Poster SA-PO0773

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Baseline Characteristics and Treatment Satisfaction of Patients (Pts) Enrolled in Immunoglobulin A Nephropathy (IgAN) Bridge: Interim Results From a Home-Reported Outcomes (HROs) Study

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KEY FINDINGS & CONCLUSIONS

- In this small initial sample, participants selected different symptoms and clinical variables to track, including objective clinical data such as blood pressure and weight
  - Fatigue was the most frequently tracked symptom selected by 74% of participants
- Mean baseline FACIT-F, EQ-5D-5L, and EQ-5D-5L VAS scores of participants were 29.8, 0.7, and 66.0, respectively
  - This is lower than what has been reported in the general population, 43.6, 0.85, and 80.4, respectively, suggesting some impairment of participants' perceived health[10,11]
- Treatment satisfaction varied at baseline, and participants with lower treatment satisfaction had greater baseline fatigue severity scores
- This heterogeneity highlights the need to understand the diverse experiences and symptom burden of patients with IgAN
- The ongoing IgAN Bridge study will continue to track HROs and PROs to gain a more comprehensive understanding of patients' lived experiences with IgAN

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This study was funded by Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA.

Poster presented at ASN Kidney Week 2025, November 5–9, 2025, Houston, TX, USA.

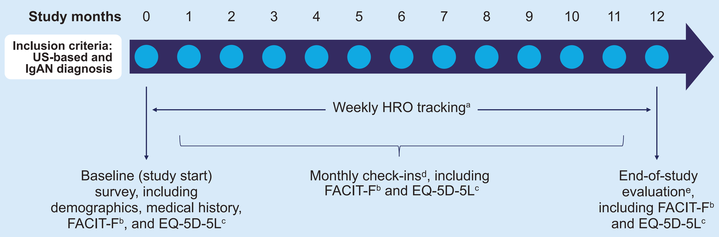
INTRODUCTION

- 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,[4,5] and most experience a worsening in kidney function[6]
- There are limited data on how patients manage disease burden outside of clinical settings[7]
- Real-world insights from patients regarding symptoms, disease burden, and treatment effects can be captured by tracking HROs:
  - HROs can enable patients to identify and track their self-identified most bothersome symptoms, alongside treatment preferences and utilization patterns
  - Collecting HROs alongside standardized PROs can provide a comprehensive yet individualized understanding of the IgAN patient experience
- Here, we present an interim analysis of baseline characteristics, disease burden, and treatment patterns of patients with IgAN enrolled 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 United States
- The primary objective is to gain a comprehensive understanding of the patient-reported burden of IgAN using HRO symptom tracking data
- The study will aim to enroll at least 300 participants, comprising ~75% self-reporting adults with IgAN 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 may choose symptoms and observations outside of the predefined selections
    - Each symptom is scored on a scale of 0 (absent) to 5 (most severe)
    - 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 HRQoL, including FACIT-F and EQ-5D-5L, starting at enrollment
    - The EQ-5D-5L index score reflects a weighted summary of health status across specific domains reflecting the general population, while the EQ-5D-5L VAS score captures the patient's own overall, subjective assessment of their health
  - Complete an end-of-study evaluation survey
- Data tracked by study participants will be automatically summarized into trend reports and can be reviewed 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 treatments), and flares. [e]The end-of-study evaluation is composed of monthly check-in questions along with additional questions regarding the 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 Characteristics

- Enrollment began in March 2025, and interim analysis has been conducted as of September 2025 on 46 participants, of which 97.8% (n = 45) were adults and 2.2% (n = 1) were pediatric patients
- Participants had a mean ± 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**)

Disease Burden

- Participants selected 42 IgAN symptoms and observations at baseline to track as HROs
  - Of the top 10 most commonly tracked IgAN symptoms and observations, fatigue was the most frequently selected (74%); additionally, 74% of participants selected to track blood pressure (**Figure 2**)
  - Participants' disease experience appeared heterogeneous based on the number of symptoms selected for tracking: most (57%) selected ≥7, 13% selected 5–6, 7% selected 3–4, and 4% selected 1–2; the remaining 20% selected none at the time of analysis
- Participants also selected 58 different IgAN treatments at baseline to track as HROs
  - Of the top 10 most commonly tracked IgAN treatments, SGLT-2is (24%) and fish oil (17%) were the most frequently selected (**Figure 3**)
  - Most participants (87%) selected ≤4 treatments for tracking, while 4% selected 5–6, and 9% selected ≥7 treatments for tracking
  - Overall, 22% of participants selected ACEis, 13% of participants selected ARBs, and 24% of participants selected SGLT2is; 46% of participants selected at least one of ACEis, ARBs or SGLT2is
- Among participants who selected fatigue as an HRO (n = 34):
  - Baseline symptom severity scores were: 1–2 in 11 (32%), 3–4 in 18 (53%), and 5 in 4 (12%) participants, indicating mild to moderate levels of fatigue
- Among participants who also completed baseline PROs (n = 22):
  - Mean ± SD baseline FACIT-F (0 to 52 scale) score was 29.8 ± 16.1, indicating a mild to moderate level of fatigue
  - Mean ± SD baseline EQ-5D-5L (<0 to 1 scale) score was 0.7 ± 0.3
  - Mean ± SD baseline EQ-5D-5L VAS (0 to 100 scale) score was 66.0 ± 25.3

Treatment Satisfaction

- Treatment satisfaction varied among the 46 participants at baseline: 8 reported being "very satisfied"; 9 were "somewhat satisfied"; 5 were "not satisfied"; 5 were "not currently taking IgAN medication"; 19 did not answer (**Figure 4**)
- Notably, treatment satisfaction also varied by baseline fatigue scores (**Figure 4**):
  - Among participants who were "very satisfied," 50% had a baseline fatigue severity score of 1–2, compared with 25% with a score of 3–4

Limitations

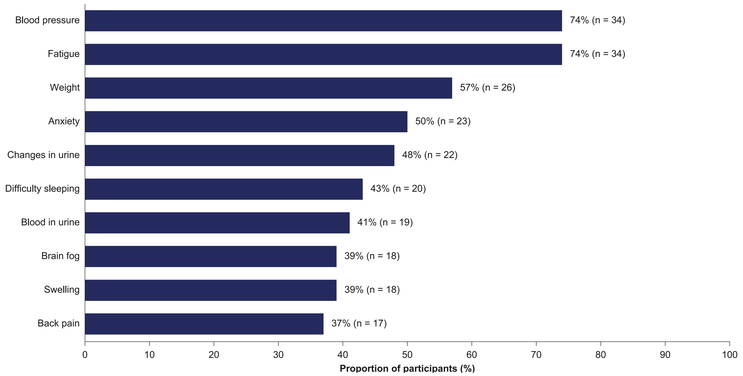
- All data collected will be self-reported, and this may impact the longitudinal tracking patterns and volume of data each participant contributes, as participants have different lived experiences of IgAN
- Selection bias could affect the type of participants, as the study requires baseline technology literacy. Additionally, participants may represent a subgroup with either more symptoms or more willingness to report symptoms

Table 1. Demographic Characteristics of Participants at Baseline

Characteristics	Enrolled participants (N = 46)
Mean age ± SD, years	36.1 ± 12.7
Adults participants (n = 45)	36.6 (±12.2)
Pediatric participants (n = 1)	11 (N/A)
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)

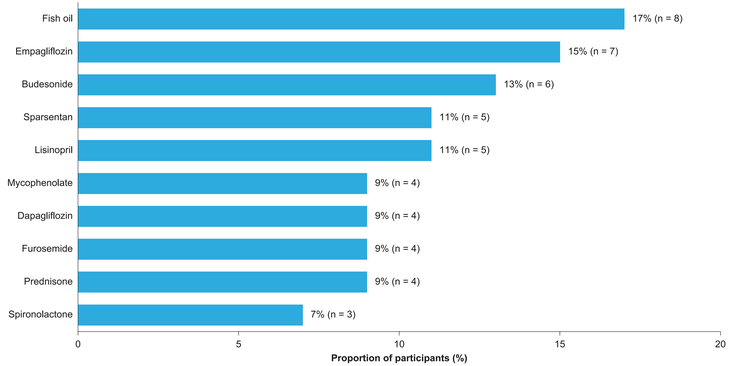
[a]Includes Native American or Alaska Native, Native Hawaiian or Other Pacific Islander, or a different race or ethnic group not listed.
N/A, not applicable; SD, standard deviation.

Figure 2. Top 10 IgAN Symptoms and Observations Selected by Participants at Baseline (N = 46)[a]



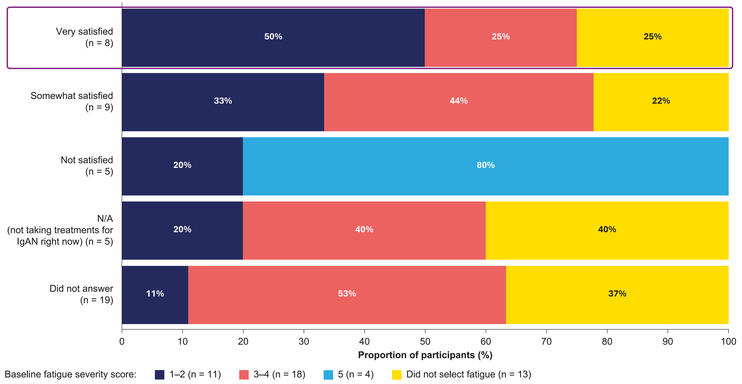
[a]This interim analysis included 46 participants who selected a total of 42 IgAN symptoms or observations to track during the study.
IgAN, Immunoglobulin A nephropathy.

Figure 3. Top 10 IgAN Treatments Selected by Participants at Baseline (N = 46)[a]



[a]This interim analysis included 46 participants who selected a total of 58 IgAN treatments to track during the study.
IgAN, immunoglobulin A nephropathy.

Figure 4. Treatment Satisfaction by Baseline Fatigue Severity Score



IgAN, immunoglobulin A nephropathy; N/A, not applicable.

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Abbreviations

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; 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 applicable; PRO, patient-reported outcome; SD, standard deviation; SGLT2i, sodium-glucose cotransporter-2 inhibitor; US, United States; VAS, visual analog scale.

Acknowledgments

Writing support was provided by Sharmin Bovill, PhD (BOLDSCIENCE Ltd., UK), and was funded by Novartis Pharmaceuticals Corporation. This poster was developed in accordance with Good Publication Practice (GPP) guidelines. The authors had full control of the content and made the final decision on all aspects of this publication.

Disclosures

BN, **RT**, and **HT** are employees of Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA. **PC** has provided paid consultations to Novartis, Otsuka Pharmaceuticals, Takeda Pharmaceuticals, Travere Therapeutics, and Vera Therapeutics; and has participated in clinical trials sponsored by Calliditas Therapeutics, Novartis, Sanofi, Vertex, and Travere Therapeutics. **HA**, **LS**, **CZ**, **SM**, **AH**, **JO**, and **SV** are employees of Folia Health. **AA** and **AR** have nothing to disclose. **MN** is an employee of Baylor Scott & White Medical Center; and has received research funding from Novartis.