Utility Values for Endoscopy and Symptoms-Based Health States in Crohn's Disease: Analysis of Data from a Phase 3 Randomized Controlled Clinical Trial

Axel Svedbom[1], Xuan Wang[1], Susanne Hartz[2],Saravanan E[2], Tommaso Panni[2]

[1]ICON Plc, Stockholm, Sweden, [2]Eli Lilly and Company, Indianapolis, USA

Scan the QR code or use this URL (https://lillyscience.lilly.com/congress/ispor-eu2024) for a list of all Lilly content presented at the congress. Other company and product names are trademarks of their respective owners.

PCR-316

BACKGROUND AND OBJECTIVE

- Treatment targets in Crohn's disease (CD) have evolved from symptom control alone towards endoscopic healing[1, 2].
- Health state utility values (HSUVs) for endoscopically defined health states are lacking, resulting in a disconnect between clinical decision-making and current approaches to cost-effectiveness analysis with Quality Adjusted Life Years (QALYs).
- We present and contrast utility values for CD health states as defined by endoscopy- and symptoms-based indices.

CONCLUSION

- Evident from Figure 1, the differences in HSUV between two adjacent health states defined using the same outcome measure were larger than the differences in HSUV in the relevant health states between the two outcome measures. While differences exist, especially among patients classified as moderate-to-severe, this finding supports the notion that endoscopic outcomes are reasonably associated with symptoms impacting health related quality of life in patients with CD.
- The differences in HSUV between remission and moderate-to-severe disease are greater for clinically defined health states than those defined endoscopically
- Whether these utility cores are driven by CD or other related causes needs to be further investigated.

Sponsored by Eli Lilly and Company

ISPOR EU 2024; Barcelona, Spain; November 17 – 20, 2024

METHODS

- Data were obtained from VIVID-1, a phase 3 trial comparing the efficacy of mirikizumab, ustekinumab, and placebo.
- Endoscopic outcomes, symptoms, and health utilities were measured using the Simple Endoscopic Score for Crohn's Disease (SES-CD), the Crohn's Disease Activity Index (CDAI), and the EQ-5D-5L (cross-walk, UK MVH value set), respectively.
- SES-CD and CDAI were categorized into remission (SES-CD<3; CDAI<150), mild disease (SES-CD: <=3 to <7 ; CDAI <=150 to <220), and moderate-to-severe disease (SES-CD>=7; CDAI >= 220).
- We fit linear mixed models to estimate the associations between health utilities and disease severity states. Least square means and confidence intervals are presented.
- The linear mixed models had EQ-5D utility as dependent variable and disease severity state (measure with CDAI or SES-CD) as fixed effect and accounted for patient repeated measures. The regression models included all time-points (baseline, weeks 12, and week 52) and treatments.
- The model assumed a compound symmetry covariance structure.
- Based on the regression coefficients we estimated linear predictions for EQ-5D health utility of remission, mild disease, and moderate-to-severe disease measured using CDAI and SES-CD, respectively.

KEY RESULTS

- In total, 1,065 individuals (mean [standard deviation] age 36.2 [13.0]; 44.9% women) were included in the analysis.
- Utility values (mean [95% confidence interval]) for SES-CD vs CDAI were 0.85 (0.83-0.87) vs 0.87 (0.85-0.88) for remission, 0.81 (0.79-0.83) vs 0.79 (0.77-0.80) for mild disease, and 0.70 (0.69-0.71) vs 0.65 (0.64-0.66) for moderate-to-severe disease.

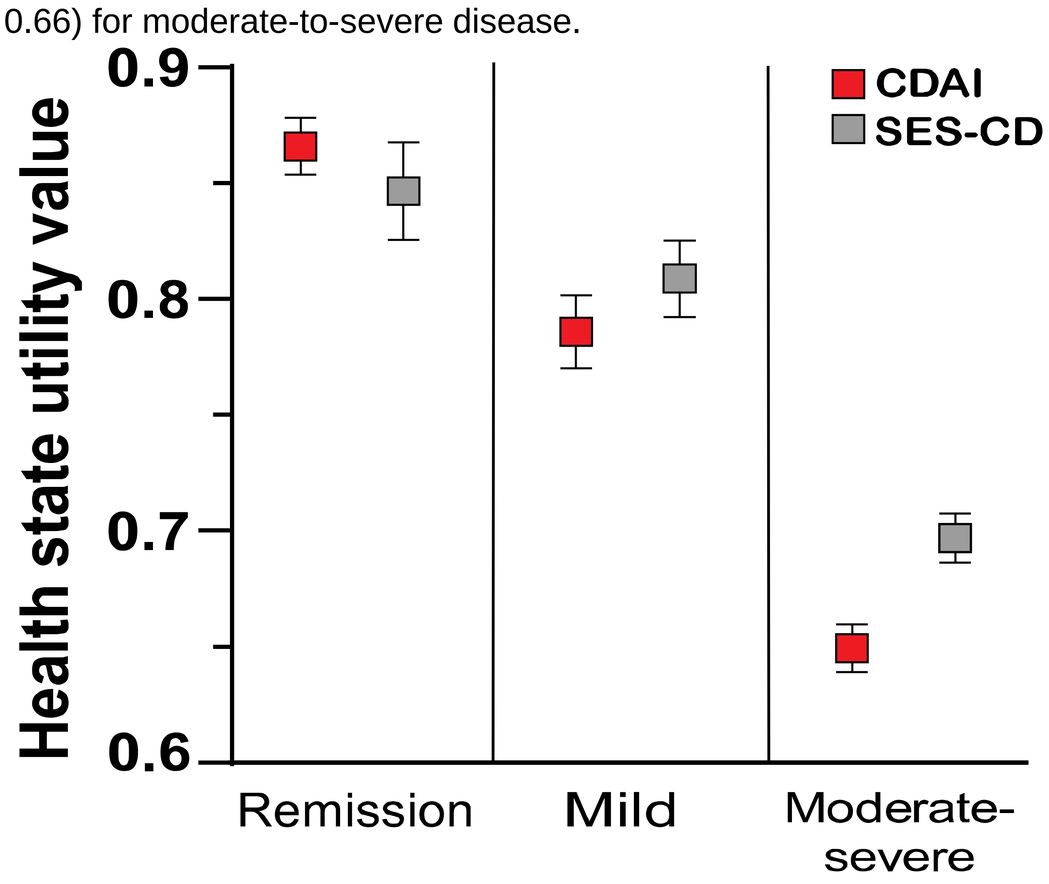

Figure 1. Health state utilities for CDAI vs. SES-CD by patient health state

Table 1: Baseline demographics and clinical characteristics of the total participants of VIVID-1 (all treatment groups)

Baseline Characteristic	Participants (N=1065)
Female, n (%)	478 (44.9)
Age (years), (median)	33.0
Race, n(%)[*a]	
American Indian/Alaska Native	6 (0.6)
Asian	264 (25.1)
Black/African American	23 (2.2)
White	753 (71.7)
Multiple	4 (0.4%)
Ethnicity, n (%)[*b]	
Hispanic/Latino	17.0 (15.7)
Not Hispanic/Latino	91.0 (84.3)
Weight (kg), mean (SD)	68.0 (18.3)
BMI (kg/m²), mean (SD)	23.4 (5.5)
Duration of CD (years), median (Q1, Q2)	4.9 (1.9, 9.7)
CDAI, mean (SD)	321.1 (87.9)
SES-CD, mean (SD)	13.5 (6.5)
Prior biologic failure, n (%)[*c]	517.0 (48.5)

*a N= 1050 (Number of participants with non-missing data, used as denominator).
*b N= 108 (Only includes responses from US sites).
*c Failure defined as reasons for prior treatment discontinuation are: loss of response, inadequate response or intolerance to medication.
Abbreviations: BMI = body mass index; CD = Crohn's disease; CDAI = Crohn's Disease Activity Index; n = number of participants in the specified category; N = number of participants in the PAS population; PAS = Primary Analysis Set; SD = standard deviation; SES-CD = Simple Endoscopic Score for Crohn's Disease.

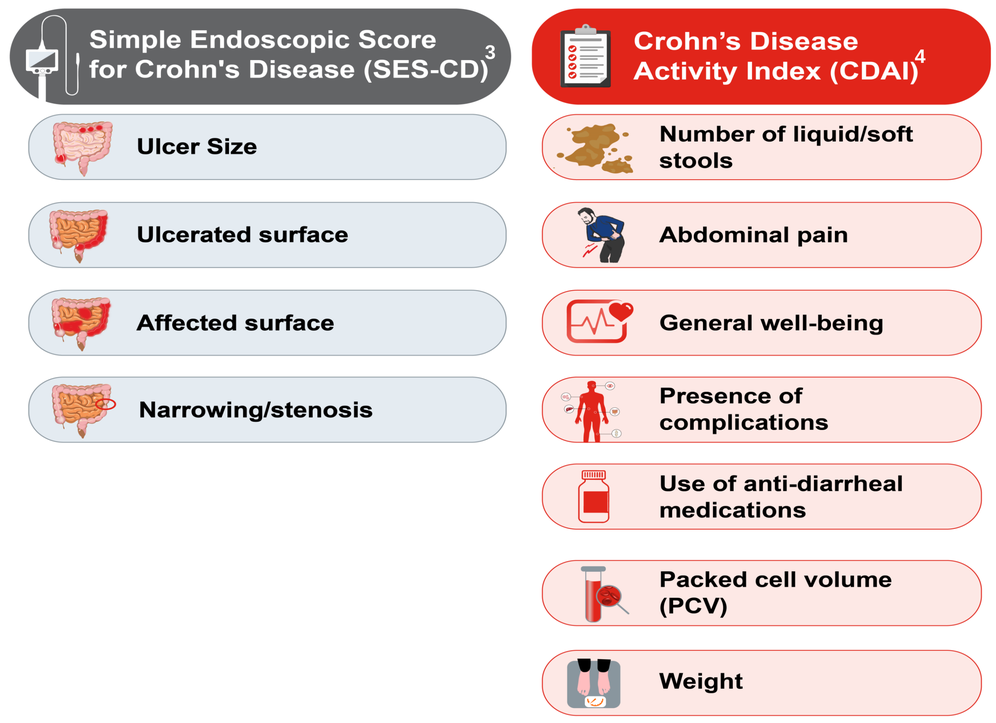

Figure 2. Parameters assessed by SES-CD and CDAI
SES-CD is a scoring system to evaluate disease severity in patients with Crohn's disease and involves internal examination. CDAI is a scoring system which uses clinical data to quantify patient symptoms.

References

1. Torres J, Mehandru S, Colombel JF, Peyrin-Biroulet L. Crohn's disease. Lancet. 2017;389(10080):1741-55. Epub 20161201.
2. Turner D, Ricciuto A, Lewis A, D'Amico F, Dhaliwal J, Griffiths AM, et al. STRIDE-II: An Update on the Selecting Therapeutic Targets in Inflammatory Bowel Disease (STRIDE) Initiative of the International Organization for the Study of IBD (IOIBD): Determining Therapeutic Goals for Treat-to-Target strategies in IBD. Gastroenterology. 2021;160(5):1570-83. Epub 20210219.
3. Koutroumpakis E, Katsanos KH. Implementation of the simple endoscopic activity score in crohn's disease. Saudi J Gastroenterol. 2016;22(3):183-91.
4. Freeman HJ. Use of the Crohn's disease activity index in clinical trials of biological agents. World J Gastroenterol. 2008;14(26):4127-30. doi: 10.3748/wjg.14.4127.

Acknowledgments: The authors would like to thank Shane Whelan and Praveen Shetty for their contributions to medical writing and visualization.
Disclosures: Axel Svedbom and Xuan Wang are employees of ICON Plc. Susanne Hartz, Saravanan E and Tommaso Panni are employees and minor shareholders of Eli Lilly and Company

Copyright ©2024 Eli Lilly and Company. All rights reserved.