

## **A common measure of the impact of glucocorticoids in patients with inflammatory and autoimmune conditions - the Steroid PRO: A cross-cultural validation study with Rasch models**

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### **Abstract**

#### **Background/Aims:**

Systemic glucocorticoids are key in the management of life-and organ threatening rheumatic diseases, but they have wide-ranging adverse effects which are of concern to patients and clinicians.

We aimed to validate a Patient Reported Outcome (PRO) measure (the Steroid PRO) for assessing the impact of glucocorticoids on health-related quality of life (HRQoL) in patients receiving this treatment for rheumatic diseases.

#### **Methods:**

This was a large cross-sectional study including adult participants from the UK, USA, Australia and New Zealand, currently taking glucocorticoids for a rheumatic disease. A large-scale online survey was designed containing two parts. Part A included: (i) demographics - age, gender, country, ethnicity, educational level (ii) clinical information - diagnosis, glucocorticoid dose (iii) 40 candidate items for the Steroid-PRO, developed in a previous qualitative study (iv) the Euroqol (EQ-5D-5L). Part B was optional, to be completed 3 days later, containing the Steroid PRO items again and a question to indicate if the participant's condition had changed.

The survey was distributed via social media platforms and patient organisations networks.

Data were first analysed descriptively, then the Steroid-PRO data were fitted to the Rasch measurement model to test the internal validity and reliability of the scale. Iterative Rasch analysis and exploratory factor analysis (EFA) informed item reduction and established

structural validity, reliability, and unidimensionality of the final Steroid-PRO. Item reduction was based on clinical importance, lack of fit to the Rasch model, and redundancy. Further evidence of Steroid-PRO validity and was established with hypothesis testing comparing Steroid-PRO scores for participants receiving low dose (up to 10 mg) versus high dose (above 10 mg) of glucocorticoids – discriminative validity. Intraclass correlation (ICC) with absolute agreement between time 1 and time 2 was computed for patients who reported ‘no change’ compared with three days ago.

### **Results:**

A total of 946 patients returned complete responses at time 1 (447 at time 2). The majority (743, 78.5%) were from the UK, 139 (14.7%) USA and 59 (6.2%) Australia. Mean age was 57.6 (SD=13.6) and 833 (88%) were women. In terms of occupation, 364 (38.4%) were employed, 347 (36.6%) retired, 154 (16.3%) disabled and 68 (8.2%) unemployed. The majority (616, 65%) had college/university degree. The conditions were grouped into three groups: inflammatory arthritis (N=194), connective tissue disease and vasculitis (N=398), and Giant cell arteritis and Polymyalgia rheumatica (N=341).

Item response structure for all items was changed from 5 to 4 Likert scales to correct threshold ordering. A total of 15 items were removed due to floor effects and lack of fit to the Rasch model. The remaining 15 items showed a satisfactory fit to the model although multidimensionality was evident in the scale. EFA suggested a scale structure with four domains: Participation (4 items), Appearance (3 items), Psychological (5 items), and Treatment concerns (3 items). This 4-domain structure was supported by the Rasch model, confirming its construct validity;  $\chi^2 = 47.82$  (DF=36),  $p=0.899$ ; reliability Person\Separation Index=0.757 and the unidimensionality of the overall scale - only 2% of independent t-tests were significant in the Smith’s test ( $p=0.022$ , 95%CI 0.008 to 0.036).

Patients on a low glucocorticoid dose had consistently lower Steroid-PRO scores on each domain than those receiving high dose, supporting discriminative validity of the Steroid-PRO. ICC between time 1 and time 2 for all items ranged from 0.892 to 0.942 (95%CI 0.868 to 0.953) suggesting excellent (test-retest) reliability.

**Conclusion:** The final Steroid-PRO is a 15-item, 4-domain scale with robust evidence of validity and reliability in measuring the impact of glucocorticoid therapy on HRQoL of people with rheumatic diseases.

**Key words:** glucocorticoid steroids, quality of life, patient reported outcome measures, Rasch analysis