance dose of prednisone >5 mg/day.
✗ Start biologics just as a steroid reduction strategy.
✗ Consider prednisone withdrawal before clinical remission has been achieved for at least 3-5 years.
✗ Taper prednisone to zero over periods shorter than 3 months.
✗ Stop HCQ unless toxicity is confirmed.

HCQ: hydroxychloroquine; MP: methylprednisolone pulses.

Martin-Iglesias D, Paredes-Ruiz D, Ruiz-Irastorza G. Use of Glucocorticoids in SLE: A Clinical Approach. Mediterr J Rheumatol. 2024;35(Suppl 2):342-353