Patient reported outcome measure for Giant Cell Arteritis (GCA-PRO): Cross-sectional validation

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Clinical Outcomes

Background/Purpose:

Giant cell arteritis (GCA) presents in people over the age of 50 with cranial, ocular, and large vessel vasculitis. This study aims to validate a disease-specific patient reported outcome measure (PROM) for patients with GCA, to capture the impact of GCA and its treatment on health-related quality of life.

Methods:

This cross-sectional study included UK patients with clinician-confirmed GCA; diagnosed within the last three years or flaring within the last year.

Patients completed the 40 candidate PROM items, the EQ-5D-5L, Cat-PROM5 and self-report of disease activity. Rasch and factor analysis were used to determine internal validity and factor structure. Item reductions were based on clinical importance, Rasch model fit, and redundancy. Tests of validity included comparison of the GCA-PRO (i) in participants with 'active disease' versus patients 'in remission' (known groups validity) and (ii) with EQ-5D-5L and Cat-PROM5 scores (convergent validity).

If you have any questions about the GCA-PRO or want to find out more about the research, please contact:

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Alternatively you can vist the COA page on Oxford University Innovation's website using the QR code!

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Results:

The survey included 428 patients, mean age (SD) of 74.2 (7.2), 285 (67%) female. 327 (76%) cranial GCA, 114 (26.6%) large vessel vasculitis and 142 (33.2%) ocular involvement. Positive diagnostic tests included 167 (39%) temporal artery biopsy, 177 (41.4%) temporal artery ultrasound, and 51 (11.9%) Positron Emission Tomography and Computed Tomography (PET-CT). One hundred and eight participants (25%) received second-line immunosuppressants, and 34 (7.9%) anti-IL6 therapy. Active disease was reported in 197 (46%).

After the initial analysis (40 items), ten items were deleted, and two response categories collapsed to ensure overall fit to the Rasch model. This resulted in a final PROM comprising a 30-item scale with a 4-response category structure.

Factor analysis confirmed four factors (domains): Acute symptoms (8 items), Activities of daily living (7 items), Psychological (7 items) and Participation (8 items), all of which individually fitted the Rasch model (X^2 = 25.219, DF=24, p=0.394 including reliability [Person Separation Index, PSI=0.828]), (construct validity).

Each domain correlated, at least moderately, with EQ-5D-5L and Cat-PROM5 scores (Spearman's Correlation Coefficients 0.44 to 0.78) (convergent validity). The new GCA-PRO discriminated between patients with active disease and remission (known groups validity) (Table 1).

Table 1: Known groups validity for the four domains of GCA-PRO

Domain (range)	Active disease, mean (SD)	Remission, mean (SD)	t-statistic	p-value
Acute symptoms (0 to 24)	15.3 (3.5)	12.8 (2.0)	7.7	<0.001
Activities of Daily Living (0 to 21)	12.1 (3.5)	10.3 (3.0)	4.3	<0.001
Psychological (0 to 21)	15.6 (2.6)	14.2 (2.0)	4.4	<0.001
Participation (0 to 24)	12.3 (4.2)	10.1 (3.0)	4.9	<0.001
Total score (0 to 90)	51.5 (8.5)	46.0 (6.3)	4.8	<0.001

Conclusion:

The 30-item GCA-PRO demonstrates internal and external validity in measuring health-related quality of life in people with GCA.

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