

Poor health-related quality of life in adult patients with lupus nephritis

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Background

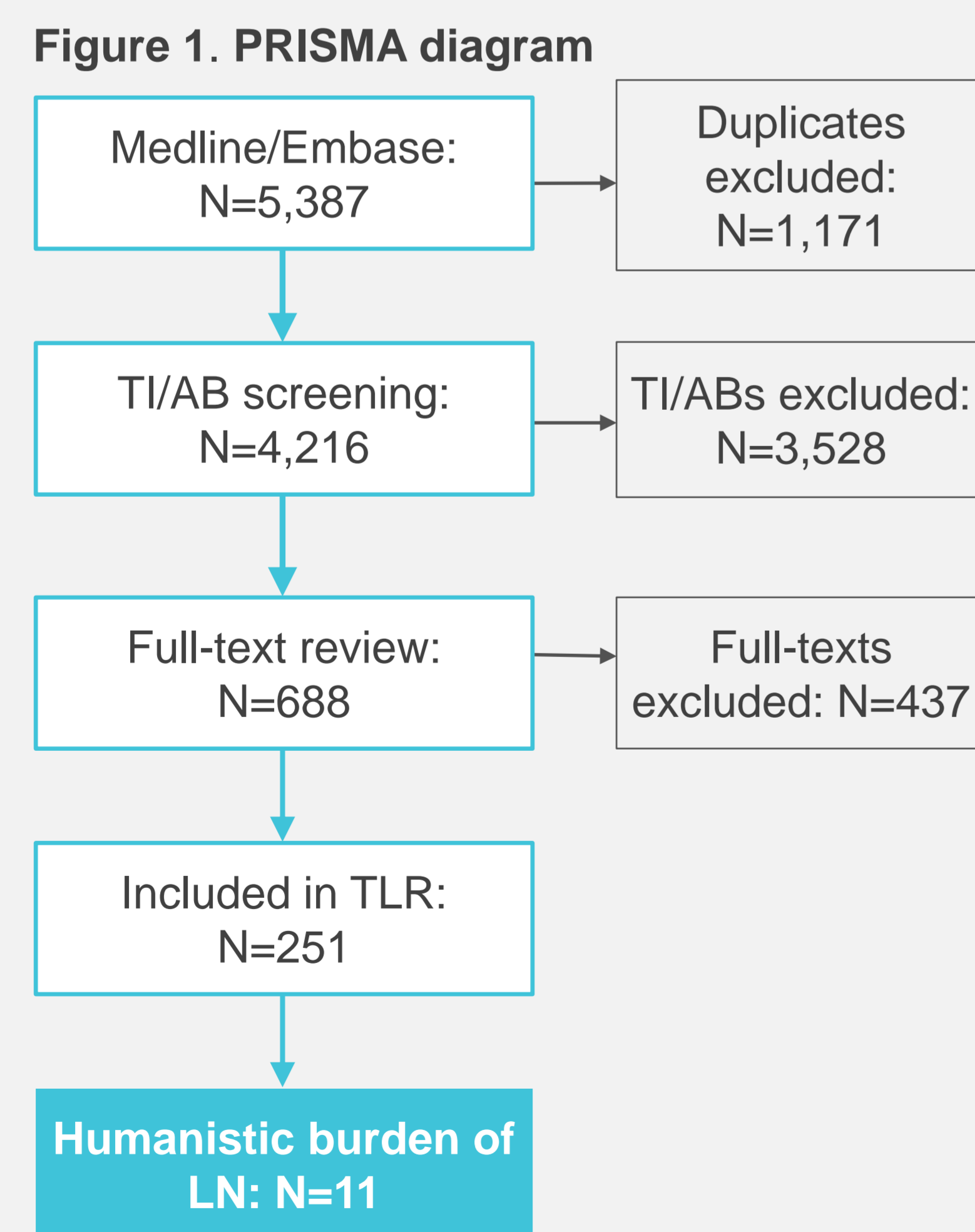
- Lupus nephritis (LN) is a serious complication of systemic lupus erythematosus (SLE) associated with considerable morbidity that has a devastating impact on a patient's life.
- Disease outcomes tend to be worse for patients with refractory LN,^{1,2} but little is known about true impact of LN on a patient's health-related quality of life (HRQoL) in an autoimmune disease that can affect several organ systems.
- The objective of this literature review was to qualitatively summarize the evidence on the humanistic burden of LN in adult patients with SLE.

Methods

- A targeted literature review (TLR) was conducted in MEDLINE/Pubmed and Embase to identify studies in adult and juvenile patients with diagnosed LN.
- A search strategy was developed separately for the two databases to identify relevant peer-reviewed articles published in English between March 2012 and March 2022, and conference abstracts indexed in Embase since 2019.
- All records were screened by a single reviewer according to pre-specified inclusion and exclusion criteria.
- The current poster summarizes data on humanistic burden of disease and treatment impact on HRQoL in adult patients with LN.

Results

- Of the 4,216 records identified in the medical databases, total of 11 studies have evaluated HRQoL in adult patients with LN:
 - 9 non-interventional studies,
 - 1 randomized clinical trial (RCT) with rituximab and standard of care (SoC)
 - 1 real-world evidence (RWE) study with induction therapy and cyclophosphamide.
- The studies were conducted in USA (n=5), multiple countries worldwide (n=3), Latin America (n=1) and Europe (n=2).



Results (cont'd)

BURDEN OF ACTIVE LN AND SEVERE RENAL IMPAIRMENT

- Patients with active LN** had significantly worse HRQoL measured by lupus-specific questionnaires such as LupusPRO and LupusQoL, compared to subjects with inactive LN or those with SLE only^{3,4}, with the most profound impact of active renal disease on fatigue, physical and emotional health. Among the most burdensome aspects of the disease, patients also indicated side effects of lupus medications, their impact on ability to have children, and the high number of lupus medications³ (Table 1, Figure 1).
- Active LN** was significantly associated with poor scores in almost all domains of SF-36 suggesting a deterioration in multiple aspects of life, especially in physical and emotional functioning (p<0.05), that was more pronounced compared to SLE manifestations in other organ systems.⁵

Table 1. Adult patients with LN, especially those with active disease, had significantly worse HRQoL compared to patients with SLE only or those with inactive LN

	Study comparison	LN vs control
GLOBAL	LN vs SLE (N=539 vs N=718) ³	Worse scores in LupusPRO medications, procreation, pain- vitality domains (p<0.03)
USA	LN vs SLE (N=67 vs N=138) ⁶	Lower disease activity, forgetfulness, muscle pain, and numbness in SLAQ assessment (p<0.05)
GLOBAL	Active vs Inactive LN (N=129 vs N=410) ³	Worse scores in LupusPRO symptoms, medications, procreation, emotional health, body image, and summary HRQoL domains (p<0.01)
USA	Active vs Inactive LN (N=34 vs N=33) ⁶	Worse SLAQ scores in disease severity and muscle pain domains (p<0.05)
USA	At least 1 flare vs no flares/year (SLE ± LN: N=904 vs N=162) ⁷	Worse LIT scores (p=0.001) and greater deterioration of HRQoL with increased flare frequency

Figure 1. Active LN significantly impacted patients' HRQoL measured by LupusQoL, compared to those with inactive LN or SLE only

Proportion of patients reporting impact of disease on LupusQoL by domain
GLADEL 2.0 cohort^{4*}

DOMAIN	ACTIVE LN (N=294)	INACTIVE LN (N=204)	SLE-ONLY (N=338)	p-value
Burden to Others	95.9%	80.9%	87.6%	<0.001
Emotional Health	95.2%	78.4%	86.7%	<0.001
Fatigue	93.2%	80.4%	86.7%	<0.001
Physical Health	91.5%	76.9%	85.5%	<0.001
Body Image	78.9%	62.8%	71.3%	<0.001
Planning	77.9%	50.9%	62.7%	<0.001
Pain	76.9%	55.9%	69.5%	<0.001
Intimate Relationships	54.8%	38.2%	48.2%	0.001

*LupusQoL responses within each domain were categorized as "never" or "present at different degree" and percentages reflect a positive response ("present"). Frequencies across SLE groups were compared using Chi-square or Fisher test, as appropriate.

Results (cont'd)

- Patients with severe renal impairment** (eGFR <30 ml/min) had significantly worse SF-36 scores pertaining to physical functioning and pain at diagnosis (p<0.01) compared to patients with normal eGFR values. Patients with LN and severe renal impairment also experienced further decline in physical and emotional well-being, adjusting for years after LN diagnosis, compared to patients with normal eGFR values.⁸

IMPACT OF CURRENT SoC ON HRQoL

- Over the last 10 years, only two studies evaluated impact of the current SoC therapy on HRQoL and well-being of patients with LN.
 - In a double-blind, placebo-controlled RCT, rituximab administered with SoC led to similar improvements in SF-36 physical functioning score after 1 year of therapy, compared to placebo and SoC (+4.8 vs +5.7, respectively; p=0.58).⁹
 - In a prospective RWE study conducted in the Dutch clinical practice, induction therapy with cyclophosphamide followed by mycophenolate reduced the overall symptom burden and distress associated with LN and other PROs, but without improvements in fatigue, the most burdensome symptom reported by 92% of patients at baseline.¹⁰

PATIENT AND PHYSICIAN SATISFACTION WITH CURRENT SoC

- Three studies examined the perspectives of patients with LN on facilitators of decision-making and satisfaction of disease control and treatment.
 - Physician- and patient-reported dissatisfaction with available therapy were reported by approximately 25% of nephrologists and 33% of patients and were associated with LN severity and various signs and symptoms of disease.¹¹
 - The key patient-relevant aspects of LN treatment were hope for being normal/healthy, improved quality of life and effective patient-physician communication regarding benefits and harms.^{12,13}

Conclusions

- LN significantly affects HRQoL across multiple domains of life, including physical and emotional functioning, that are particularly affected during periods of active disease and in patients with severe renal impairment.**
- There is very limited evidence on humanistic benefits of the current SoC therapy in LN from controlled trial settings and real-world practice.**
- Dissatisfaction with current therapies was reported in 1 in 3 patients and 1 in 4 physicians.**
- There is a high unmet need for expanding current therapeutic options for LN that would help improve patients' HRQoL.**

References

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