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INTRODUCTION

Background

- Chronic spontaneous (also known as idiopathic) urticaria (CSU/CIU) is characterised by the occurrence of wheals/hives, angioedema or both for 6 weeks or longer due to known or unknown causes¹
- Chronic urticaria affects 0.5%–1% of the general population worldwide², and more than two-thirds of cases are spontaneous³
- Although CSU is not life threatening, it has a significant yet underestimated impact on patients' work productivity, particularly when it is not sufficiently controlled by medical treatment⁴
- Real-world evidence quantifying the economic burden of CSU is scarce, especially in patients with inadequate response to treatment

OBJECTIVE

- The ASSURE-CSU (ASsessment of the Economic and Humanistic Burden of Chronic Spontaneous/ Idiopathic URticaria PatiEnts) is the first international study to quantify the humanistic and economic burden of illness of patients with CSU who are symptomatic despite treatment
- This non-interventional, multinational study was conducted in 7 countries (Canada, France, Germany, Italy, UK, Spain and Netherlands)
- The current analysis reports the pooled results on work productivity and activity impairment in patients with CSU who are symptomatic despite treatment

METHODS

Study design

• This study included a 1-year retrospective medical record abstraction, a cross-sectional patient reported outcomes 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 for this analysis

- The patient-reported absenteeism, presenteeism and activity impairment over the previous 7 days were collected via the Work Productivity and Activity Impairment-Specific Health Problem (WPAI-SHP) questionnaire⁵ that was completed by patients on day 8 from inclusion
- Disease activity was collected during 7 days from inclusion with the Urticaria Activity Score⁶ (the twice daily version)
- Table 1 presents the list of variables that were collected in the study, along with their scoring methodology

Table 1. Variables and scoring methodology of data sources

Work Productivity and Activity Impairment– **Specific Health** Problem (WPAI-SHP) questionnaire completed on day 8 from inclusion (recall period -prior 7 days)

Source

Variables

- Employed: yes/no Absenteeism: Percentage of work time
- Presenteeism: Percentage of impairment due to CSU experienced while at work, rated on a scale of 0 (no effect) to 10 (completely impaired)

missed due to CSU in the past 7 days

- Overall work impairment: A combination of absenteeism and presenteeism
- Activity Impairment: Percentage of impairment due to CSU experienced in executing normal non-work daily activities scored on a scale from 0 (no effect) to 10 (completely impaired)
- 7-day patient diary (from Urticaria Activity Score assessed the inclusion to day 7) severity of itch and number of hives twice-daily over 7 days (UAS7_{TD})
 - At each assessment point, patients rated itch severity on a 4-point scale: 0 = none, 1 = mild, 2 = moderate,3 = severe. At the same time, patients recorded the number of hives on a 4-point scale: 0 = none, 1 = 1-6 hives, 2 = 7-12 hives, 3 = more than 12 hives

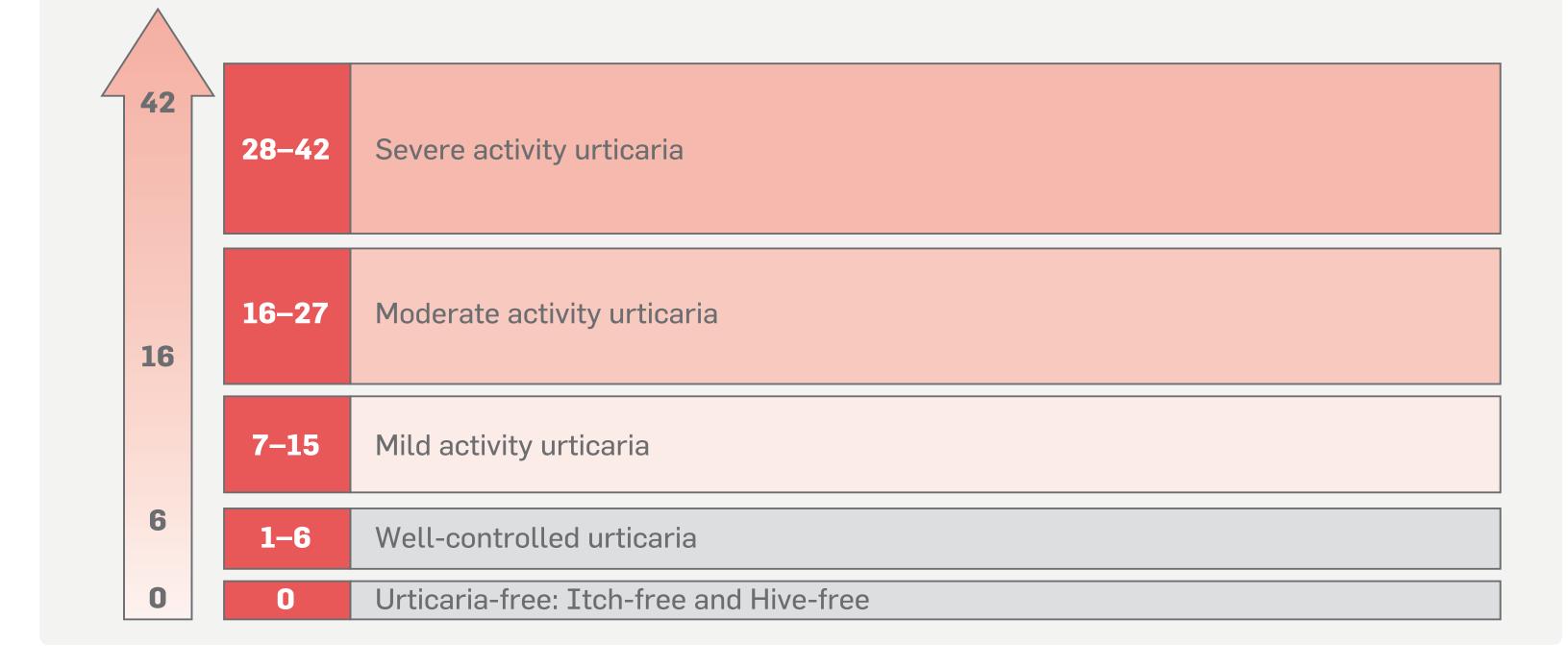
Scoring Methodology

- Scores were multiplied by 100 to be expressed as percentages, with higher scores reflecting greater impairment and reduced productivity
- Percentages of absenteeism, presenteeism, and overall work impairment were summarised for employed patients who answered all of the questions corresponding to the respective score
- Percentage of activity impairment was summarised for all patients
- Summaries included values of zero as a result of patients indicating zero work hours missed due to CSU, or zero effect on productivity while working, or on normal non-work daily activities
- The daily hives and daily itch scores were calculated as the average of each morning and evening assessment respectively. The weekly scores for both itch (weekly itch severity score) and hives (weekly hives score) were obtained by summing the daily scores for each component (each score range from 0–21)
- The UAS7_{TD} was obtained by summing the weekly itch score and the weekly hives score (range from 0-42)
- Higher scores indicate greater activity

Analysis

- Study measures were summarized using mean values and standard deviations (SD) for continuous variables and counts and proportions for categorical variables
- Descriptive statistics were provided and stratified by score bands of disease activity, measured by the weekly UAS7_{TD} (Table 2)

Table 2. Disease activity levels per UAS7_{TD} score bands



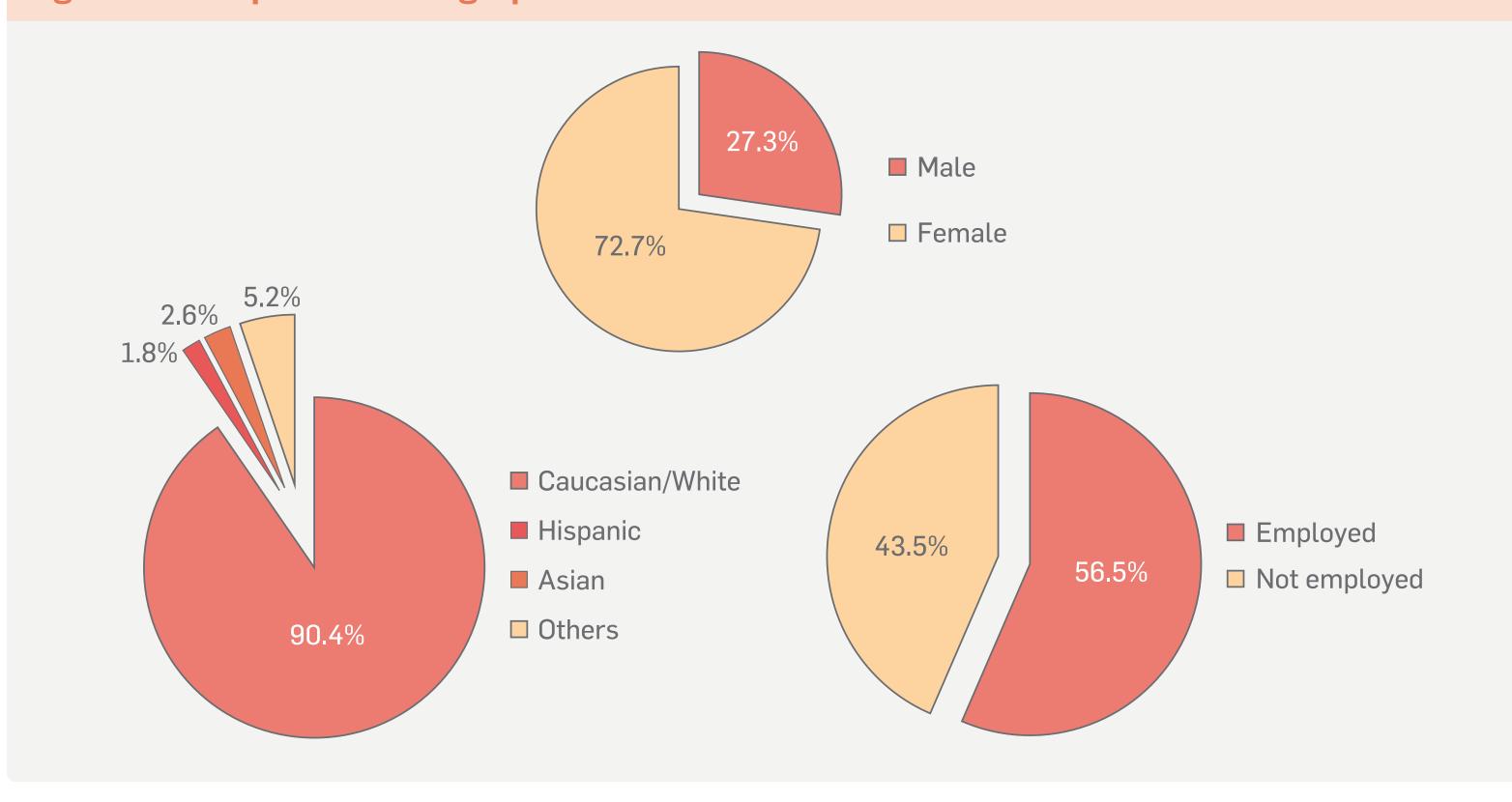
RESULTS

- Medical records were abstracted for 673 patients
- 614 patients returned the UAS7_{TD} and WPAI-SHP questionnaire

Patient demographics (Figure 1)

- The majority of enrolled patients were female (72.7%) and White/Caucasian (90.4%)
- The mean (SD) age of patients at enrollment was 48.8 (15.47) years
- Among the 604 patients who answered the question on employment status, 341 (56.5%) indicated that they were currently employed

Figure 1. CSU patient demographics



Impact of CSU on work absence and productivity (Figure 2a-2d)

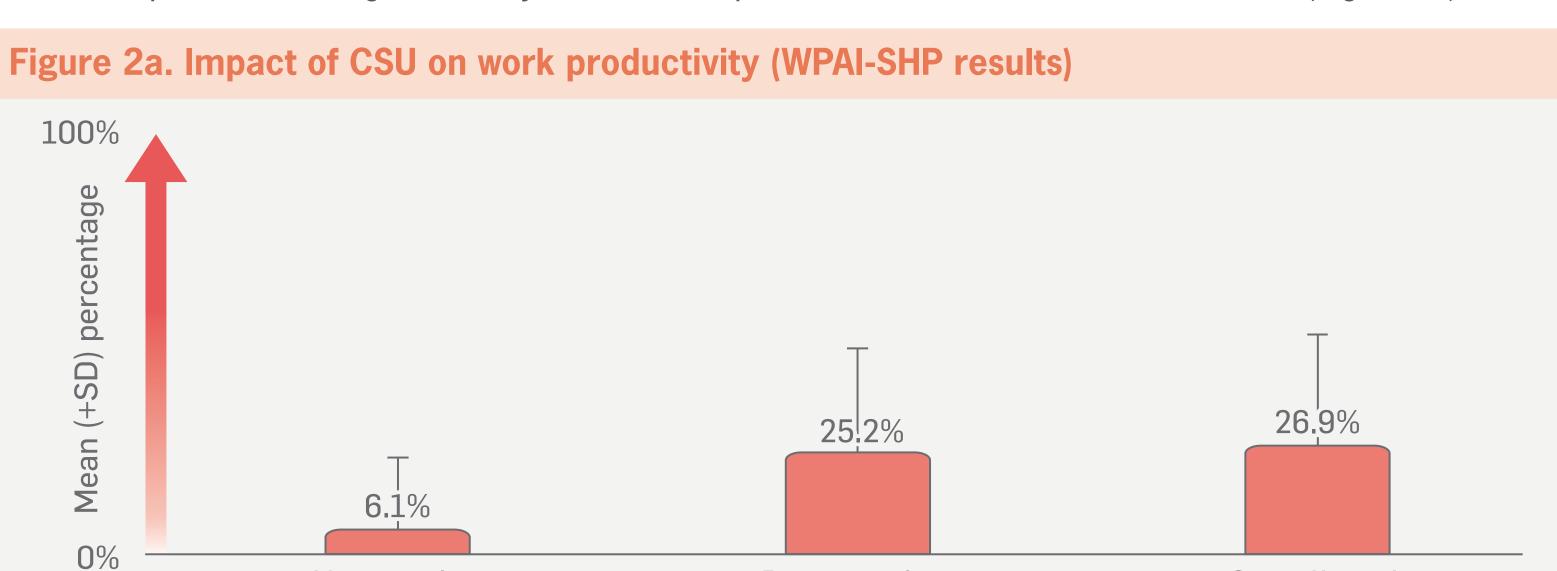
- Employed patients reported a mean (SD) proportion of absenteeism, presenteeism and overall work impairment of 6.1% (17.83%), 25.2% (25.78%), and 26.9% (27.53%) respectively (Figure 2a)
- Specifically, the highest percentages of absenteeism, presenteeism and overall work impairment were reported by patients with the greatest disease activity (UAS7_{TD}=28-42) (9.5%, 40.4% and 43.6% respectively) (Figure 2b)

PSS17

Overall work

impairment

- Among the employed patients 21.9% reported at least 1 hour missed from work in the previous 7 days and among them:
 - 43.1% of the patients reported between 1 and 4 hours missed; 19.4% reported 5 to 8 hours missed, 18.1% reported 9 to 16 hours missed, and 19.4% reported more than 16 hours missed (Figure 2c)
 - More patients with higher activity of urticaria reported at least 1 hour missed from work (Figure 2d)



Presenteeism

Work-related score completed only by employed patients (56.5%); recall period 7 days

Absenteeism

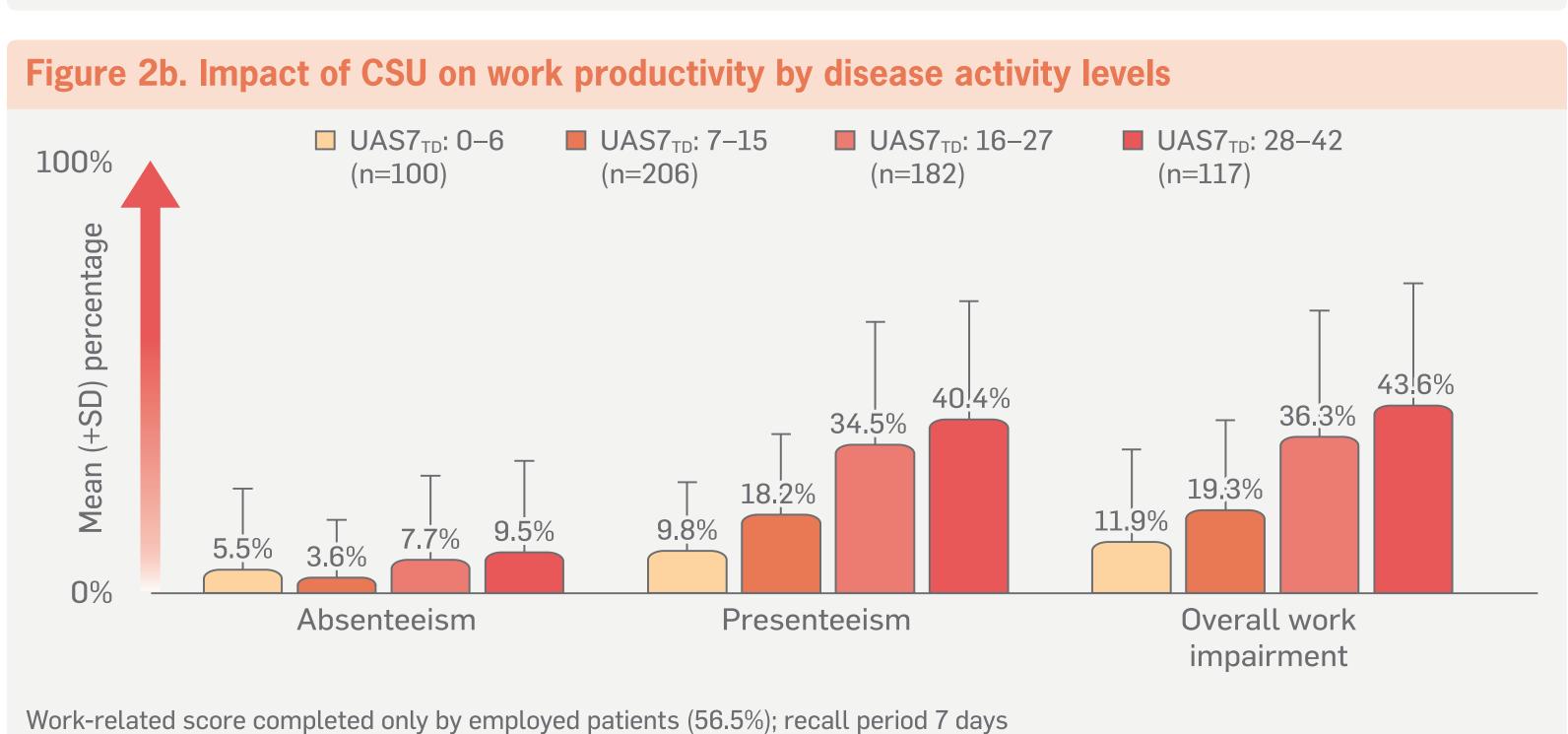


Figure 2c. Number of work hours missed in the past 7 days among patients who reported at

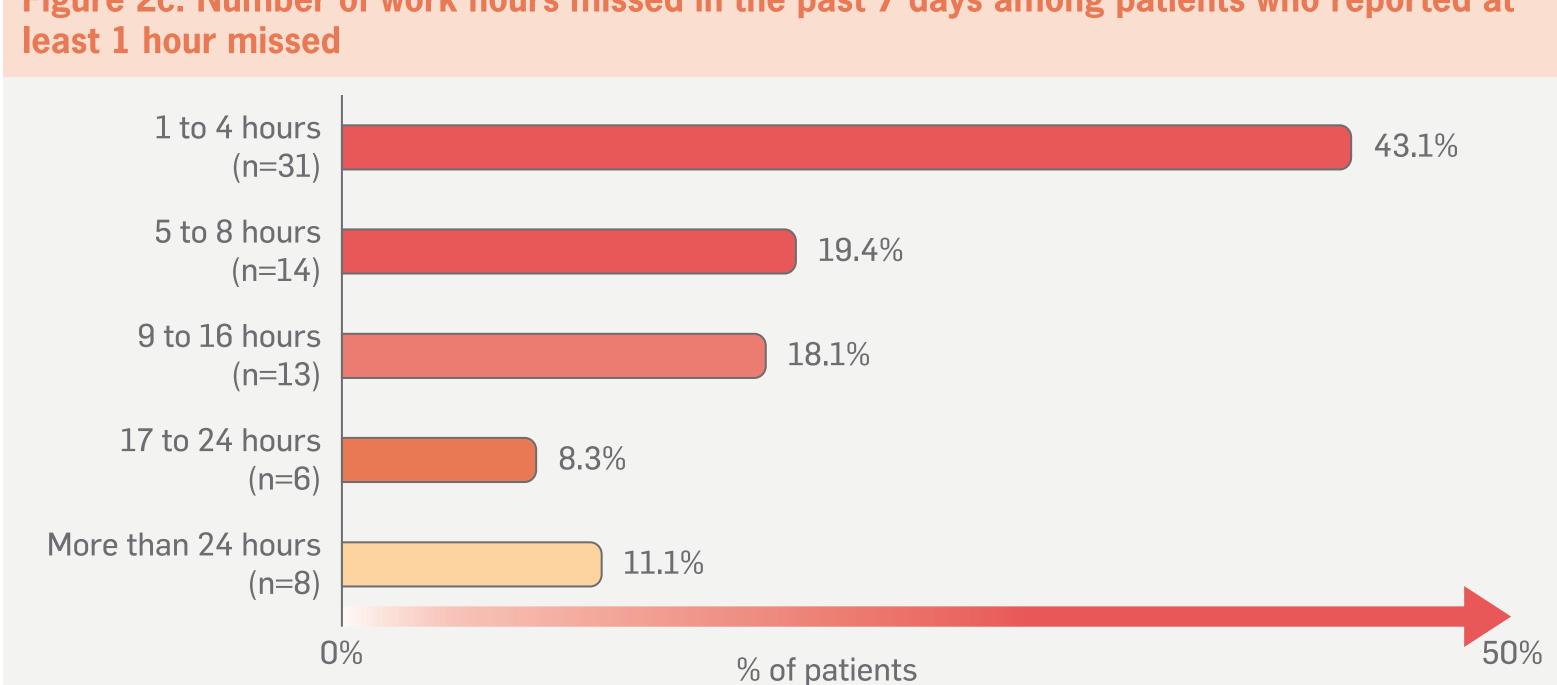
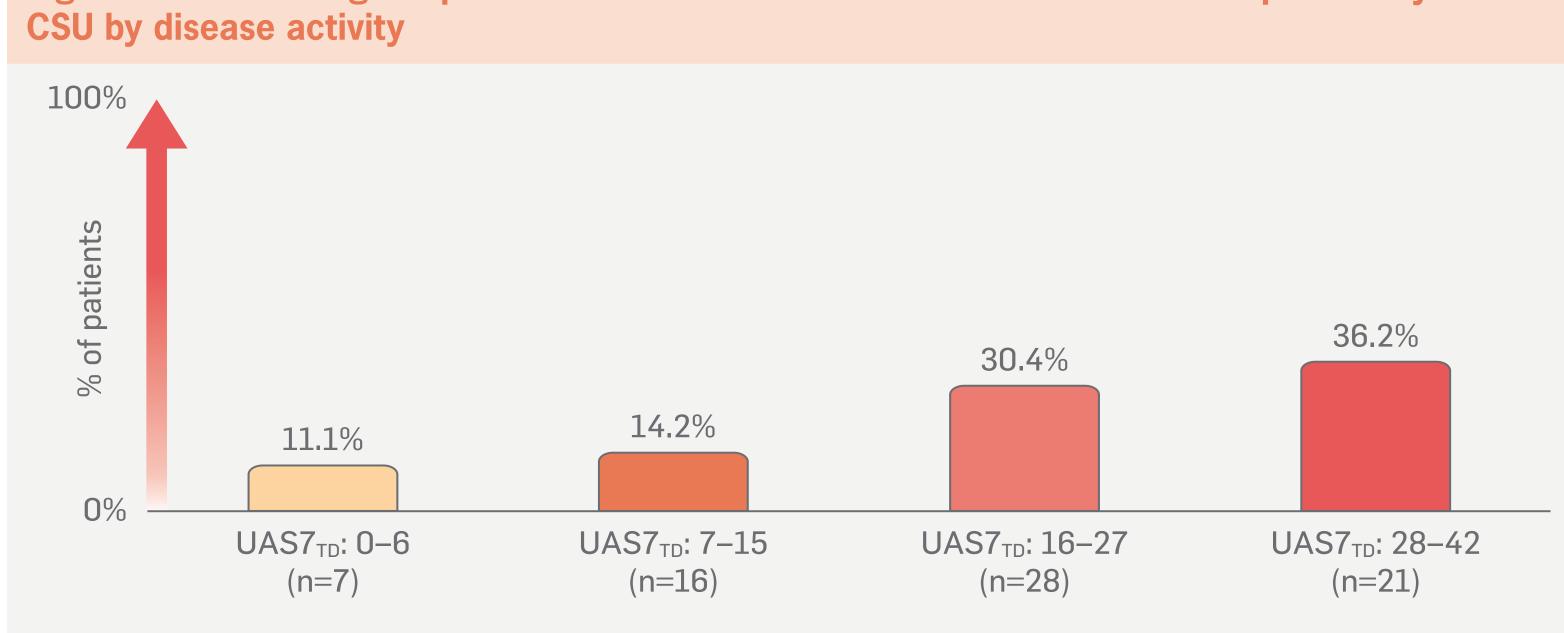


Figure 2d. Percentage of patients with at least 1 hour of work missed in the past 7 days due to

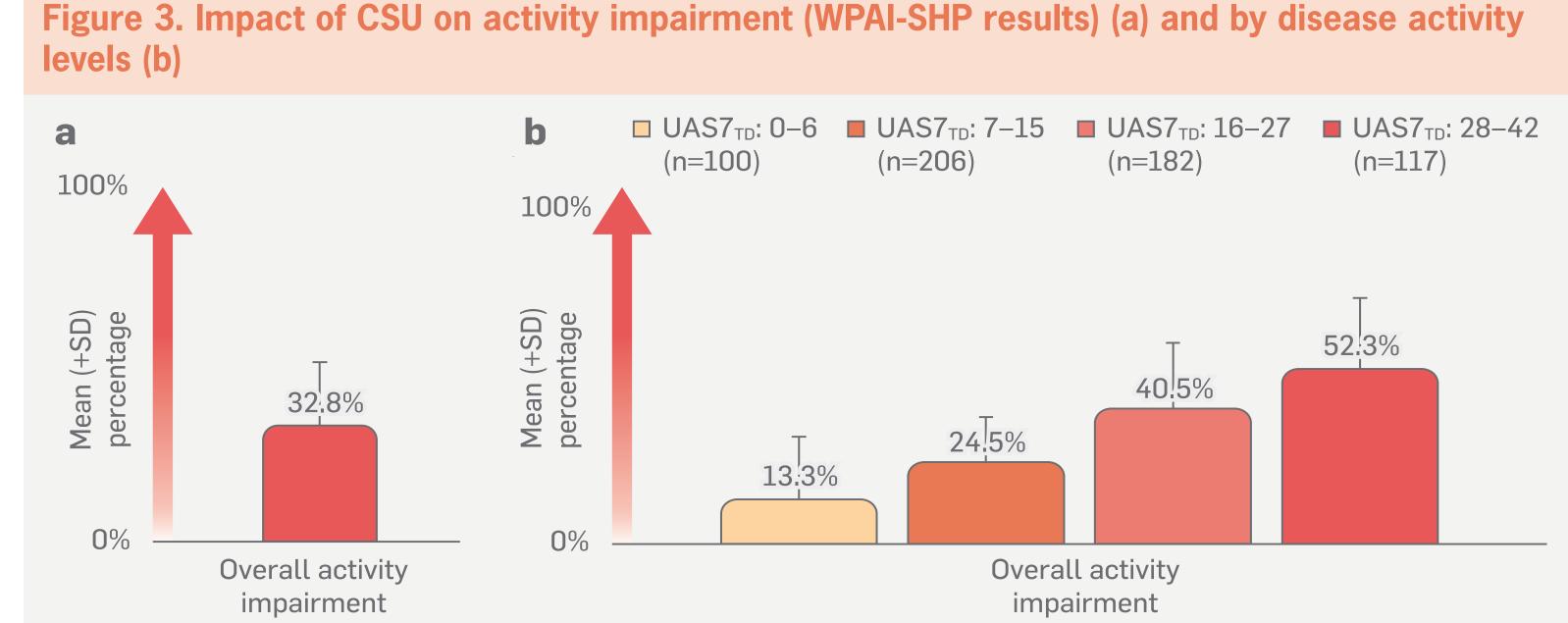


Work-related scores completed only by employed patients (56.5%); recall period 7 days

Work-related scores completed only by employed patients (56.5%); recall period 7 days

Impact of CSU on activity impairment (Figure 3a-3b)

- The overall mean (SD) score of activity impairment among all CSU patients was 32.8% (28.96%) (Figure 3a)
- The extent of impairment increased with increasing disease activity levels during the same time period - The highest percentage of activity impairment (52.3%) was reported by patients with the highest disease
 - activity (Figure 3b)



CONCLUSIONS

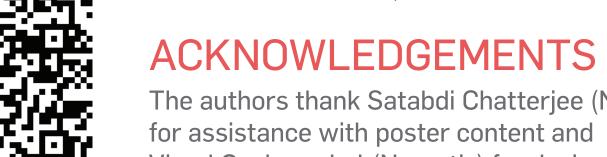
- The current analysis using data from the ASSURE-CSU study found that CSU patients experience substantial work productivity loss and activity impairment
- The study additionally found that the extent of work productivity loss and activity impairment among the CSU patients increased with the increase in disease activity levels
- Overall, results from this study demonstrated that CSU is associated with significant societal and economic burden, particularly among patients with higher disease activity and suggests high unmet need of effective treatment in this population

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