

# ASSESSING HEALTH-UTILITY VALUES FOR CHRONIC SPONTANEOUS/IDIOPATHIC URTICARIA IN REAL-WORLD USING THE EQ-5D: RESULTS FROM ASSURE-CSU STUDY

PSS50



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## INTRODUCTION

### Background

- Chronic spontaneous (also known as idiopathic) urticaria (CSU/CIU) is defined as the occurrence of wheals/hives, angioedema or both for 6 weeks or longer due to known or unknown causes and no identifiable external triggers<sup>1</sup>
- Although CSU is not life threatening, it has a major impact on patients' lives, particularly when it is not sufficiently controlled by medical treatment<sup>1,2</sup>
- CSU patients experience disturbing itch, sometimes pain, lack of sleep, occupational disabilities, and social isolation, which result in a negative impact on their daily function, thus drastically lowering their health-related quality of life (HRQoL)<sup>3-5</sup>
- CSU has an impact on society in terms of both humanistic and economic burden<sup>6</sup>
- Real-world data on health status and utility values for CSU are unavailable
- The ASSURE-CSU (ASsessment of the Economic and Humanistic Burden of Chronic Spontaneous/Idiopathic Urticaria PatiEnts) is the first international non-interventional study to quantify the humanistic and economic burden of illness in patients with inadequately-controlled CSU. The study was a non-interventional, multinational, and multicentre study and was conducted in Canada, France, Germany, Italy, Netherlands, Spain, and United Kingdom (UK)

## OBJECTIVE

- This analysis reports EQ-5D results from the ASSURE-CSU study

## METHODS

### Study Design

- This study included a 12 month retrospective medical record abstraction, a cross-sectional patient survey, and a 7-day prospective patient diary

### Patient Population

- Adult patients (aged 18 years or older) with a clinician-confirmed, guideline-defined diagnosis of CSU
- Patients had been symptomatic for more than 12 months at least 3 days per week and were currently symptomatic, despite treatment

### Outcomes

- EuroQoL 5 Dimensions-3 Levels (EQ-5D-3L) was completed by the patients at the time of study enrolment
  - The EQ-5D-3L is a standardised, preference-based measure of health status comprised of five questions/dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression
  - Each domain is scored on a scale of 1 to 3 (no problems, some problems, and extreme problems, respectively)
  - A single index value for health states (called utility) can be calculated from a patient's responses to the 5 questions. Utility values range from 0 (death) to 1 (perfect health)
- Urticaria activity was assessed prospectively with the twice-daily Urticaria Activity Score completed over 7 days (UAS<sub>7TD</sub>)
  - The UAS<sub>7TD</sub> was calculated by summing up daily UAS scores. Each daily UAS score was calculated by averaging morning and evening itch and hives scores, and summing the averages. UAS<sub>7TD</sub> scores can range from 0 to 42 (highest activity)
  - UAS<sub>7TD</sub> scores were used to define categorical disease states (Table 1). For the present analysis, UAS<sub>7TD</sub> scores of 0 and 1-6 were grouped into one state (0-6)

Table 1. UAS<sub>7TD</sub> score ranges and corresponding disease states

UAS <sub>7TD</sub> Score	Disease States
0	No symptoms
1 to 6	Well-controlled urticaria
7 to 15	Mild activity
16 to 27	Moderate activity
28 to 42	Severe activity

- Utility values were calculated and further stratified by the UAS<sub>7TD</sub> disease states

### Analysis

- Pooled country data were analysed using descriptive statistics and stratified by UAS<sub>7TD</sub> disease states
- Mean values and standard deviations were reported for continuous variables and counts and proportions were reported for categorical variables

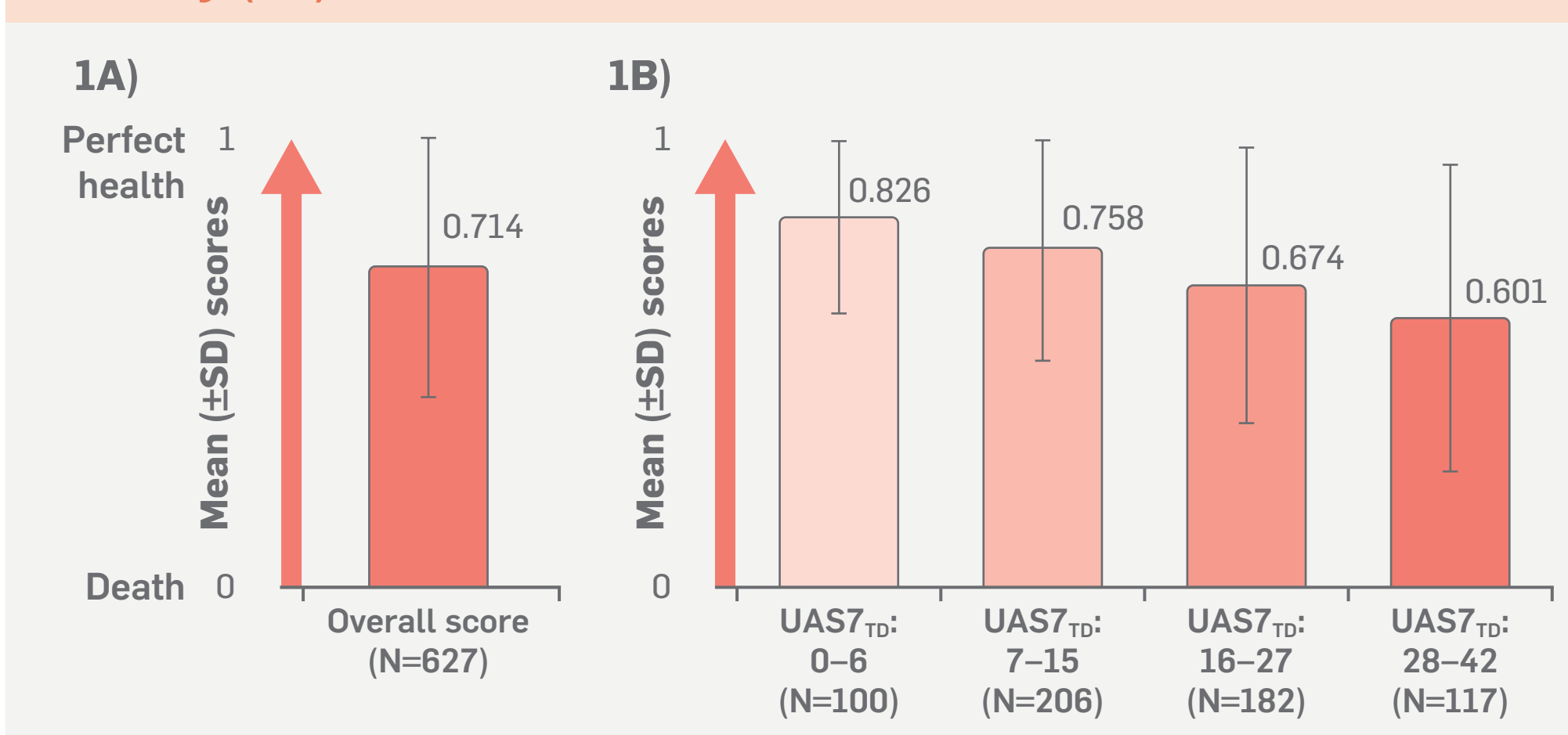
## RESULTS

- A total of 64 centres recruited 673 patients with a mean age of 48.8 years and a mean disease duration of 4.8 years from diagnosis to enrolment. The majority of enrolled patients were female (72.7%) and Caucasian/white (90.4%)
- Among 673 patients enrolled in the study, 627 patients completed EQ-5D

### EQ-5D Utility Scores: Overall and by Disease Activity (Figure 1A and 1B)

- The mean (SD) EQ-5D utility score for the cohort was 0.714 (0.2907)
- Utility estimates decreased as the disease activity increased,
- Patients with UAS<sub>7TD</sub> 0-6 (no symptoms or well-controlled urticaria) had a mean (SD) EQ-5D utility score of 0.826 (0.2147)
- The mean (SD) EQ-5D score decreased to 0.601 (0.3423) for the patients with UAS<sub>7TD</sub> 28-42 (severe activity) (Figure 1)

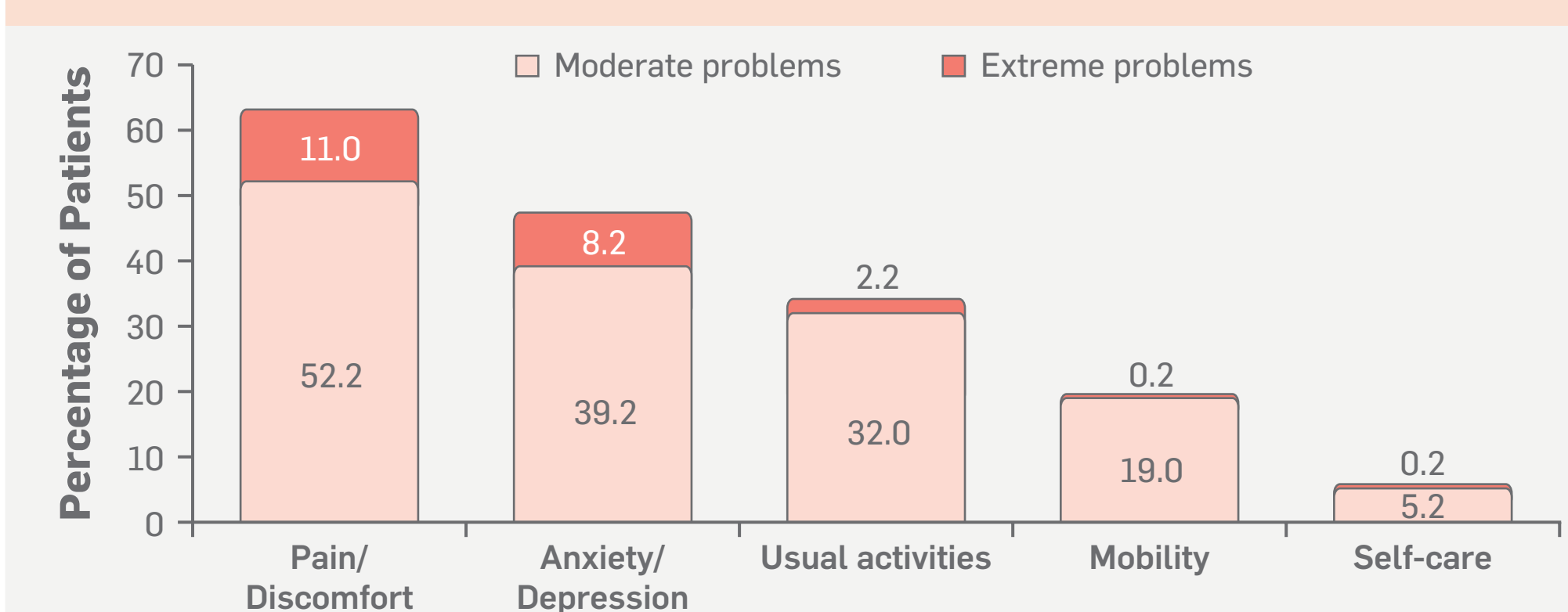
Figure 1. EQ-5D Utility Scores, Overall (1A) and by Disease Activity (1B)



### EQ-5D Dimensions (Figure 2)

- The most affected dimensions were pain/discomfort, anxiety/depression, and usual activities
- In these 3 dimensions, patients reported moderate problems (52.2%, 39.2%, and 32.0% of patients, respectively) and extreme problems (11.0%, 8.2%, and 2.2% of patients, respectively)
- Fewer patients reported moderate and severe problems with mobility and self-care dimensions

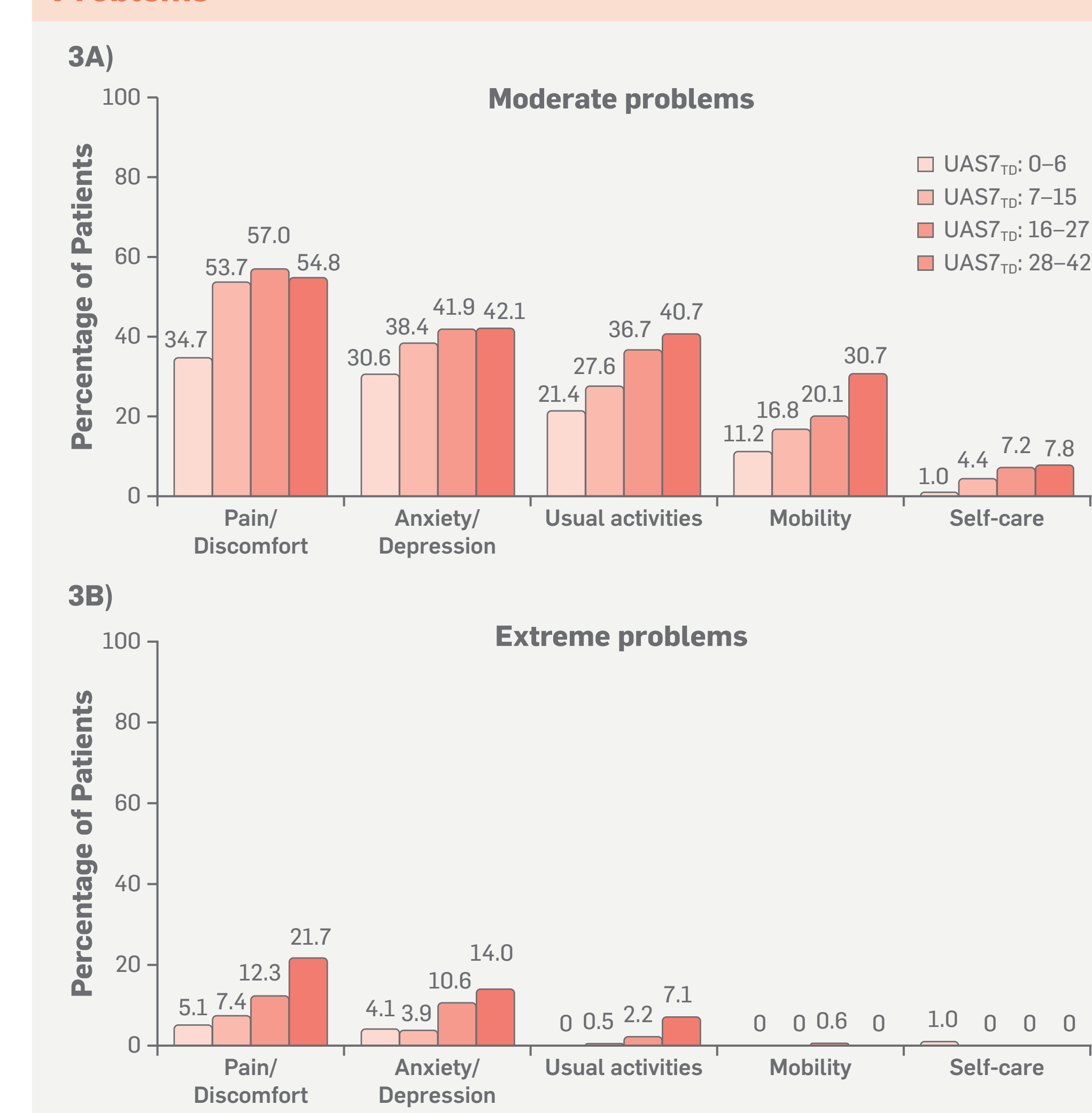
Figure 2. EQ-5D Dimensions: Percentage of Patients Reporting Moderate and Extreme Problems



### EQ-5D Dimensions by Disease Activity (Figure 3A and 3B)

- The percentage of patients reporting moderate or extreme problems was generally higher on all dimensions among those in the higher UAS<sub>7TD</sub> bands (higher disease activity)

Figure 3. EQ-5D Dimensions Stratified by Disease Activity: Percentage of Patients with Moderate (3A) and Extreme (3B) Problems



## CONCLUSIONS

- ASSURE-CSU is the first international study reporting real-world utility values in CSU using the EQ-5D
- Utility values reported from the ASSURE-CSU study are consistent with those recently published based on omalizumab in CSU phase III trials<sup>7</sup>
- Patients with higher disease activity as measured by UAS<sub>7TD</sub> had consistently lower utility scores reflecting a diminished quality of life
- Patients were most frequently affected on the pain/discomfort, anxiety/depression, and usual activities dimensions
- Utility values in CSU reported here confirm the impact of CSU on patients, allow for HRQoL comparisons with different disease areas, and could be used as inputs for economic models

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