

INCIDENCE OF VENOUS THROMBOEMBOLISM, RISKS FACTORS AND IMPACT ON QUALITY OF LIFE IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS FROM A LATIN AMERICAN COHORT.



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BACKGROUND

Patients with SLE are at increased risk of thrombotic events (1,2).

Venous thromboembolism (VTE) has a negative impact on patient quality of life (QoL)(3,4).

To report the incidence of VTE, the associated risk factors and the impact of VTE on QoL among Latin American SLE patients.

RESULTS

1083 patients included in the GLADEL 2.0 cohort - 970 (89.6%) female.

Reported ethnicities: 701 (64.7%) mestizo, 277 (25.6%) white, 90 (8.3%) Afro-Latin American, 6 (0.6%) other or unknown.

Sixty patients (5.5%) died during follow-up.

22/1083 (2%) patients → new VTE during a 5-year follow-up → **incidence of 5.94 VTE cases per 1000 person/years.**

16/22 new events, 6/22 recurrences.

From baseline, median time to VTE was 22.8 months (IQR 5.6-36.5).

At baseline

→ VTE group had higher SDI and mortality than controls.

→ VTE group showed a higher prevalence of anti-β2GPI and double aPL positivity.

All data is summarised in Table 1.

TABLE 1. Baseline characteristics of VTE vs no VTE groups (at cohort enrollment).

	VTE		P
	NO n=42(%)	YES n=22 (%)	
Female gender (n,%)	38 (90.5)	19 (86.4)	0.62
Age at SLE diagnosis (mean ± SD)	28.3±12.2	30.9±10.5	0.26
Age at VTE diagnosis (n=20, mean ± SD)		41.1±12.4	
Ethnicity (n,%)			0.95
Mestizo	30 (71.4)	15 (68.2)	
White	10 (23.8)	6 (27.3)	
Indigenous	2 (4.8)	1 (4.5)	
Classification group at cohort entry (n,%)			0.99
SLE without history of lupus nephritis	22 (52.4)	12 (54.5)	
SLE with prevalent inactive lupus nephritis	8 (19)	4 (18.2)	
SLE with prevalent active lupus nephritis	8 (19)	4 (18.2)	
SLE with incident lupus nephritis	4 (9.5)	2 (9.1)	
Mortality (n,%)	0 (0)	2(9.1)	0.05*
Comorbidities (n,%)			
Hypertension	12 (28.6)	3 (13.6)	0.18
T2DM	2 (4.8)	1 (4.5)	0.97
Obesity	6 (14.3)	5 (22.7)	0.40
Dyslipidemia	8/40 (20)	3/21 (14.3)	0.58
Tobacco use	4 (9.5)	6 (27.3)	0.06
SLE Characteristics			
Time since diagnoses at cohort entry (in years, mean ± SD)	11 ±11.66	9.7 ±9.43	0.80
SLEDAI (median, IQR)	4.0 (0.0-3.0)	3.0 (0.0-24.0)	0.83
SDI (median, IQR)	0.0 (0.0-6.0)	1.5 (0.0-7.0)	0.06
Clinical manifestations (n,%)			
General	33 (78.6)	16 (72.7)	0.60
Musculoskeletal	30 (71.4)	18 (81.8)	0.36
Skin	39 (92.9)	21 (95.5)	0.68
Serositis	13/42 (31)	8/21 (38.1)	0.57
Lupus nephritis class III, IV, V	15 (35.7)	5 (22.7)	0.29
Thrombocytopenia	2 (4.8)	1 (4.5)	0.97
Leukopenia	4/41 (9.6)	4/21 (19)	0.30
Neutrophils/lymphocytes ratio (mean ± SD)	2.8 (1.8)	2.8 (2.16)	0.85
APS (n,%)	1/3 (33.3)	6/10 (60)	0.42
aPL (n,%)	4 (9.5)	6 (27.3%)	0.06
Lupus anticoagulant (n,%)	1/33 (3)	3/20 (15)	0.11
aCL (IgM and/or IgG) (n,%)	3/35 (8.6)	4/21 (19)	0.25
Anti-β2GPI (IgM and/or IgG) (n,%)	0/32 (0)	3/16 (18.8)	0.01*
Double positive (any combination) (n,%)	0/32 (0)	3/20 (15)	0.02*
Triple positive (LA+aCL+anti-Anti-β2GPI) (n,%)	0/35 (0)	1/21 (4.8)	0.19
Treatment (n,%)			
Antimalarials	41 (97.6)	22 (100)	0.47
Corticosteroids (prednisone or equivalent)	24/24 (100)	16/17 (94.1)	0.23
Immunosuppressants	27 (64.3)	19 (86.4)	0.06
ASA	6/9 (66.7)	3/11 (27.3)	0.09

SLE: Systemic lupus erythematosus. VTE: Venous thromboembolism. T2DM: Type 2 diabetes mellitus. SLEDAI: SLE Disease Activity Index. SDI: SLICC/ACR Damage Index. APS: Antiphospholipid syndrome. aPL: antiphospholipid antibodies. aCL: anticardiolipin antibodies. Anti-β2GPI: anti-β2 glycoprotein I antibodies ASA: Acetylsalicylic acid. #aPL: number (%) of patients with positivity of at least 1 aPL * Statistical significance

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PATIENTS & METHODS

Case control study - Sub analysis of data from GLADEL 2.0 cohort.

Incidence of VTE was evaluated over a five-year follow-up.

Cases → patients who experienced a VTE event during follow-up.

Controls → matched by sex, ethnicity, renal-involvement, disease duration at cohort entry (±5 years).

Demographic characteristics, clinical and paraclinical features of SLE, VTE risk factors, and treatment were analysed.

Differences between cases & controls were analyzed using data collected at enrollment and prior to the VTE event for cases. For controls, we used data from the corresponding time points.

LupusQoL scores before and after the VTE for cases, temporally comparable data for controls.

Change in LupusQoL score between the two time points was calculated for each participant.

Prior to the development of thrombosis, the VTE group showed:

- » higher prevalence of previous VTE (27.3% vs. 0%, p=0.0004)
- » higher SLEDAI (4 (0-16) vs. 2 (0-18), p=0.005)
- » higher SDI (3 (0 - 12) vs. 0 (0 - 11), p<0.0001)
- » higher prevalence of:
 - a) at least 1 aPL (63.6% vs. 19.0%, p=0.0004)
 - b) IgG/IgM anti-β2GPI (75% vs. 28%, p=0.006)
 - c) IgG/IgM aCL (81% vs 30%, p=0.002)
 - d) double aPL positivity (75% vs 26.3%, p=0.004)

After developing VTE, the VTE group showed a significant decrease in physical function (Table 2).

TABLE 2. LupusQoL pre and post VTE in cases vs controls.

LupusQoL domains (mean ± SD) pre- and post-thrombotic event	VTE		P
	NO n=28/42	YES n=17/22	
Physical function pre	85.30±21.37	75.80±30.13	0.34
Physical function post	87.20±17.80	77.30±22.30	0.04*
Pain pre	84.60±15.45	80.10±20.76	0.52
Pain post	86.20±13.32	72.10±29.82	0.14
Planning pre	84.20±25.59	86.30±20.61	0.90
Planning post	87.05±20.85	77.50±31.29	0.33
Intimacy pre	81.08±30.17 (n=24)	84.02±26.08 (n=15)	0.74
Intimacy post	84.40±29.08 (n=24)	80.80±27.77 (n=13)	0.29
Emotional burden pre	74.30±21.93	71.50±28.16	0.89
Emotional burden post	77.50±20.79	65.90±27.68	0.16
Body image pre	81.70±18.04	82.10±16.76	0.14
Body image post	84.50±16.74	76.40±21.45	0.78
Cognition pre	71.40±29.43	72.10±34.10	0.07
Cognition post	81.30±24.18	66.20±30.54	0.07
Fatigue pre	77.04±22.78	79.40±18.66	0.91
Fatigue post	77.40±21.14	65.20±29.50	0.15

All data is presented as mean±SD. * Statistical significance

CONCLUSIONS

The incidence rate of VTE in this cohort is 5.94 per 1000 person/years.

VTE was associated with:

- » a history of previous thrombosis.
- » a higher activity and damage index.
- » the presence of aPL.

VTE impacted QoL by reducing physical function.