

Symptom Burden of Patients with IgA Nephropathy In a Real World Setting Across Geographies

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Introduction

- Immunoglobulin A nephropathy (IgAN) is the most common form of primary glomerulonephritis worldwide¹.
- The estimated annual global incidence of IgAN is 25 per million, with the peak incidence observed in young adults aged 20–30 years².
- IgAN patients commonly present with symptoms such as proteinuria and hematuria³.
- Despite known symptoms, there is a limited availability of data on symptom burden in IgAN patients.
- The aim of this analysis was to better understand the symptom burden of IgAN patients at the time of diagnosis in a real world setting from a global perspective.

Methods

- Real world data were drawn from the Adelphi IgAN Disease Specific Programme (DSP), a point in time physician-based survey of nephrologists conducted between June and October 2021 across the United States (US), EU5 (France, Germany, Italy, Spain, and the United Kingdom), China, and Japan.
- The DSP methodology has been published previously in detail⁴.
- Ethics exemption was obtained from the Pearl Institutional Review Board and Hospital Clinic de Barcelona.
- Nephrologists completed structured online records for successive patients presenting with IgAN.
- Nephrologist completed forms that included information on: demographics, symptoms and clinical characteristics of the disease, lab/test values, treatment history including motivations for treatment choice and satisfaction, concomitant conditions, and healthcare resource use.
- The physician inclusion criteria for the IgAN DSP were:
 - Primary speciality in nephrology
 - Providing medical consultation to at least 1 eligible patient per month
 - Responsible for treatment decisions on drug therapy for patients with IgAN
- Only data on clinical characteristics and symptom burden of patients at diagnosis that have been reported by nephrologists were considered in this analysis.

Results

- In total, 295 nephrologists completed record forms for 1792 patients with IgAN. The mean patient age was 43.6 year and 59% were men (Table 1).
- Out of 1766 patients who had data on method of diagnosis, 1515 (86%) were diagnosed via a kidney biopsy and 251 (14%) were not diagnosed with kidney biopsy (Table 1).
- Clinical characteristics are presented in Table 2. Proteinuria, estimated glomerular filtration rate (eGFR), systolic and diastolic blood pressure levels were recorded by physicians at the time of diagnosis.
- The most commonly occurring physician-reported clinical characteristics (proteinuria and hematuria) stratified by geography are depicted in Figure 1.
- Proteinuria/foamy urine:** This was the most commonly occurring physician-reported clinical characteristic at diagnosis with 74% in the overall population. The proportion was highest in China (83%), followed by EU5 (72%), US (69%), and Japan (68%).
- Hematuria/visible blood in urine:** This was the next commonly occurring physician-reported clinical characteristic in the overall population (64%). Among all geographies, EU5 reported the highest proportion of patients with hematuria (71%) followed by Japan (70%), US (68%), and China (53%).

Abbreviations

BMI: Body Mass Index; DSP: Disease Specific Programme; eGFR: Estimated Glomerular Filtration Rate; EU5: France, Germany, Italy, Spain, and the United Kingdom; IgAN: Immunoglobulin A Nephropathy; Q1: 1st Quartile; Q3: 3rd Quartile; SD: Standard Deviation; US: United States;

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Conclusions

- This comprehensive study across various geographies presents evidence that IgAN patients have substantial symptomatic burden at diagnosis.
- The symptom burden of IgAN could affect patient health-related quality of life and usual activities, which may be particularly impactful given the relatively young age of this population.
- Symptom burden patterns vary across geographies, with some symptoms reported more frequently than others in different countries.
- As many therapies are under development for IgAN, there is an opportunity to investigate in more depth the diverse symptom burden of these patients beyond proteinuria and GFR assessments, for example such as incorporating quality of life instruments.

Results

Table 1. Patient demographics and diagnosis through biopsy by geographical regions

| | US | EU5 | China | Japan | All regions |
|--|--------------|-------------|--------------|--------------|--------------|
| Number of patients, n | 305 | 618 | 587 | 282 | 1792 |
| Age, mean (SD) | 44.7 (14.71) | 45 (14.91) | 39.8 (13.74) | 47.1 (16.22) | 43.6 (14.96) |
| Sex, male, n (%) | 169 (55%) | 413 (67%) | 329 (56%) | 141 (50%) | 1052 (59%) |
| BMI, mean (SD) | 26.1 (4.71) | 25.5 (4.33) | 23 (2.64) | 22.8 (3.90) | 24.3 (4.11) |
| Number of patients, n | 301 | 606 | 577 | 282 | 1766 |
| Diagnosis confirmed via kidney biopsy, n (%) | 265 (88%) | 484 (80%) | 489 (85%) | 277 (98%) | 1515 (86%) |

Abbreviations: BMI: Body Mass Index; EU5: France, Germany, Italy, Spain, and the United Kingdom; SD: Standard Deviation; US: United States

Table 2. Clinical characteristics of IgAN patients at diagnosis

| | US | EU5 | China | Japan | All regions |
|--|---------------|---------------|---------------|----------------|---------------|
| Proteinuria (g/day) (n) | 234 | 470 | 467 | 212 | 1383 |
| Mean (SD) | 2.7 (6.31) | 3.1 (4.31) | 3.8 (11.99) | 1.1 (0.90) | 3 (7.90) |
| Median (Q1-Q3) | 2 (1-3) | 1.9 (1-4) | 2 (1.1-3.1) | 1 (0.5-1.4) | 1.7 (0.9-3) |
| eGFR (ml/min/1.73m²) (n) | 240 | 467 | 438 | 213 | 1358 |
| Mean (SD) | 58.1 (25.70) | 63.7 (30.21) | 83.9 (28.91) | 66.8 (21.41) | 69.7 (29.54) |
| Median (Q1-Q3) | 55.5 (40-78) | 66 (41-87) | 86 (62.5-100) | 68 (51.5-82.9) | 70 (49-90) |
| Systolic blood pressure (mmHg) (n) | 159 | 362 | 311 | 75 | 907 |
| Mean (SD) | 141.9 (18.99) | 147.6 (19.78) | 135 (18.85) | 127 (14.46) | 140.6 (20.08) |
| Median (Q1-Q3) | 142 (127-154) | 150 (135-160) | 135 (123-146) | 124 (120-136) | 140 (125-155) |
| Diastolic blood pressure (mmHg) (n) | 150 | 360 | 309 | 75 | 894 |
| Mean (SD) | 84.1 (11.43) | 86.8 (10.65) | 83.1 (11.96) | 73.3 (11.71) | 83.9 (11.88) |
| Median (Q1-Q3) | 84 (78-90) | 90 (80-94) | 85 (75-90) | 72 (66-80) | 85 (77-90) |

Abbreviations: eGFR: Estimated Glomerular Filtration Rate; EU5: France, Germany, Italy, Spain and the United Kingdom; Q1: 1st Quartile; Q3: 3rd Quartile; SD: Standard Deviation; US: United States

Table 3. Symptom burden of IgAN patients at diagnosis

| | US n=302 | EU5 n=597 | China n=567 | Japan n=264 | All regions N=1730 |
|--|----------|-----------|-------------|-------------|--------------------|
| Edema (swelling) in extremities | 36% | 37% | 49% | 19% | 38% |
| Discolored urine | 30% | 22% | 36% | 12% | 27% |
| Fatigue | 32% | 27% | 31% | 6% | 26% |
| Pain in back/sides/abdomen | 12% | 16% | 22% | 2% | 15% |
| Appetite loss | 11% | 7% | 15% | 3% | 10% |
| Sleep problems | 7% | 8% | 11% | 3% | 8% |
| Aching joints | 12% | 7% | 9% | 2% | 8% |
| Headaches/migraine | 7% | 10% | 8% | 2% | 7% |
| Nausea | 6% | 6% | 11% | 3% | 7% |
| Gastrointestinal pain | 9% | 9% | 4% | 2% | 6% |
| Drowsiness | 9% | 5% | 8% | 2% | 6% |
| Muscle cramps | 6% | 5% | 2% | 1% | 4% |

Key to the proportions depicted in the heat map

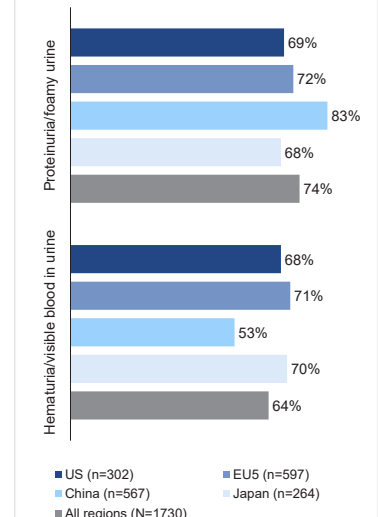
Abbreviations: EU5: France, Germany, Italy, Spain and the United Kingdom; IgAN: Immunoglobulin A Nephropathy; US: United States

Results

Symptom Burden

- The physician reported symptom burden in IgAN patients at diagnosis across various geographies is presented in Table 3.
- Edema in extremities:** Overall, edema was a commonly reported symptom. It was reported most often in Chinese patients (49%) and least often in Japanese patients (19%).
- Discolored urine:** This was the next commonly reported symptom with 27% in the overall population. The proportion was highest in China (36%) and lowest in Japan (12%).
- Fatigue:** Overall, 26% of patients presented with fatigue at diagnosis. US patients showed the highest reporting (32%), followed by China (31%), EU5 (27%), and Japan (6%).
- Pain in back/sides/abdomen:** 15% of all patients suffered from this symptom. It was most common in Chinese patients (22%) and least reported in Japanese patients (2%).
- Appetite loss:** Among all geographies, appetite loss was most commonly reported in Chinese patients (15%) and least often in Japanese patients (3%).
- Overall, sleep problems, aching joints, headaches/migraine, nausea, gastrointestinal pain, drowsiness, and muscle cramps were reported in less than 10% of patients.
- Overall, variations in the symptom burden across different geographies was observed. Chinese patients showed a slightly higher symptom burden when compared to other geographies and Japanese patients reported fewer symptoms overall.

Figure 1. Most commonly occurring physician-reported clinical characteristics of IgAN patients at diagnosis by geographical region



Limitations

- Patients included in this study were successive patients presenting with IgAN in the nephrologist's practice; therefore, it is not a truly random sample and may not truly represent the overall population of patients.
- The quality of the data depends on the reporting accuracy information by physician and patients which may be subjected to recall bias.

Disclosures

- Data collection for the DSP was undertaken by Adelphi Real World as part of an independent survey and data is owned by Adelphi. Novartis is one of multiple subscribers to this DSP and supported this analysis.
- Richard Lafayette has received research funding from NIH, UMichigan, Omeros, Vera, Traverre, Pfizer, Roche, Chinook, Alexion, Otsuka, Calilditas and NephroNet. He has provided consultancy for Alexion, Omeros, Vera, Traverre, Pfizer, Roche, Calilditas, Chinook, Aurinia, GSK, Otsuka, Novartis.
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