

Description and Healthcare Resource Utilization of Patients with Moderate or Severe Lupus using US Insurance Claims

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KEY FINDINGS & CONCLUSIONS

- Ethnicity plays an important role in lupus as highlighted by the higher proportion of AA with moderate and severe disease compared to patients of other ethnicities. Furthermore, organ involvement (including renal) was more prevalent in Asians, AA and Hispanics compared to Caucasians, regardless of disease severity
- Patients with moderate or severe lupus have distinct demographic and clinical characteristics, with a higher CCI, more prevalent clinical diagnoses and a higher mortality
- These patients also showed a low use of biologics and a high HRCU, highlighting the need for better treatment options
- Limitations include:
 - No direct validation to confirm disease severity
 - Risk of missing data, miscoding and under-reporting, inherent to claims
 - Possible impact of the COVID pandemic



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INTRODUCTION

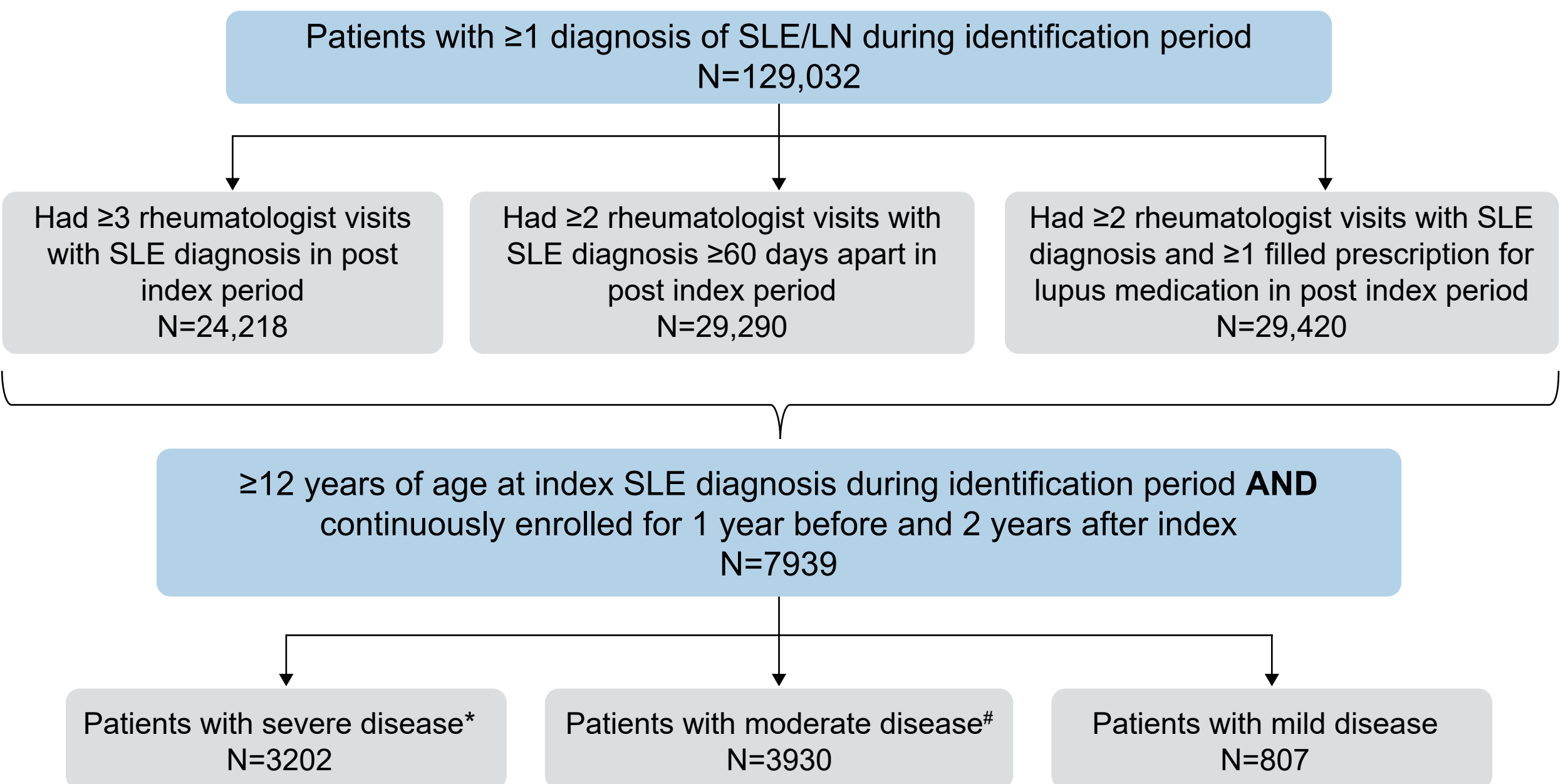
- Systemic lupus erythematosus (SLE), is a complex autoimmune disease with a heterogenous clinical presentation and effect on multiple organs¹⁻³
- Despite advances in the treatment of SLE, there is a significant unmet need for new and more effective therapies, particularly for patients with moderate to severe lupus
- Achieving and maintaining remission with current therapies remains challenging for these patients, often necessitating prolonged dependence on high doses of glucocorticoids which have undesirable effects on patients⁴⁻⁷
- Thus, there is a need for precise targeting of pathogenic cells to improve treatment efficacy and reduce toxicity in patients with moderate to severe disease
- However, to better channel the emerging therapies, to the right subpopulations, it is crucial to have a better understanding of the key demographics and clinical characteristics of patients with moderate to severe lupus

RESULTS

Patient Flow and Demographics

- A total of 129,032 patients with ≥1 SLE/LN diagnosis during the identification period were identified from the Optum CDM database (**Figure 1**). Of these patients, 7939 had 1-year of continuous enrollment (CE) during the pre-index period and 2 years of CE post-index. Within this population, 3202 patients were identified with severe lupus, 3930 with moderate lupus, and 807 with mild lupus
- Severe patients were slightly older than moderate and mild patients, with mean±SD age of 60.6±16.0, 55.2±15.4, and 54.0±16.5 years, respectively. Majority of patients were female, irrespective of disease severity. African American (AA), and Hispanic races were relatively prevalent across the 3 groups. A higher proportion of AA was observed in severe and moderate subpopulations (**Table 1**)

Figure 1. Patient flow



SLE, systemic lupus erythematosus

*Severe conditions are defined as having any of the following: Acute confusional state/psychosis, aortitis, arterial/venous thrombosis, aseptic meningitis, cardiac tamponade, cranial neuropathy, intestinal pseudo-obstruction, end stage renal disease, optic neuritis, pulmonary hemorrhage, stroke/transient ischemic attack
*Moderate conditions are defined as having any of the following: Acute pancreatitis, choroideritis, demyelinating syndrome/acute inflammatory demyelinating polyradiculoneuropathy, episcleritis/scleritis, hemolytic anemia, hepatitis (non-viral), ischemic necrosis of bone, nephritis, renal impairment other than nephritis or end stage renal disease, lupus enteritis/colitis, mononeuropathy/polymyoneuropathy, myelopathy, myocarditis, pericarditis, pleurisy/pleural effusion, pseudotumor cerebri, seizure, uveitis vasculitis (excluding aortitis)

Table 1: Patient demographics

Characteristic	Mild patients N=807	Moderate patients N=3,930	Severe patients N=3,202
Age (years), mean±SD	54.0±16.5	55.2±15.4	60.6±16.0
Gender, female, n (%)	727 (90.1)	3564 (90.7)	2797 (87.4)
Race, n (%)			
Caucasian	534 (66.2)	2437 (62.0)	1934 (60.4)
African American	103 (12.8)	631 (16.1)	671 (21.0)
Hispanic	107 (13.3)	580 (14.8)	399 (12.5)
Asian	40 (5.0)	156 (4.0)	108 (3.4)

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OBJECTIVE

- To identify patients with moderate or severe lupus in US insurance claims and describe their demographic and clinical characteristics as well as their health care resource utilization (HCRU)

METHODS

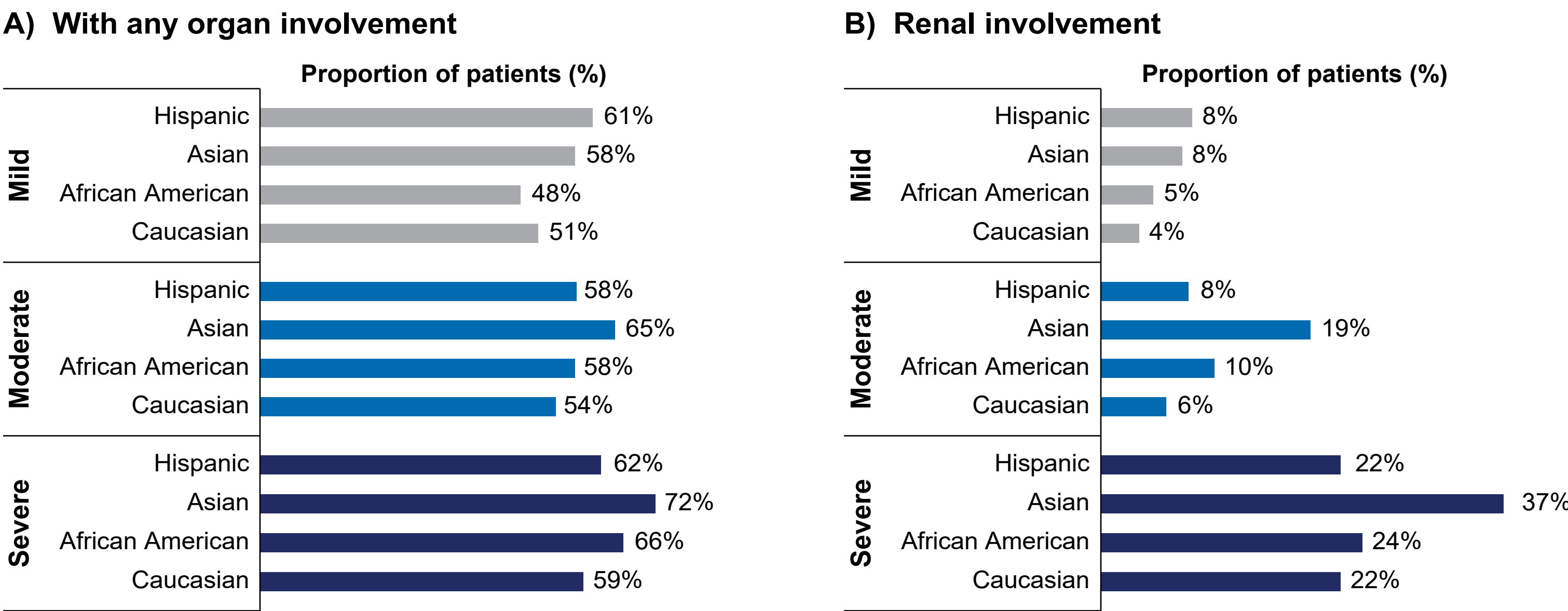
Study Design and Patients

- This was a non-interventional cohort study based on secondary data in the US using Optum's de-identified Clinformatics® Data Mart Databases
- This study identified adult patients diagnosed with moderate to severe SLE (with or without LN). An algorithm was developed by combining diagnostic codes (International Classification of Diseases version 10 [ICD-10] codes M32.1x, M32.8, and M32.9 for SLE, and M32.14 and M32.15 for LN), treatment episodes, and rheumatologist visits⁸
- The study period was from 01 January 2015 to 31 March 2023. Index date was defined as the start date when the moderate or severe stage of the disease was reached
- Lupus severity was determined based on the exposure to specific drugs and clinical events indicative of organ damage associated with moderate and severe stages. Disease severity defined as*:

Organ damage

- More than half of each subpopulation had organ involvement, post-index organ damage increased with severity (mild: 51.7%, moderate: 55.6%, severe: 61.6%) and the trend was even more marked for renal involvement (mild: 4.5%, moderate: 7.6%, severe: 18.2%)
- More Asians, AA and Hispanics have organ involvement (including renal) compared to Caucasians, regardless of their disease severity (**Figure 2**)

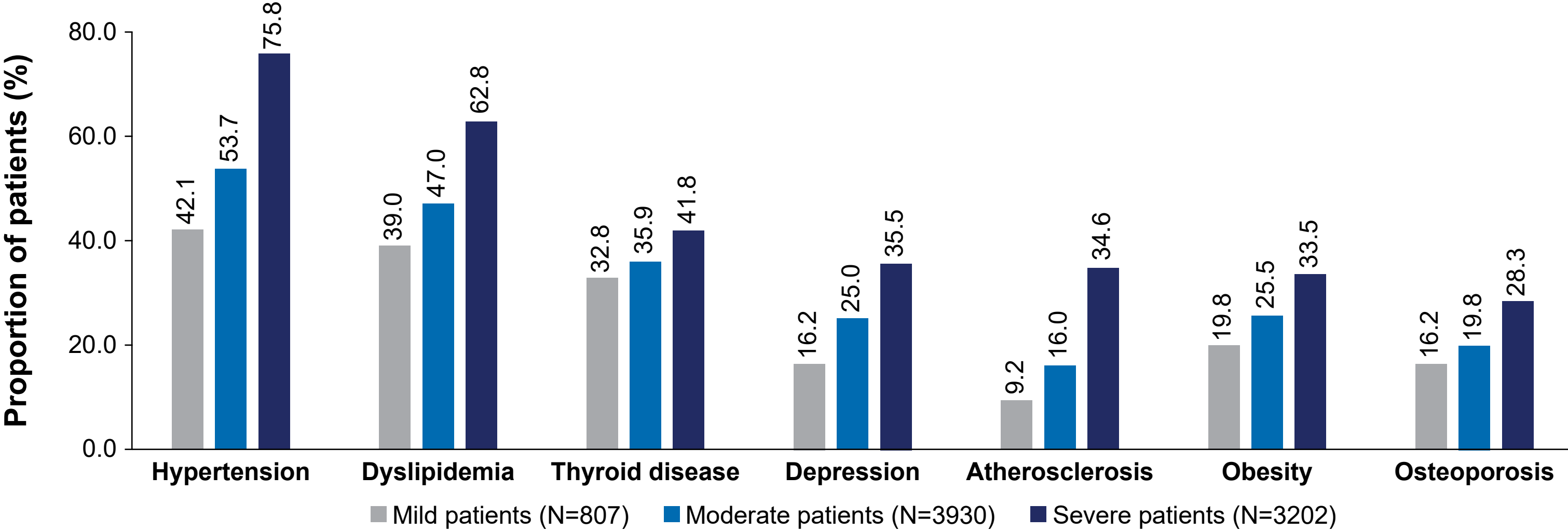
Figure 2. Organ damage in patients with lupus by disease severity and race A) Any organ involvement, B) Renal involvement



Comorbidities

- Mean±SD Charlson Comorbidity Index (CCI) score was highest for patients with severe disease (3.1±2.2) than patients with moderate (2.0±1.5) and mild disease (1.5±1.0). The most commonly reported comorbidities were hypertension, dyslipidaemia, thyroid and depression across three groups in 2-years post-index period. Patients with severe disease experienced a higher number of comorbidities versus those with moderate or mild disease (**Figure 3**) while some confounding factors such as age, different treatment exposures cannot be ignored

Figure 3. Most commonly reported clinical diagnoses (≥20%) in patients with lupus by disease severity (2-years post-index)



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Disclosures

PW, AH, BT and **PK** are employees of Novartis Ireland Limited, Dublin, Ireland and hold company stocks. **MK** is Novartis Pharmaceuticals UK Ltd., UK and hold company stocks. **CG** and **JM** are employees of Novartis Pharma AG, Switzerland and hold company stocks.

Severe disease:

- Had ≥1 filled prescription for cyclophosphamide or rituximab or oral corticosteroid with ≥60mg/day of prednisone equivalent dose
- OR**
- Had ≥1 non-laboratory claims with a diagnosis listed as “severe” where the diagnosis occurs in any position on the claim

Moderate disease:

- Had ≥1 non-laboratory claim with a diagnosis of a condition listed as “moderate” where the diagnosis occurs in any position on the claim
- OR**
- Had ≥1 filled prescription for an oral corticosteroid with a prednisone equivalent dose of ≥7.5mg/day and <60mg/day or for an immunosuppressive agent (other than cyclophosphamide)
- AND**
- Had no filled prescription for cyclophosphamide or rituximab or oral corticosteroid with ≥60mg/day of prednisone equivalent dose and no claims with a diagnosis of a “severe” condition

Study outcomes

- Demographic and clinical characteristics of the study population including organ damage and comorbidities as well as their HCRU were reported

Statistical analysis

- Descriptive statistics (n, %, min, max, mean, SD, median, IQR) were used to report the study outcomes

Use of biologics and mortality rate in entire follow up period

- Although, the use of biologics such as belimumab, rituximab and anifrolumab increased with disease severity (mild: 1.9%, moderate: 9.7%, severe: 16.8%), the overall use was low across the groups. Mortality rate (mild: 2.4%, moderate: 4.1%, severe: 15.0%) also increased with disease severity

HCRU

- Irrespective of the disease severity, around 90% of patients have visited their GP or internal medicine doctor within 2-years post-index and reported a high HCRU. For most medical services categories (GP, ER, inpatient, nephrology, cardiology and immunology visits), HCRU was at least doubled in the severe population compared to the mild population (**Table 2**)
- Asians have visited their nephrologist five times more often compared to Caucasians

Table 2. HCRU by disease severity

	2-year post-index period		
	Mild patients N=807	Moderate patients N=3930	Severe patients N=3202
Mean±SD HCRU visits per patient			
Number of office visits per patient	25.0±19.4	32.4±23.7	39.4±29.4
Number of GP or internal doctor visits per patient	5.7±5.8	7.8±8.3	10.0±10.6
Number of ER visits per patient	1.1±4.2	1.4±4.7	2.4±4.6
Number of inpatient visits per patient	0.1±0.3	0.2±0.6	1.0±1.6
Mean±SD specialist visits per patient			
Number of rheumatology visits per patient	5.2±3.5	6.4±6.2	6.1±6.7
Number of nephrology visits per patient	0.3±1.2	0.5±1.8	3.4±9.8
Number of cardiology visits per patient	1.0±2.5	1.9±4.2	4.9±8.0
Number of ophthalmology visits per patient	1.5±2.8	1.4±2.5	1.8±3.1
Number of immunology visits per patients	0.2±1.7	0.4±2.7	0.4±2.9

ER, emergency room; GP, general practitioner; HCRU, healthcare resource utilization, N number of patients in each group