Descriptive analysis of self-reported HRQoL using EQ-5D-5L among symptomatic outpatients with COVID-19 in the United States during an Omicron predominant period

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INTRODUCTION

- There is limited data regarding healthrelated quality of life (HRQoL) in patients with COVID-19 treated with Paxlovid in the US during an Omicron predominant period.
- COVID-19 has significant implications for patients' well-being and social function, leading to a decline in health-related quality of life, impairments in daily activities, and the ability to work.[1, 2]
- Prior research from the UK has showed patients observe a steep decrement to self-reported health-related quality of life within the first week of acute infection.[3]
- In a nationwide prospective patientreported outcomes (PRO) survey-based study among symptomatic outpatient (NCT05160636), the positive impact of the BNT162b2 COVID-19 vaccine (Pfizer-BioNTech) on HRQoL endpoints is reported, with this study presenting the exploratory analysis of a subgroup of patients who received Paxlovid for their index infection.[4]

OBJECTIVE

This descriptive analysis aims to address the evidence gap regarding health-related quality of life (HRQoL) in patients with COVID-19 treated with Paxlovid in the US during an Omicron predominant period.

METHODS

- A prospective longitudinal survey study recruited symptomatic, COVID-19 positive individuals aged ≥18 years tested at a national retail pharmacy between 03/02/2023 and 05/18/2023 (NCT05160636).
- Among all patients with Paxlovid prescription within 7 days of laboratoryconfirmed diagnosis, HRQoL was assessed using the EQ-5D-5L at pre-COVID (questions asked retrospectively at enrollment), Day 3, Week 1, Week 4, Month 3, and Month 6 post-infection.
- Descriptive statistics were used to summarize HRQoL measures with means of EQ-5D-5L scores, percentages without limitation by EQ-5D-5L domain, and proportions of health state change from pre-COVID, including subgroups by adherent Paxlovid use (self-reported receipt within 5 days of symptom onset and completion of 5 days of treatment) and high-risk eligibility criteria (≥50 years or ≥1 underlying comorbid condition).

RESULTS

- Among the cohort of 173 individuals, 150 (87%) took Paxlovid within five days of symptom onset and 126 (73%) completed treatment. The mean (SD) age was 55 years (15), 70% female, 61% White, and 97% vaccinated with a median of 7 months from last vaccination. There were 66% of individuals aged 50 years or older and 35% with ≥1 comorbid condition. (Table 1)
- There was a steep decrement to self-reported HRQoL within the first week following acute infection. EQ-5D visual analogue scale (VAS) changed from 86.2 to 68.0, and EQ-5D-5L UI changed from 0.92 to 0.80. Individuals treated with Paxlovid showed improvement in HRQoL, returning to pre-COVID levels by Week 4 within 0.2 SD. Similar trends were observed across each subgroup. (Figures 1 (a) - (b)) [5,6]
- Within the first week following infection, more than 80% of respondents reported experiencing pain or discomfort and more than 68% of respondents reported problems with usual activities. Relative to pre-COVID responses, 72% of respondents reported a worsened health state on day 3 following positive COVID-19 test (Figures 2 and 3).

Table 1. Baseline characteristics

	All patients with Paxlovid Prescription	Adherent Paxlovid use	Adherent Paxlovid use & high-risk eligibility criteria	Adherent Paxlovid use & Age ≥50
Total n	173	126	94	78
Age, years, mean (SD)	54.5 (14.6)	54.0 (14.6)	59.2 (12.5)	63.7 (7.3)
Age ≥50 years	65.9% (114)	61.8% (78)	83.0% (78)	100% (78)
Female, % (n)	69.9% (121)	71.4% (90)	73.4% (69)	71.8% (56)
Race/Ethnicity				
White or Caucasian	60.7% (105)	61.1% (77)	68.1% (64)	69.2% (54)
Black or African American	12.7% (22)	12.7% (16)	13.8% (13)	12.8% (10)
Hispanic	12.1% (21)	12.7% (16)	11.7% (11)	12.8% (10)
Other	14.4% (25)	13.5% (17)	6.4% (6)	5.1% (4)
Vaccinated	97.1% (5)	99.2% (1)	98.9% (1)	98.7% (1)
Median time since last vaccination, months, (Q1, Q3)	7.1 (5.6, 14.0)	6.7 (5.2, 12.3)	6.6 (5.3, 11.2)	6.4 (5.4, 10.9)
≥1 comorbid condition*	35.3% (61)	37.3% (47)	50.0% (47)	39.7% (31)

^{*} Comorbid conditions include asthma or chronic lung disease, cirrhosis of the liver, immunocompromised conditions or weakened immune system, diabetes, heart conditions or hypertension, overweight or obesity, smoking

Figure 1. Mean EQ-VAS and UI Scores from Pre-COVID to 6 Months

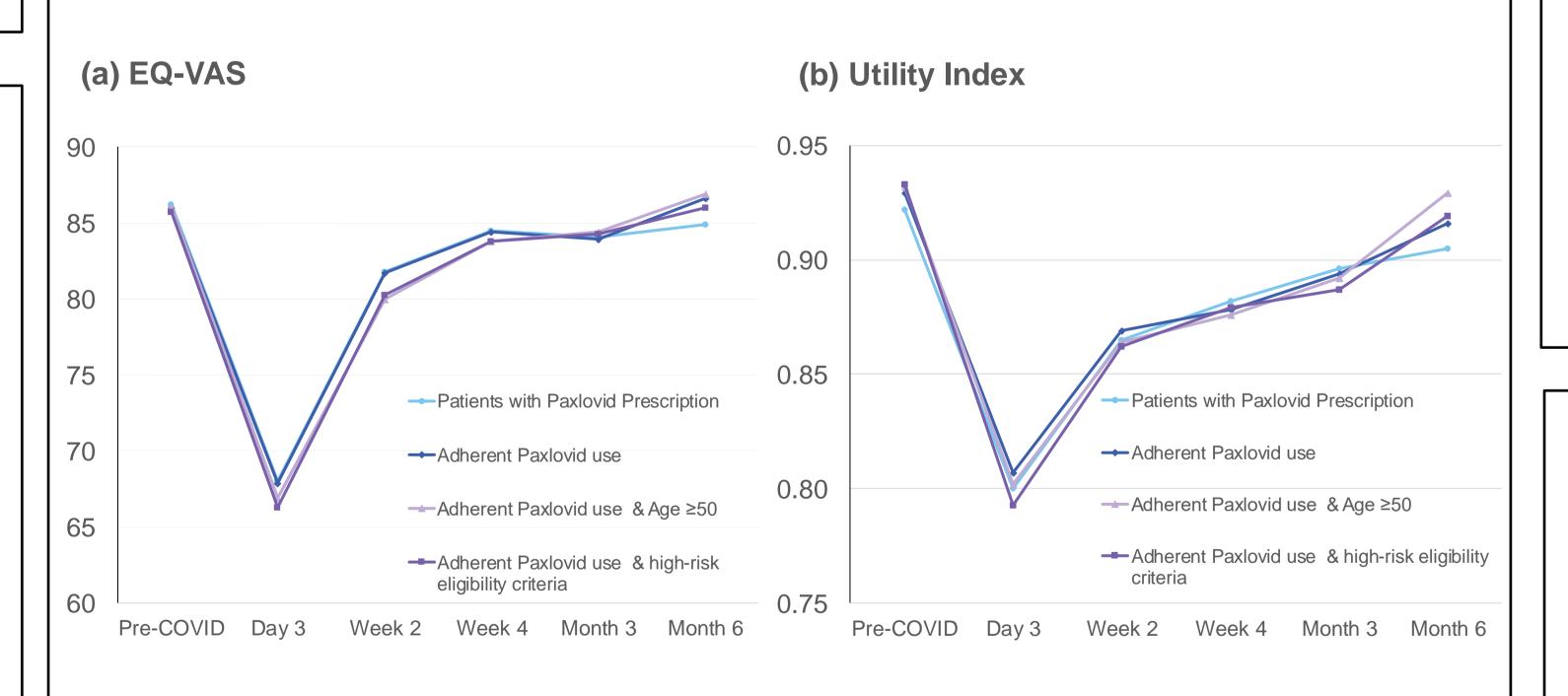
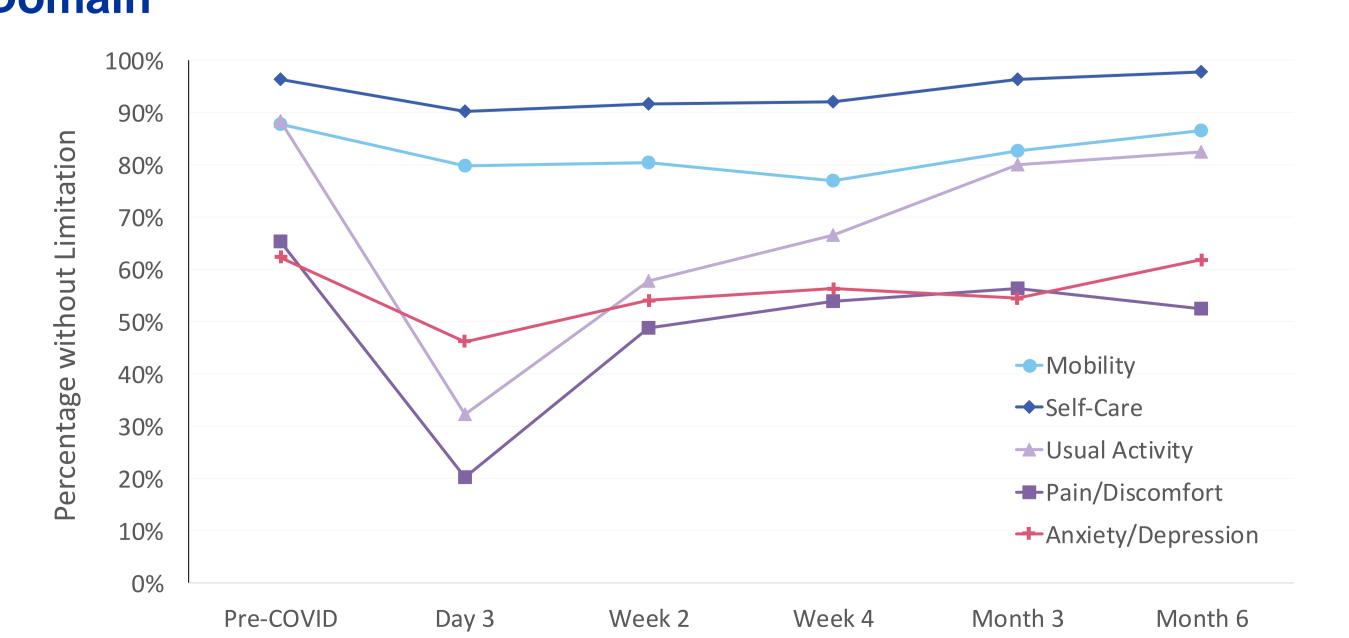
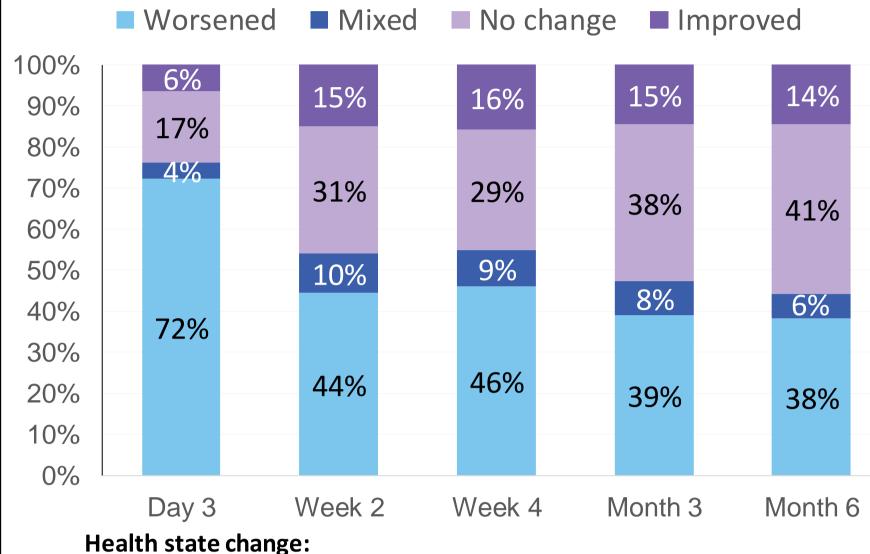


Figure 2. Percentages without Limitation Over Time by EQ-5D-5L Domain



RESULTS (continued)

Figure 3. Proportions of Health State **Change from Pre-COVID over Time** among All Patients with Paxlovid **Prescription**



- Worsened: at least domain worsened, and no change in other domains
- Mixed: at least domain improved and at least domain worsened
- No change: no change in all 5 domains
- Improved: at least domain improved, and no change in other domains

CONCLUSIONS

- The study adds to the growing evidence characterizing the humanistic burden of COVID-19 on HRQoL, particularly during the first week of acute infection, and shows improvement in HRQoL returning to pre-COVID observations among patients receiving Paxlovid.
- The study cohort was predominantly female and healthy (based on number of comorbid conditions) and may not be generalizable to other populations or future variants or sublineages.
- Further research is needed that directly aligns date of symptom onset and date of Paxlovid treatment initiation with assessment of HRQoL measures following treatment exposure.

REFERENCES

- 1. Poudel AN, Zhu S, Cooper N, et al. Impact of Covid-19 on health-related quality of life of patients: A structured review. PLoS One. 2021;16(10):e0259164. Published 2021 Oct 28.
- 2. Amdal CD, Pe M, Falk RS, et al. Health-related quality of life issues, including symptoms, in patients with active COVID-19 or post COVID-19; a systematic literature review. Qual Life Res. 2021;30(12):3367-3381. 3. Sandmann FG, Tessier E, Lacy J, et al. Long-Term Health-Related Quality of Life in Non-Hospitalized Coronavirus Disease 2019 (COVID-19) Cases With Confirmed Severe Acute Respiratory Syndrome Coronavirus
- 4. Di Fusco M, Sun X, Anatale-Tardiff L, et al. Impact of Bivalent BA.4/5 BNT162b2 COVID-19 Vaccine on Acute Symptoms, Quality of Life, Work Productivity and Activity Levels among Symptomatic US Adults Testing Positive for SARS-CoV-2 at a National Retail Pharmacy. Vaccines (Basel). 2023;11(11):1669. Published 2023 Oct 31.

2 (SARS-CoV-2) Infection in England: Longitudinal Analysis and Cross-Sectional Comparison With Controls. Clin Infect Dis. 2022;75(1):e962-

- 5. Mouelhi Y, Jouve E, Castelli C, Gentile S. How is the minimal clinically important difference established in health-related quality of life instruments? Review of anchors and methods. Health Qual Life Outcomes. 2020;18(1):1–17.
- 6. del Corral T, Fabero-Garrido R, Plaza-Manzano G, Navarro-Santana MJ, Fernández-de-las-Peñas C, López-de-Uralde-Villanueva I. Minimal Clinically Important Differences in EQ-5D-5L Index and VAS after a Respiratory Muscle Training Program in Individuals Experiencing Long-Term Post-COVID-19 Symptoms. Biomedicines. 2023; 11(9):2522.

Disclosures

A.S.C.-S., J.C.C., M.D.F., J.R., K.E.A., L.P. are employees of Pfizer and may hold stock or stock options of Pfizer. X.S. is employee of CVS Health and holds stock of CVS Health.