Development of a Cross-walk of the Assessment of SpondyloArthritis International Society Health Index (ASAS HI) and Ankylosing Spondylitis Quality of Life (ASQoL) scores using data from patients with Ankylosing Spondylitis and Non-radiographic Axial Spondyloarthritis

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This study was sponsored by Eli Lilly and Company.

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Disclosures

- J. Piercy, J. Pike, N. Booth, and E. Holdsworth are current employees of Adelphi Real World; Y. Dong and T. Hunter, are current employees and shareholders of Eli Lilly and Company
- This study was sponsored by Eli Lilly and Company

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Background and Objective

Background

- Axial spondyloarthritis (axSpA) is chronic inflammatory disease that predominantly affects the spine and sacroiliac joints and encompasses patients with ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA).[1]
- The Ankylosing Spondylitis Quality of Life (ASQoL) was developed in 2003 and has been used in clinical trials and observational studies to assess health-related quality of life (HRQoL) among axSpA patients.[2]
- The Assessment of Spondyloarthritis International Society Health Index (ASAS HI) is a relatively new measure to assess function, disability, and health in patients with axSpA, and has recently been used in clinical trials and observational studies.[3-4]

Objective

- To conduct a cross-walk analysis of the ASAS HI to the ASQoL in patients with rheumatologist confirmed AS and nr-axSpA in the United States.

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Disease Specific Programme™ (DSP) Data Source

- The Disease Specific Programme (DSP) is a large, cross-sectional survey of real-world clinical practice.
- Data are collected from both physicians and their consulting patients via physician completed patient record forms (PRFs) and patient self-completed forms (PSCs).
- Patient enrolment in the DSP is completed on a prospective basis, and physicians are asked to provide data for a consecutive series of patients.
- Physicians provide data on patient demographic characteristics, clinical status, and treatment history.
- Patients are invited to complete patient-reported outcome measures (PROMs), such as EQ5D-5L, ASQoL, and ASAS HI.

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Methods

- Data from a cross-sectional survey conducted with rheumatologists and their consulting patients in the United States were analyzed.
- Data were collected from Jun-Aug 2018 via rheumatologist-completed patient record forms and patient self-completed forms.
- To ensure eligibility to participate, rheumatologists provided confirmed diagnoses of AS and nr-axSpA plus basic demographic and clinical information.
- Quality of Life measures were reported by the patient using the validated ASAS HI and ASQoL questionnaires.
- Model performance was assessed by comparing root-mean squared error (RMSE) from 10-fold cross validation, to determine the best mapping from ASAS HI to ASQoL, and also ASQoL to ASAS HI. Models assessed included mean score, nonparametric local-linear regression and generalized linear models. RMSE was calculated overall, and for lower, middle and upper thirds of the predicted scale. Lower values indicated better fit and well fitting models had an RMSE which was lower than the clinically meaningful difference in the ASAS HI or ASQoL.

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ASQoL Questionnaire



ASQoL[2]

- Comprises 18 dichotomous items:
  - Addressing categories of function, emotional, pain, fatigue, and quality of life
  - Each statement of ASQoL is given score of 1 = “Yes” or 0 = “ No”
- Total score ranging from 0 (good HRQoL) to 18 (poor HRQoL)

1. My condition limits the places I can go
2. I sometimes feel like crying
3. I have difficulty dressing
4. I struggle to do jobs around the house
5. It’s impossible to sleep
6. I am unable to join in activities with my friends/family
7. I am tired all the time
8. I have to keep stopping what I am doing to rest
9. I have unbearable pain
10. It takes a long time to get going in the morning
11. I am unable to do jobs around the house
12. I get tired easily
13. I often get frustrated
14. The pain is always there
15. I feel I miss out on a lot
16. I find it difficult to wash my hair
17. My condition gets me down
18. I worry about letting people down

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ASAS HI Questionnaire

ASAS HI[3-4]

- Comprises 17 dichotomous items:
  - Addressing categories of pain, emotional functions, sleep, sexual function, mobility, self care, and community life
  - Each statement of ASAS HI given score of 1 = "I agree" or 0 = " I do not agree" (or "not applicable" for Items 7 and 8)
- Total score ranging from 0 (good health) to 17 (poor health)

1. Pain sometimes disrupts my normal activities
2. I find it hard to stand for long
3. I have problems running
4. I have problems using toilet facilities
5. I am often exhausted
6. I am less motivated to do anything that requires physical effort
7. I have lost interest in sex
8. I have difficulty operating the pedals in my car
9. I am finding it hard to make contact with people
10. I am not able to walk outdoors on flat ground
11. I find it hard to concentrate
12. I am restricted in traveling because of my mobility
13. I often get frustrated
14. I find it difficult to wash my hair
15. I have experienced financial changes because of my rheumatic disease
16. I sleep badly at night
17. I cannot overcome my difficulties

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Results-Patient Demographics

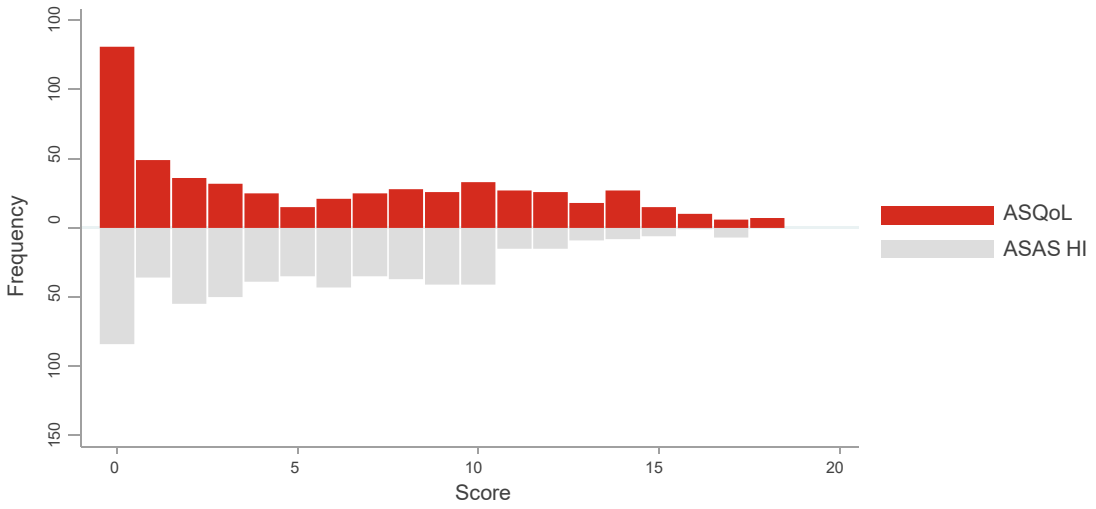
Data from 63 rheumatologists were included in this analysis.

	Overall (N=557)	AS (N=283)	Nr-axSpA (N=274)
Age, years	45.3 (13.7)	47.1 (14.3)	43.4 (12.7)
Male, n (%)	338 (60.7)	195 (68.9)	143 (52.2)
BMI	27.3 (4.7)	27.5 (4.7)	27.1 (4.8)
White/Caucasian, n (%)	458 (82.2)	236 (83.4)	222 (81.0)
Time since axSpA diagnosis, years	5.1 (6.9)	6.7 (8.5)	3.7 (4.7)
Working Full-time, n(%)	382 (68.6)	193 (68.2)	189 (69.0)
Biologic Use, n (%)	166 (29.8)	68 (24.0)	98 (35.8)
Physician perceived disease severity			
Mild	357 (64.1)	170 (60.1)	187 (68.2)
Moderate	181 (32.5)	94 (33.2)	87 (31.8)
Severe	19 (3.4)	19 (6.7)	0 (0.0)
Number of concomitant conditions, mean (SD)	1.2 (1.4)	1.3 (1.6)	1.1 (1.2)

Data are mean (standard deviation) unless otherwise stated
*Calculated on available data: Base sizes: Time since axSpA diagnosis: (AS=224, nr-axSpA=243), Number of concomitant conditions: (AS=280, nr-AxSpA=270)

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Distribution of ASQoL and ASAS HI scores



ASAS HI and ASQoL have different numbers of responses and score range. ASAS HI has a score range between 0-17. ASQoL has a score range of 0-18

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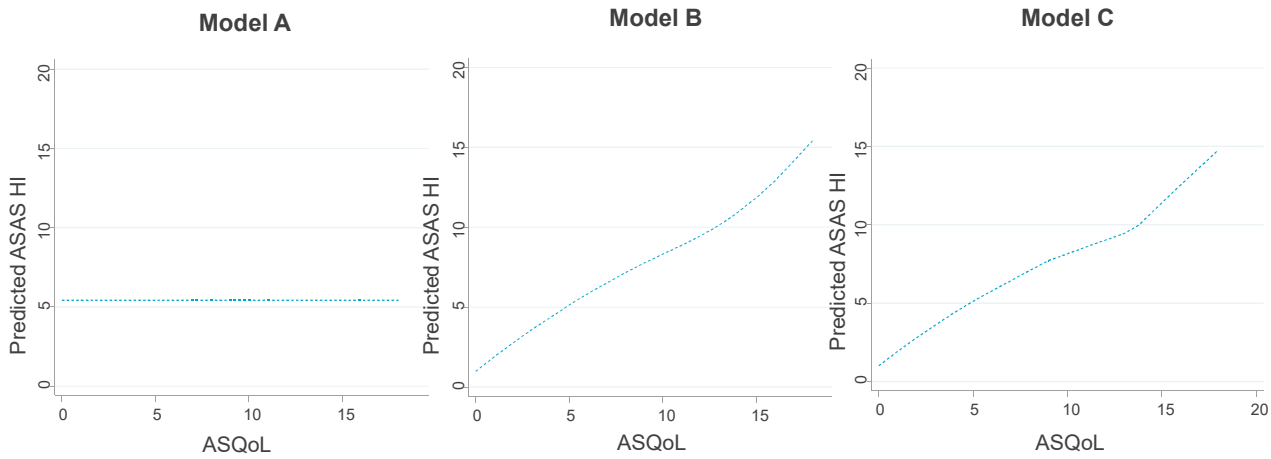
Regression Cross-Validation: Predicting ASAS HI score

Model	Description	Covariates	Overall RMSE	Lower RMSE	Middle RMSE	Upper RMSE
Predicting ASAS HI						
Mean **(A)**	Constant Model	Constant only	4.246	3.789	3.199	8.438
Without Covariates **(B)**	Nonparametric local-linear regression	ASQoL	1.851	1.597	1.871	2.871
With Covariates **(C)**	GLM with gaussian family and power link (^1.15)	Linear splines of ASQoL, age, employment status, age/employment status interaction	1.806	1.601	1.758	2.839

- Predicting ASAS HI using ASQoL values, the best model was non-parametric local-linear regression, with overall RMSE 1.851.
- In predicting ASAS HI, models performed better in predicting lower values in the predicted scale (RMSE 1.597, 1.871, 2.871 across thirds for ASAS HI

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Predicting ASAS HI score



- Models B and C (with and without covariates) both had superior performance when predicting lower ASQoL values than higher values.

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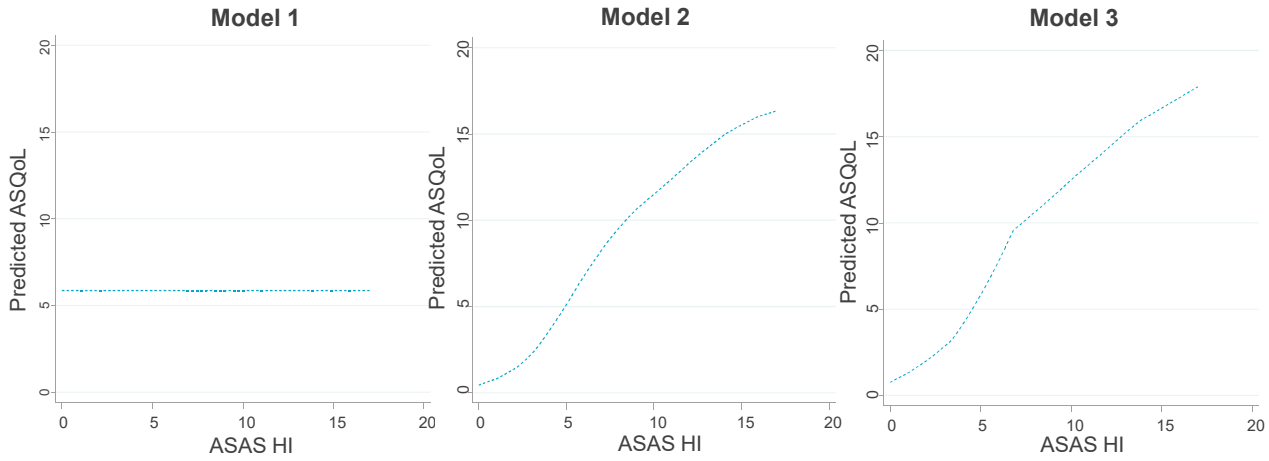
Regression Cross-Validation: Predicting ASQoL score

Model	Description	Covariates	Overall RMSE	Lower RMSE	Middle RMSE	Upper RMSE
Predicting ASQoL						
Mean **(1)**	Constant Model	Constant only	5.389	4.714	3.947	8.966
Without Covariates **(2)**	Nonparametric local-linear regression	ASAS HI	2.254	1.719	2.577	3.140
With Covariates **(3)**	GLM with gaussian family and power link (^0.55)	Linear splines of ASQoL, age, sex, BMI, ethnicity, disease severity, male/disease severity interaction, male/ethnicity interaction, sex/BMI interaction	2.173	1.626	2.509	3.048

- Predicting ASQoL using ASAS HI values, the best model also used non-parametric local-linear regression, with overall RMSE 2.254.
- In predicting ASQoL, models performed better in predicting lower values in the predicted scale (RMSE 1.719, 2.577, 3.140) across thirds for ASQoL.

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Predicting ASQoL using ASAS HI score



- Model 2 and 3 (with and without covariates) both had superior performance when predicting lower ASQoL values than higher values.

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Conclusions

- ASAS HI and ASQoL are both PRO measures which have been used in axSpA patients. Scoring methods of the two instruments are similar.
- Our study has demonstrated that it is both possible and also appropriate to cross-walk the ASAS HI to the ASQoL.
  - Similarly it is possible to cross-walk the ASQoL to the ASAS HI.
- Lower values indicated better fit and well fitting models had an RMSE which was lower than the clinically meaningful difference in the ASAS HI or ASQoL.
  - One potential reason for this is that most patients included had relatively low scores – there was more potential variability for patients with higher scores as there were fewer numbers.
- Future research is needed to confirm our findings in sub-groups of axSpA patients.

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References

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