


Item Response Theory Analysis of the ILQI

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KEY FINDINGS & CONCLUSIONS

- All IRT items had good discrimination (slopes ≥ 1.96)
- Response thresholds covered a wide range of the latent scale (between -3.31 and 6.70 logits).
- The group IRT model showed statistically significant country-level effects for Canada, China, Columbia, Japan, Turkey and the UK, relative to the United States.
- These findings do not preclude the use of the ILQI in non-USA countries but suggest that patient report of the disease impacts may vary between countries.
- The ILQI effectively measures a wide range of ITP impacts and can differentiate between patients with higher and lower disease impact.

INTRODUCTION

- The Immune Thrombocytopaenia (ITP) Life Quality Index (ILQI, Figures 1 and 2) is a 10-item patient-reported outcome (PRO) used in clinical practice to measure the impact of ITP.
- The ILQI was developed following input from clinical experts and patients with ITP and has undergone qualitative testing and validation.¹
- The ILQI was administered as part of the ITP World Impact Survey (I-WISh), a global observational study.²
- Data collected from the I-Wish study was used to perform psychometric evaluation of the ILQI and confirm the scoring algorithm.³

Figure 1. The ITP Life Quality Index (ILQI)

ITP Life Quality Index (ILQI)

The aim of this questionnaire is to measure how much your ITP has affected your life **OVER THE PAST MONTH**. The aim is to try to standardise how, besides bleeding, your ITP affects your life. Please tick one box.

- How often has your ITP impacted on your working life or studies?**
☐ Never ☐ Sometimes ☐ More than half the time ☐ All the time
☐ I am not currently working/studying due to ITP
☐ I am not currently working/studying due to other reasons (0)
- How often have you taken time off work or education because of your ITP?**
☐ Never ☐ Sometimes ☐ More than half the time ☐ All the time
☐ I am not currently working/studying due to ITP
☐ I am not currently working/studying due to other reasons (0)
- How often has your ITP impacted your ability to concentrate on everyday tasks?**
☐ Never ☐ Sometimes ☐ More than half the time ☐ All the time
- How often has your ITP impacted your social life?**
☐ Never ☐ Sometimes ☐ More than half the time ☐ All the time
- How often has your ITP impacted your sex life?**
☐ Never ☐ Sometimes ☐ More than half the time ☐ All the time
☐ Not applicable/prefer not to say
- How often has your ITP impacted your energy levels?**
☐ Never ☐ Sometimes ☐ More than half the time ☐ All the time
- How often has your ITP impacted your undertaking of daily tasks?**
☐ Never ☐ Sometimes ☐ More than half the time ☐ All the time
- How often has your ITP impacted your ability to support people close to you?**
☐ Never ☐ Sometimes ☐ More than half the time ☐ All the time
- How often has your ITP negatively impacted your hobbies?**
☐ Never ☐ Sometimes ☐ More than half the time ☐ All the time
- How often has your ITP negatively impacted your normal capacity to exercise?**
☐ Never ☐ Sometimes ☐ More than half the time ☐ All the time

Figure 2. Scoring of the ILQI

KEY:
Never=1, Sometimes=2, More than half of the time=3, All the time=4, I am currently not working/studying due to ITP=4

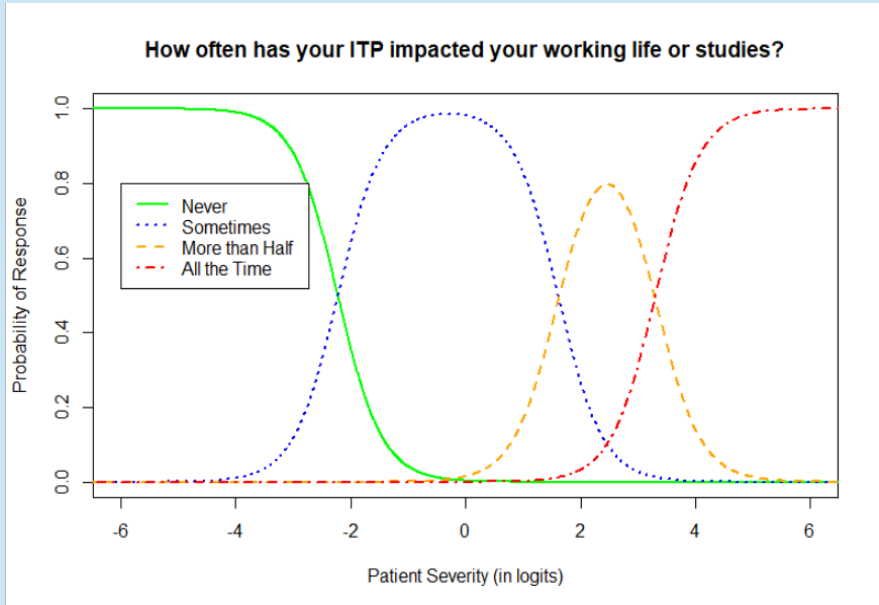
Missing: I am not currently working for to other reasons=0, not applicable/prefer not to say=0

Min score: 7
Max score: 40
Score of 16 or above suggests significantly impaired quality of life
Score of 23 or above suggests severely impaired quality of life

METHODS

- Item response theory (IRT) is a family of statistical models which place patient severity and item severity on a common scale through the analysis of item response patterns.⁴
- Figure 3 shows an example of how IRT relates patient severity (in logits) to the probability of response choice.

Figure 3. Polytomous category response functions for Item 1 of the ILQI



- Two IRT models were considered:
 - First the sample was treated as a single-group and a graded response model,⁵ the latter was employed to calibrate item discrimination and impact response thresholds.⁶
 - To assess the severity of impacts in patients in various countries, multiple-group one-parameter IRT models were assessed.
- As the largest cohort in the study, US patients were treated as a reference group.

Disclosures

This work was performed by Adelphi Values and funded by Novartis Pharma AG.
P Griffiths was employed by Adelphi Values at the time this work was conducted. L Grant and E Arenson are employees of Adelphi Values. V Maheshwari is employed by Novartis Healthcare Pvt. Ltd and R Viana is employed by Novartis Pharma AG.

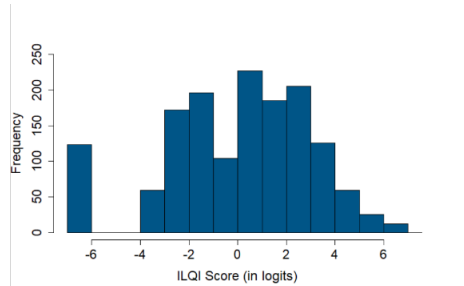
RESULTS

- 1,507 patients aged 18-90 years (mean=46.9, SD=16.2) participated in the study (Table 1).

Table 1. Demographic statistics of the I-WISH study

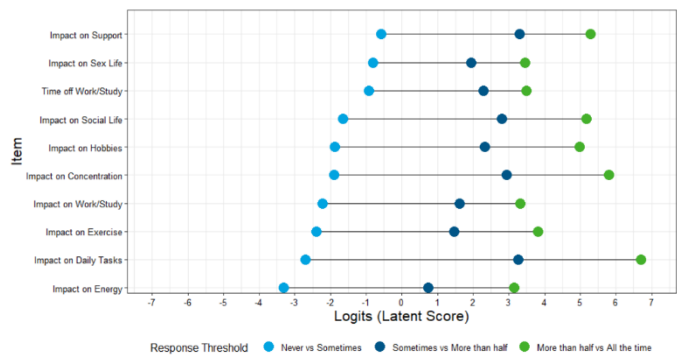
Demographic/clinical characteristics	Patients (N=1,507)
Age	
Mean (SD)	46.9 (16.22)
Range	18-90 years
Missing	n=1
Gender, n (%)	
Female	975 (64.7%)
Male	532 (35.3%)
Country, n (%)	
USA	501 (33.2%)
China	286 (19.0%)
UK	120 (8.0%)
France	87 (5.8%)
Germany	82 (5.4%)
Italy	74 (4.9%)
India	65 (4.3%)
Canada	61 (4.0%)
Turkey	60 (4.0%)
Japan	56 (3.7%)
Colombia	51 (3.4%)
Spain	48 (3.2%)
Egypt	16 (1.1%)
Current employment status, n (%)	
Working full time	624 (44.6%)
Retired	267 (19.1%)
Working part time	221 (15.8%)
Homemaker	82 (5.8%)
Student	60 (4.3%)
Disability allowance	34 (2.4%)
Long term sick leave	13 (0.9%)
Other	99 (7.1%)
Patient self-reported current health state, n (%) (7-point Likert scale, 7=excellent health)	
1-3 (low score)	207 (14.8%)
4	306 (21.9%)
5-7 (high score)	887 (63.3%)
Time since ITP diagnosis	
Mean (SD)	8.9 years (10.75)
Range	0.1-89.7 years
Participants had been diagnosed with ITP for a mean of 8.9 years (range=0.1-89.7 years, SD=10.75).	
The majority of participants (63.3%, n=887) rated their current health state between 5-7 on a 1-7 point scale indicating better health.	
Results of the single-group IRT analysis showed that: <ul style="list-style-type: none">– IRT-derived logit scores ranged from -6.7 to 8.4 (mean=0.06, SD=3.1; Figure 4).	

Figure 4. Histogram of the ILQI logit scores



- Items discriminated well between less severe and more severe patients (IRT slopes ranged from 1.96 to 3.83).
- Item category severities covered most of the severity scale (step parameters ranged from -3.31 to 6.70; Figure 5).
- These findings indicate that the ILQI can measure a range of disease impacts with good precision.

Figure 5. ILQI graded response model severity thresholds



- Multi-group IRT analysis showed that: (USA is reference group; Table 2):
 - China, Columbia, and Turkey patients indicated statistically significant less severity in ILQI scores than the US (95% confidence intervals excluded 0).
 - Japanese and UK patients indicated statistically significant greater severity in ILQI scores compared to the US (95% confidence intervals excluded 0).

Table 2. Country-level effects from multi-group IRT model

Country	Mean	95% Conf. Int.	
		Low	Hi
USA		Reference group	
Canada	-0.74	-1.46	-0.02
China	-1.73	-2.12	-1.33
Colombia	-0.79	-1.57	-0.01
Egypt	-1.17	-2.54	0.20
France	0.63	0.00	1.25
Germany	-0.08	-0.71	0.56
India	0.20	-0.52	0.91
Italy	-0.12	-0.79	0.55
Japan	1.35	0.53	2.17
Spain	0.77	-0.05	1.59
Turkey	-1.57	-2.34	-0.81
UK	0.68	0.08	1.28

References

1. Cooper N, Cuker A, Bonner N, et al. Qualitative study to support the content validity of the immune thrombocytopaenia (ITP) Life Quality Index (ILQI). British Journal of Haematology. 2021;194(4):759-766. 2. Cooper N, Kruse A, Kruse C, et al. Immune thrombocytopaenia (ITP) World Impact Survey (I-WISh): Impact of ITP on health-related quality of life. Am J Hematol. 2021;96(2):199-207. 3. Viana R, D'Alessio D, Grant L, et al. Psychometric Evaluation of ITP Life Quality Index (ILQI) in a Global Survey of Patients with Immune Thrombocytopaenia. Advances in Therapy. 2021;38(12):5791-5808. 4. Embretson SE, Reise SP. Item response theory. Psychology Press; 2013. 5. Samejima F. Graded response model. In: Handbook of modern item response theory. Springer; 1997:85-100. 6. De Boeck P, Wilson M. Explanatory item response models: A generalized linear and nonlinear approach. Vol 10: Springer; 2004.