

Title:**The Diagnostic Journey of Patients with Immunoglobulin A Nephropathy: Data Analysis of a Real-World Survey**

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Background and Aims: Although rare (estimated global annual incidence of 25 cases per million people), immunoglobulin A nephropathy (IgAN) is the most common form of primary glomerulonephritis. IgAN is associated with a poor prognosis, with 30% or more of patients with >1g/day of proteinuria progressing to kidney failure within 10 years. As poor prognosis is partly due to delayed diagnosis, this analysis aims to describe aspects of the diagnostic pathway for patients with IgAN.

Method: Data were drawn from the Adelphi IgAN Disease Specific Programme (DSP)[™], a point-in-time survey of IgAN-treating nephrologists and their consulting patients, conducted in the United States (US), Europe (EU5: France, Germany, Italy, Spain, United Kingdom [UK]), Japan, and China, between June and October 2021. Nephrologists completed structured online patient record forms for successive patients presenting with IgAN, including demographics, clinical data, time to diagnosis, reasons for delayed diagnosis, and treatment history. A duration of greater than four weeks between first consultation with a physician and diagnosis was considered a delayed diagnosis.

Results: A total of 295 nephrologists completed records for 1537 patients which had data characterizing the time from first consultation and diagnosis. Mean (standard deviation (SD)) patient age was 43.0 (15.0) years, and 59% were male. At diagnosis, mean (SD) proteinuria (n=1254) was 2.3 (2.4).

Median time from first physician consultation to confirmed IgAN diagnosis varied by physician speciality. When patients initially consulted a nephrologist regarding their IgAN symptoms, median (interquartile range) duration from first consultation to diagnosis was 2.4 (0.7-5.6) weeks (n=582). For family doctors/ General Practitioners (GPs)/ Primary Care Physicians (PCPs) (n=656), this was 6.6 (3.0-13.8) weeks, for internal medicine/ internists (n=120) and urologists (n=113) the duration was 4.4 (1.3-9.4 and 1.5-12.5) weeks. Most patients were diagnosed by a nephrologist (US 95%, n=263; EU5 96%, n=491; Japan 99%, n=236; China 98%, n=547).

A delayed diagnosis was found in 56% of patients. Across countries, waiting to conduct tests (41%), waiting for referral to a specialist (34%) and waiting for test results (32%)

were the top three reasons for delay, except for Japan where 29% of patients were unable to consult sooner. A smaller proportion of patients who experienced a delay initially consulted with a nephrologist (27%) compared to those who did not experience a delay (52%). 78% of patients in China, diagnosed within 4 weeks, were diagnosed by a nephrologist. Of the patients who experienced a delay in diagnosis, a higher proportion initially consulted a family doctor/ GP/ PCP (53%) compared to other physician types.

In most cases, a kidney biopsy was used for diagnosis (US 89%, n=263; EU5 81%, n=491; Japan 98%, n=236; China 85%, n=547) and these were typically performed by a nephrologist in most countries (US 59%, n=233; EU5 81%, n=397; Japan 95%, n=231; China 97%, n=464) except in the US, where 40% of cases were done by a radiologist. However, some patients were unable to undergo a biopsy (6%, n=1531) and in some cases the physician chose to diagnose the patient using non-invasive methods (8%, n=1531).

Conclusion: Most of the patients with IgAN in this survey were diagnosed by a nephrologist using a kidney biopsy. These data suggest that initially consulting a family doctor/ GP/ PCP led to a delayed diagnosis for patients. This may be due to the time taken for onward referral to a nephrologist. China had the highest proportion of patients diagnosed within 4 weeks from the first consultation (57%) and the highest proportion of patients who first visited a nephrologist regarding their symptoms. The results from this study suggest that speeding up referral from PCPs to nephrologists may reduce the amount of time taken to confirm IgAN diagnosis.