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Immunoglobulin A Nephropathy Patient Reported Health Utility and Quality of Life: Evidence from Real-world Data

Richard Lafayette[1], Carolina Aldworth[2], Aneesh Thomas George[3], Jonathan de Courcy[4], Keisha Golden[4], Michel Kroes[5], Clare Proudfoot[5], Briana Ndife[2]

[1]Stanford University Medical Center, Stanford, California, United States; [2]Novartis Pharmaceuticals Corporation, East Hanover, New Jersey, United States; [3]Novartis Healthcare Private Limited, Hyderabad, India; [4]Adelphi Real World, Bollington, United Kingdom; [5]Novartis Pharma AG, Basel, Switzerland

Introduction

- Immunoglobulin A nephropathy (IgAN) is a rare kidney disease with an annual incidence of ~25 per million worldwide[1].
- Patients with IgAN commonly present with clinical manifestations including proteinuria, hematuria, hypertension and deteriorating kidney function (estimated glomerular filtration rate; eGFR), which impact their quality of life (QoL)[2,3].
- Approximately 50% of patients with IgAN who have proteinuria ≥1 g/day progress to kidney failure within 15 years, despite current therapies like renin angiotensin system inhibitors and corticosteroids or other immunosuppressive agents[4].
- There are limited published health utility and QoL data from patients with IgAN in clinical practice to date. This analysis aimed to report patient-reported QoL and utility scores from a multi-country study.

Methods

- The Adelphi IgAN Disease Specific Programme (DSP) was a point-in-time survey of IgAN-treating nephrologists and their patients in the United States (US), France, Germany, Italy, Spain and the United Kingdom (EU5), China and Japan between June and October 2021.
- The DSP methodology has been published previously in detail[5].
- Ethics exemption was obtained from the Pearl Institutional Review Board and Hospital Clínic de Barcelona.
- Physicians reported patient demographics and clinical characteristics. Patients completed the following questionnaires:
  - EQ-5D-5L utility index score (1 = perfect health – 0 = death, US tariff).
  - EQ-VAS (0 worst to 100 best imaginable health).
  - Kidney Disease QoL-36 (KDQOL-36; higher scores = better QoL).
- Patients who answered all of the above questionnaires were split by proteinuria (P1: <1 g/day and P2: ≥1 g/day) and eGFR (G1: ≥45 mL/min/1.73m^2 and G2: <45 mL/min/1.73m^2).
- All analyses were descriptive.

Results

- At the time of survey, of the 883 patients with physician reported proteinuria data, 843 had responses for EQ-5D-5L, EQ-VAS and KDQOL-36 questionnaires (P1: 536, P2: 307). Similarly, of the 894 patients with physician reported eGFR data, 850 had responses for EQ-5D-5L, EQ-VAS and KDQOL-36 questionnaires (G1: 714, G2: 136).
- Mean patient age was 42 years, 56% of patients with matched proteinuria and 58% with matched eGFR were male respectively.

Health utility and QoL scores by proteinuria levels

- At the time of survey, the health utility and QoL scores were lower in patients with proteinuria ≥1 g/day (P2) compared to patients with proteinuria <1 g/day (P1) across all geographies (**Table 1**).
  - **EQ-5D-5L utility index:** the mean scores for all regions for the group split by proteinuria were 0.84 (P1: 0.87 vs P2: 0.79); highest in Japan (0.92) and lowest in China (0.81).
  - **EQ-VAS:** the mean scores for all regions were 72.6 (P1: 75.5 vs P2: 67.5); highest in EU5 (76.8) and lowest in US (69.5).
  - **KDQOL burden of kidney disease:** the mean scores for all regions were 55.2 (P1: 60.1 vs P2: 46.7); highest in EU5 (68.4) and lowest in China (49.1).
  - **KDQOL symptoms or problems:** the mean scores for all regions were 86.4 (P1: 90.1 vs P2: 80.0); highest in Japan (89.1) and lowest in US (85.5).
  - **KDQOL effects of kidney disease:** the mean scores for all regions were 73.7 (P1: 77.5 vs P2: 67.0); highest in Japan (89.5) and lowest in China (68.7).
  - **KDQOL SF-12 physical health composite:** the mean scores for all regions were 45.6 (P1: 47.7 vs P2: 42.1); highest in EU5 and Japan (48.6) and lowest in China (44.3).
  - **KDQOL SF-12 mental health composite:** the mean scores for all regions were 45.7 (P1: 47.3 vs P2: 43.2); highest in EU5 (49.9) and lowest in US (43.7).

Health utility and QoL scores by eGFR levels

- At the time of survey, the health utility and QoL scores were lower in patients with eGFR <45 mL/min/1.73m^2 (G2) compared to patients with eGFR ≥45 mL/min/1.73m^2 (G1) across all geographies (**Table 2**).
  - **EQ-5D-5L utility index:** the mean scores for all regions for the group split by eGFR were 0.83 (G1: 0.86 vs P2: 0.71); highest in Japan (0.93) and lowest in China (0.80).
  - **EQ-VAS:** the mean scores for all regions were 71.6 (G1: 73.8 vs G2: 60.0); highest in EU5 (74.9) and lowest in US (69.2).
  - **KDQOL burden of kidney disease:** the mean scores for all regions were 54.1 (G1: 56.9 vs G2: 39.4); highest in Japan (66.9) and lowest in China (47.3).
  - **KDQOL symptoms or problems:** the mean scores for all regions were 85.8 (G1: 87.8 vs G2: 75.3); highest in Japan (88.8) and lowest in China (84.8).
  - **KDQOL effects of kidney disease:** the mean scores for all regions were 72.7 (G1: 74.9 vs G2: 60.8); highest in Japan (89.5) and lowest in China (67.2).
  - **KDQOL SF-12 physical health composite:** the mean scores for all regions were 45.2 (G1: 46.2 vs G2: 39.7); highest in EU5 and Japan (47.9) and lowest in China (43.9).
  - **KDQOL SF-12 mental health composite:** the mean scores for all regions were 45.4 (G1: 46.3 vs G2: 40.5); highest in EU5 (49.5) and lowest in US (43.3).

Table 1. Health utility and quality of life scores in patients with IgAN across various geographies at the time of survey, as per proteinuria levels*

	US			EU5			China			Japan		
	Total	<1#	≥1#	Total	<1#	≥1#	Total	<1#	≥1#	Total	<1#	≥1#
N	**57**	**22**	**35**	**164**	**94**	**70**	**542**	**351**	**191**	**80**	**69**	**11**
EQ-5D-5L – US tariff, mean (SD)	0.84 (0.17)	0.90 (0.20)	0.80 (0.13)	0.90 (0.16)	0.95 (0.11)	0.83 (0.19)	0.81 (0.19)	0.84 (0.17)	0.76 (0.23)	0.92 (0.12)	0.94 (0.10)	0.82 (0.15)
EQ-VAS, mean (SD)	69.5 (20.4)	80.0 (19.1)	62.9 (18.4)	76.8 (14.8)	80.4 (13.8)	71.8 (14.8)	71.3 (17.0)	73.6 (16.0)	67.0 (18.1)	74.8 (16.6)	76.6 (16.4)	63.6 (13.8)
KDQOL-36												
Burden of kidney disease, mean (SD)	58.9 (31.9)	80.1 (24.7)	45.5 (28.7)	68.4 (23.2)	74.0 (22.4)	61.0 (22.3)	49.1 (26.9)	53.0 (25.9)	41.8 (27.2)	67.0 (22.6)	70.6 (20.5)	44.9 (23.2)
N	**57**	**22**	**35**	**163**	**94**	**69**	**542**	**351**	**191**	**80**	**69**	**11**
Symptoms/problems, mean (SD)	85.5 (14.7)	91.1 (12.0)	82.0 (15.3)	88.0 (16.6)	94.2 (9.9)	79.6 (20.0)	85.6 (14.6)	88.8 (10.4)	79.9 (19.0)	89.1 (10.1)	90.9 (9.1)	77.7 (8.7)
N	**57**	**22**	**35**	**162**	**94**	**68**	**542**	**351**	**191**	**79**	**68**	**11**
Effects of kidney disease, mean (SD)	79.4 (20.0)	88.4 (15.5)	73.8 (20.6)	80.5 (19.9)	86.0 (15.9)	73.0 (22.4)	68.7 (19.4)	72.0 (17.1)	62.7 (21.7)	89.5 (9.5)	90.8 (8.4)	81.2 (11.9)
N	**38**	**9**	**29**	**160**	**92**	**68**	**541**	**350**	**191**	**54**	**44**	**10**
SF-12 Physical Health Composite, mean (SD)	45.6 (7.8)	47.1 (8.2)	45.1 (7.7)	48.6 (7.8)	52.0 (5.5)	44.1 (8.2)	44.3 (10.0)	46.3 (9.6)	40.8 (9.5)	48.6 (7.6)	49.7 (6.1)	43.5 (11.2)
SF-12 Mental Health Composite, mean (SD)	43.7 (10.6)	49.9 (10.7)	41.8 (9.9)	49.9 (9.3)	52.6 (7.8)	46.2 (10.1)	44.4 (10.1)	45.5 (9.6)	42.3 (10.6)	48.5 (9.5)	49.7 (9.7)	43.3 (6.8)

Abbreviations: 5D: 5 Dimension; 5L: 5 Level; EQ: EuroQol; EU5: France, Germany, Italy, Spain and the United Kingdom; IgAN: Immunoglobulin A Nephropathy; KDQOL: Kidney Disease Quality of Life; SD: Standard Deviation; SF: Short Form; US: United States; VAS: Visual Analogue Scale; *Patients had to have a response for EQ-5D-5L, EQ-VAS and KDQOL burden of kidney disease. #proteinuria levels measured in g/day.

Table 2. Health utility and quality of life scores in patients with IgAN across various geographies at the time of survey, as per eGFR levels*

	US			EU5			China			Japan		
	Total	≥45#	<45#	Total	≥45#	<45#	Total	≥45#	<45#	Total	≥45#	<45#
N	**55**	**34**	**21**	**187**	**138**	**49**	**517**	**473**	**44**	**91**	**69**	**22**
EQ-5D-5L – US tariff, mean (SD)	0.84 (0.17)	0.89 (0.15)	0.76 (0.18)	0.88 (0.18)	0.93 (0.14)	0.76 (0.23)	0.80 (0.21)	0.82 (0.18)	0.56 (0.32)	0.93 (0.11)	0.94 (0.11)	0.87 (0.12)
EQ-VAS, mean (SD)	69.2 (20.7)	77.4 (18.5)	56.0 (17.0)	74.9 (16.1)	79.2 (12.7)	62.8 (18.5)	70.2 (17.7)	71.6 (16.7)	55.0 (20.3)	73.9 (17.6)	75.9 (17.7)	67.6 (16.2)
KDQOL-36												
Burden of kidney disease, mean (SD)	57.8 (32.0)	73.3 (26.7)	32.7 (22.8)	65.5 (23.9)	70.3 (22.6)	51.8 (22.1)	47.3 (27.3)	49.6 (26.6)	22.4 (22.7)	66.9 (23.9)	71.6 (20.1)	52.0 (28.8)
N	**55**	**34**	**21**	**186**	**137**	**49**	**517**	**473**	**44**	**91**	**69**	**22**
Symptoms/problems, mean (SD)	85.3 (14.9)	87.7 (15.2)	81.5 (14.0)	87.0 (17.3)	91.7 (12.7)	73.9 (21.5)	84.8 (15.4)	86.2 (13.6)	69.8 (23.4)	88.8 (10.7)	90.5 (9.7)	83.6 (12.0)
N	**55**	**34**	**21**	**186**	**138**	**48**	**517**	**473**	**44**	**90**	**68**	**22**
Effects of kidney disease, mean (SD)	78.9 (20.1)	84.7 (20.9)	69.6 (14.9)	77.8 (21.6)	84.2 (16.7)	59.4 (23.5)	67.2 (20.0)	69.1 (18.8)	47.3 (22.1)	89.5 (11.1)	91.8 (8.3)	82.4 (15.2)
N	**37**	**17**	**20**	**183**	**134**	**49**	**516**	**472**	**44**	**59**	**43**	**16**
SF-12 Physical Health Composite, mean (SD)	45.4 (7.8)	46.0 (8.6)	44.9 (7.2)	47.9 (8.2)	50.0 (7.0)	42.2 (8.7)	43.9 (10.0)	44.9 (9.5)	33.1 (8.3)	47.9 (8.4)	49.4 (7.6)	43.8 (9.2)
SF-12 Mental Health Composite, mean (SD)	43.3 (10.5)	47.8 (9.8)	39.6 (9.7)	49.5 (9.1)	51.7 (7.6)	43.3 (10.3)	43.7 (10.2)	44.5 (9.8)	35.3 (11.0)	48.5 (9.3)	48.9 (9.5)	47.4 (8.8)

Abbreviations: 5D: 5 Dimension; 5L: 5 Level; eGFR: Estimated Glomerular Filtration Rate; EQ: EuroQol; EU5: France, Germany, Italy, Spain and the United Kingdom; IgAN: Immunoglobulin A Nephropathy; KDQOL: Kidney Disease Quality of Life; SD: Standard Deviation; SF: Short Form; US: United States; VAS: Visual Analogue Scale; *Patients had to have a response for EQ-5D-5L, EQ-VAS and KDQOL burden of kidney disease; #eGFR levels measured in mL/min/1.73m^2.

Conclusions

- This study highlights the humanistic burden in patients with IgAN, across all geographies health utility and QoL scores worsened with increasing IgAN severity (i.e higher proteinuria or lower eGFR).
- There is a high unmet need for effective therapies that can control the disease and improve QoL.

Limitations

- The DSP is not based on a true random sample of physicians or patients. While minimal inclusion criteria governed the selection of the participating physicians, participation is influenced by willingness to complete the survey.
- Physicians are asked to provide data for a consecutive series of patients to avoid selection bias, but no formal patient selection verification procedures are in place.
- Not all patients enrolled into this study completed all QoL questionnaires, so this analysis might not be representative of total study sample.
- When calculating EQ-5D-5L utility index scores, US tariff was applied across all geographies for consistency and to allow comparison between regions.

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 the DSP and supported this analysis.
- Richard Lafayette has received research funding from NIH, UMichigan, Omeros, Vera, Travere, Pfizer, Roche, Chinook, Alexion, Otsuka, Calliditas and NephroNet. He has provided consultancy for Alexion, Omeros, Vera, Travere, Pfizer, Roche, Calliditas, Chinook, Aurinia, GSK, Otsuka and Novartis.

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