Poster IR029

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Stratifying Home-Reported Outcomes by Time Since Diagnosis in IgAN: Methodology and Early Findings

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KEY FINDINGS & CONCLUSIONS

- HRO data capture provides a detailed view of symptom burden in IgAN
- Although sample sizes were small, preliminary results suggest patients diagnosed ≥5 years ago may be experiencing fewer symptoms and achieving improved PRO scores compared with those diagnosed more recently, except for those diagnosed ≤1 year ago
  - This may reflect a recent trend toward increased condition awareness and changes in diagnostic patterns
  - These early findings also highlight the population heterogeneity in IgAN
- The ongoing IgAN Bridge study will continue to assess the potential of HRO data to reveal how length of time since diagnosis impacts symptom patterns and management

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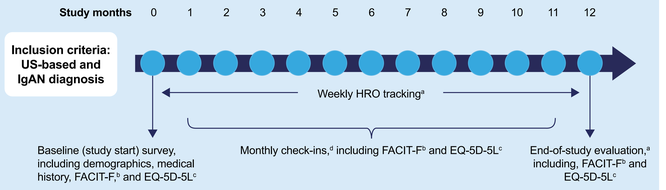
INTRODUCTION

- Immunoglobulin A nephropathy (IgAN) is the most common form of primary glomerulonephritis globally, with an incidence of ~2.5 cases per 100,000 adults per year[1,2]
- Marked heterogeneity exists in multiple disease aspects for IgAN, including disease progression[3]
  - IgAN progresses to kidney failure in ~50% of patients within 10–20 years[4-6]
- There are limited data on how patients manage their disease burden outside of clinical settings[7]
- Home-reported outcomes (HROs), reported as often as daily and defined by each patient's individual priorities, offer a more granular view of disease burden and treatment experience compared with standardized patient-reported outcomes (PROs)
- Collecting HROs alongside standardized PROs can provide a comprehensive yet individualized understanding of the experience of patients with IgAN
- Additionally, stratifying HRO data based on time since diagnosis allows:
  - Creation of a cross-sectional view of how individuals report their current experience with IgAN at different time points
  - Better insights into how patients' needs and experiences may evolve over time, helping to identify where additional support may be needed
- Here, we present a preliminary analysis assessing how the length of time since diagnosis affects patient-reported experiences, such as symptom burden, in the ongoing IgAN Bridge study

METHODS

- The IgAN Bridge study is an ongoing, remote, prospective, 12-month observational study (NCT06952426)[8] using the Folia Health mobile app to collect HROs, supplemented by PROs, from patients with IgAN in the US
- The primary objective is to gain a comprehensive understanding of the patient-reported burden of IgAN using HRO symptom tracking data
- The study will enroll at least 300 participants, comprising ~75% self-reporting adults and ~25% caregivers reporting on behalf of children with IgAN. Details of the study design have been presented previously[9]
- During the IgAN Bridge study, participants are required to (**Figure 1**):
  - Report on their demographics, health status, and treatment satisfaction at enrollment
  - Customize their mobile app profile at enrollment by selecting symptoms and treatments to track as HROs
    - Participants can choose symptoms and observations outside of the predefined selections
    - Changes in symptoms, treatment plans, treatment utilization, and any flare events are required to be tracked at least once per week
  - Complete monthly surveys assessing health-related quality of life (HRQoL), including Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-F) and EuroQol 5-Dimension 5-Level (EQ-5D-5L), starting at enrollment
  - Complete an end-of-study evaluation survey
- Data tracked by study participants will be automatically summarized into trend reports that can be used during medical appointments to inform their care directly

Figure 1. Study Design



[a]Changes in symptoms (incidence, severity), changes to treatment plans, treatment utilization (including non-use), and any flare events (heightened symptom severity vs baseline) are required to be tracked at least once per week. [b]The FACIT-F total scores range from 0 to 52, with higher scores indicating less fatigue. [c]The EQ-5D-5L Index scores range from less than 0 to 1, with higher scores indicating better HRQoL; and VAS scores range from 0 to 100, with higher scores indicating better self-rated health. [d]The monthly check-in questions include topics such as missed school or work, satisfaction with treatment (and any changes to treatment), and flares. [e]The end-of-study evaluation comprises monthly check-in questions with additional questions regarding study experience and perceived value.

EQ-5D-5L, EuroQol 5-Dimension 5-Level; FACIT-F, Functional Assessment of Chronic Illness Therapy – Fatigue; HRO, home-reported outcome; HRQoL, health-related quality of life; IgAN, immunoglobulin A nephropathy; US, United States; VAS, visual analog scale.

RESULTS

Baseline Disease Characteristics

- Enrollment began in March 2025, and as of September 2025, preliminary analysis has been conducted on 46 participants
- Participants had a mean ± standard deviation (SD) age of 36.1 ± 12.7 years, 43% were female, 37% were White, and one-third reported a bachelor's degree as their highest level of education (**Table 1**)
- At enrollment, time since IgAN diagnosis varied, with 30% of participants diagnosed ≤1 year ago; 41% of participants did not provide a response
  - Mean age at enrollment for participants diagnosed ≤1, >1 to ≤2, >2 to <5, and ≥5 years ago ranged between 32 and 42 years (**Table 2**)

Table 1. Demographic Characteristics of Participants at Baseline

Characteristic	Enrolled participants (N = 46)
Mean age ± SD, years	36.1 ± 12.7
Sex, n (%)	
Male	7 (15%)
Female	20 (43%)
Did not answer	19 (41%)
Race or ethnic group, n (%)	
Asian	5 (11%)
Black or African American	0
White or Caucasian	17 (37%)
Other[a]	1 (2%)
Prefer not to answer	1 (2%)
Selected more than one race	3 (7%)
Did not answer	19 (41%)
Highest level of education, n (%)	
High School Diploma	7 (15%)
Bachelor's degree	15 (33%)
Master's degree	4 (9%)
Trade School	1 (2%)
Did not answer	19 (41%)

[a]Includes Native American or Alaska Native, Native Hawaiian or Other Pacific Islander, or a different race or ethnic group not listed.
SD, standard deviation.

Table 2. Disease Characteristics Stratified by Time Since IgAN Diagnosis (N = 46)

Time since IgAN diagnosis, category	≤1 year (n = 14)	>1 to ≤2 years (n = 5)	>2 to <5 years (n = 5)	≥5 years (n = 3)	Did not answer (n = 19)
Mean ± SD time since IgAN diagnosis, months	2.6 ± 3.3	19.6 ± 3.1	31.8 ± 5.6	375.3 ± 140.5	N/A
Mean ± SD age at study enrollment, years	34.9 ± 11.5	40.4 ± 9.1	32.2 ± 18.1	42.0 ± 7.0	36.0 ± 13.9

IgAN, immunoglobulin A nephropathy; N/A, not available; SD, standard deviation.

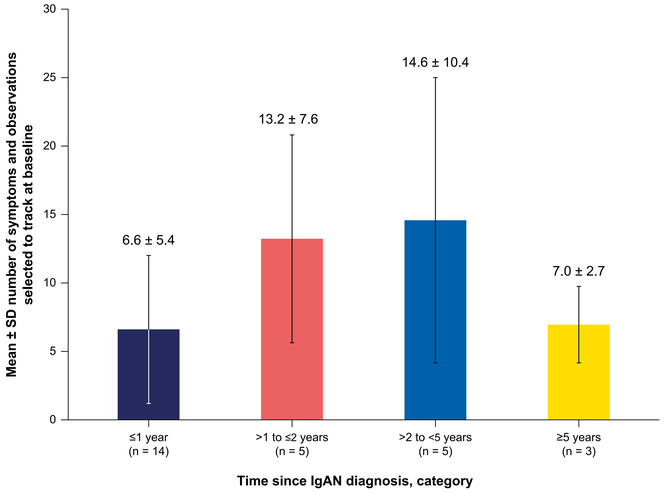
Patient-Selected Symptoms and Observations Tracked as HROs, Stratified by Time Since IgAN Diagnosis

- All 46 participants selected symptoms and observations to track as HROs during the study (**Figure 2**)
- Those diagnosed with IgAN ≥5 years ago added fewer symptoms and observations (mean ± SD: 7.0 ± 2.7) compared with those diagnosed >1 to ≤2 years ago and >2 to <5 years ago (mean ± SD: 13.2 ± 7.6 and 14.6 ± 10.4, respectively)
- Participants diagnosed ≤1 year ago added the fewest symptoms and observations (mean ± SD: 6.6 ± 5.4)

Baseline Responses to PROs, Stratified by Time Since IgAN Diagnosis

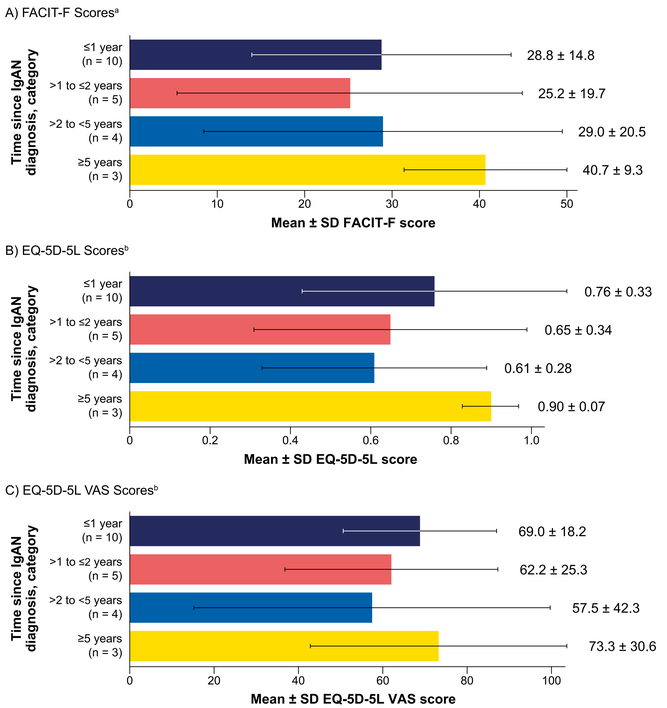
- Twenty-two of 46 participants had completed baseline PROs at the time of analysis
- Mean ± SD FACIT-F scores were 40.7 ± 9.3 in those diagnosed ≥5 years ago compared with 28.8 ± 14.8, 25.2 ± 19.7, and 29.0 ± 20.5 in those diagnosed ≤1, >1 to ≤2, and >2 to <5 years ago (**Figure 3A**)
- Mean ± SD EQ-5D-5L scores were 0.90 ± 0.07 in those diagnosed ≥5 years ago compared with 0.76 ± 0.33, 0.65 ± 0.34, and 0.61 ± 0.28 in those diagnosed ≤1, >1 to ≤2, and >2 to <5 years ago (**Figure 3B**)
- Mean ± SD EQ-5D-5L visual analog scale (VAS) scores were generally similar by time since IgAN diagnosis: 69.0 ± 18.2, 62.2 ± 25.3, 57.5 ± 42.3, and 73.3 ± 30.6 in those diagnosed ≤1, >1 to ≤2, >2 to <5, and ≥5 years ago (**Figure 3C**)

Figure 2. Patient-Selected Symptoms and Observations Tracked as HROs, Stratified by Time Since IgAN Diagnosis



HRO, home-reported outcome; IgAN, immunoglobulin A nephropathy; SD, standard deviation.

Figure 3. Baseline Responses to PROs, Stratified by Time Since IgAN Diagnosis



[a]The FACIT-F total scores range from 0 to 52, with higher scores indicating less fatigue. [b]The EQ-5D-5L Index scores range from less than 0 to 1, with higher scores indicating better HRQoL; and VAS scores range from 0 to 100, with higher scores indicating better self-rated health.
EQ-5D-5L, EuroQol 5-Dimension 5-Level; FACIT-F, Functional Assessment of Chronic Illness Therapy – Fatigue; HRQoL, health-related quality of life; IgAN, immunoglobulin A nephropathy; PRO, patient-reported outcome; SD, standard deviation; VAS, visual analog scale.

Limitations

- All data collected will be self-reported, and as participants have different lived experiences of IgAN, this may impact on the longitudinal tracking patterns and volume of data each participant contributes
- Selection bias could affect the type of participants, as the study requires baseline technology literacy

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Abbreviations

EQ-5D-5L, EuroQol 5-Dimension 5-Level; FACIT-F, Functional Assessment of Chronic Illness Therapy – Fatigue; HRO, home-reported outcome; HRQoL, health-related quality of life; IgAN, immunoglobulin A nephropathy; N/A, not available; PRO, patient-reported outcome; SD, standard deviation; US, United States; VAS, visual analog scale.

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Disclosures

BN and **RK** are employees of Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA. **SM**, **CZ**, **AH**, **HA**, and **SV** are employees of Folia Health, Boston, MA, USA.