Seminars in Arthritis and Rheumatism 63 (2023) 152285

Contents lists available at ScienceDirect

Seminars in Arthritis and Rheumatism

journal homepage: www.elsevier.com/locate/semarthrit

Beyond the symptoms: Personalizing giant cell arteritis care through multidimensional patient reported outcome measure

Y El Miedany [a,b,*], M El Gaafary [c], M Toth [b,d], D Palmer [e], Ayman Ali [d], S Bahlas [f], S Mahran [g], W Hassan [h], MH Abu-zaid [i], S Saber [j], W. Elwakil [k]

[a] Professor Canterbury Christ Church University, England
[b] H. Senior Clinical Lecturer, King's College London, England
[c] Professor Community and Public Health, Ain Shams University, Cairo, Egypt
[d] Darent Valley Hospital, Kent, England
[e] North Middlesex University Hospital, London, England
[f] Professor of Internal Medicine/Rheumatology, College of Medicine, King Abdulaziz University, Saudi Arabia
[g] Professor Rheumatology, Physical Medicine and Rehabilitation, Assiut University, Egypt
[h] Professor Rheumatology and Rehabilitation, Benha University, Benha, Egypt
[i] Assistant Professor Rheumatology and Rehabilitation, Tanta University, Tanta, Egypt
[j] Rheumatology and Rehabilitation, Ain Shams University, Cairo, Egypt
[k] Lectuer Rheumatology and Rehabilitation, Alexandria University, Alexanrdia, Egypt

ARTICLE INFO

Keywords:
Giant cell arteritis
GCA
PROMs
GCA-PROMs
Patient education
Patient stratification
Benefit/risk ratio

ABSTRACT

Background: Giant Cell Arteritis (GCA) is the commonest form of systemic vasculitis in people over the age of 50. Published research highlighted the lack of a disease-specific patient reported outcomes (PROMs) for GCA.
Objectives: To assess the validity, reliability and responsiveness to change of a devised disease specific patient self-reported outcome measures questionnaire for Giant Cell Arteritis (GCA).
Methods: The GCA-PROMs was conceptualized based on frameworks outlined in the OMERACT developed core set of Outcome Measures for Large-Vessel Vasculitis and the guiding principles of the FDA guidance. Initially, cognitive interviews were conducted to identify item pool of questions. Item selection and reduction was achieved based on patients as well as an interdisciplinary group of specialists. Rasch and internal consistency reliability analyses were implemented.
Results: A total of 54 GCA patients completed the questionnaire. The GCA-PROMs questionnaire was reliable as demonstrated by a high standardized alpha (0.878–0.983). Content construct assessment of the GCA-PROMs functional disability and QoL revealed significant correlation ($p< 0.01$) with both HAQ and EQ-5D. Changes in functional disability, QoL showed significant ($p< 0.01$) variation with diseases activity status in response to therapy.
Conclusions: The developed GCA-PROMs questionnaire is a reliable and valid instrument for assessment of GCA patients. A stratified treatment regimen depending on the individual patient's risk factors as well as preferences and associated comorbidities is the best approach to tailored patient management.

Key Points

- Patient reported outcome measures tool assesses the medical care outcomes as perceived by the patients, including treatment effectiveness and safety.
- Giant cell arteritis disease specific patient reported outcome measures tool is vital for both standard practice as well as clinical trials.
- Giant cell arteritis disease specific patient reported outcome measures tool facilitate the assessment of the impact of the GCA symptoms and intervention on the individual patient's health related quality of life measure and set up a treatment plan tailored to the patient's needs.

* Corresponding author at: Consultant Rheumatologist, Professor Canterbury Christ Church University, England.
E-mail address: secretary@rheumatology4u.com (Y. El Miedany).

https://doi.org/10.1016/j.semarthrit.2023.152285

Available online 28 October 2023

Introduction

Giant cell arteritis (GCA) is a type of vasculitis that affects medium and large arteries, particularly those in the head and neck. It is a chronic condition that can lead to permanent visual loss, stroke, and other serious complications if left untreated [1]. In addition to the characteristic cranial symptoms of GCA, extracranial Large Vessel Vasculitis "LVV-GCA" disease spectrum may also expand to include affection of the aorta and its main branches without cranial involvement [2]. Because of the relatively high risk of permanent visual loss (reported in about 20 % of the patients), GCA has been considered a medical emergency [3,4]. Therefore, prompt management is urgently required to safeguard the patient's sight [5] and glucocorticoids have been the corner stone of GCA treatment for decades.

Personalized patient care is an approach to healthcare that considers the unique needs and preferences of each individual patient. Patient-reported outcome measure (PROMs) provide valuable information about how patients experience their illness and the impact it has on their daily lives. This information can help healthcare providers make more informed decisions about treatment options and monitor the effectiveness of interventions over time [6]. In GCA patient-reported outcome measures (PROMs) can be used to assess the impact of the disease on patients' functional abilities as well as quality of life and help tailor treatment plans to their specific needs [7]. Current disease activity assessment tools were found to be inadequate to assess and monitor disease activity in GCA [8]. This situation leads to significant variations in clinical practice. Therefore, there has been a real need for a disease-specific patient-reported outcome measures (PROMs) for GCA to fill this gap in the literature. This study was carried out aiming to develop a disease-specific self-reported PROMs questionnaire for GCA; assess its validity, reliability as well as responsiveness to change for use as an outcome measure in clinical studies (e.g. randomised controlled trials).

Methods

The PROMs tool was conceptualized based on frameworks outlined in the OMERACT developed core set of Outcome Measures for Large-Vessel Vasculitis [9] and the guiding principles of the FDA guidance [10]. This was multicentre study carried over 18-months period. The developed questionnaire was prepared and validated in both English and Arabic formats. The patients' cohort included in this work included 28 native English speaking and 26 Arabic speaking patients living in the catchment area of the contributing middle east centres. Participants were made aware of the study by their treating healthcare professionals. All patients who shared in the study signed an informed consent according to the declaration of Helsinki. The study protocol was approved by Tanta university ethical committee, ethical approval number 36264PR45/1.

Step I: development of the GCA specific item tool

Driven by the OMERACT report (2018) [11] regarding the development of outcome measure in Large-vessel Vasculitis: the information, content, and format of the PROMs were developed via a) systematic review of the available evidence, b) cognitive interviews with 12 patients (6 men and 6 women mean age 63.4 + 7.81) mean disease duration 6.7 + 4.8 weeks) diagnosed according to American College of Rheumatology/EULAR classification criteria for giant cell arteritis [12], with a range of severity to identify the item pool questions. Data were recorded using a structured proforma sheet. Interviews took place in a private room and lasted between 30 and 60 min. The patients were given the opportunity to identify areas of their lives that were important from their point of view. c) steering committee input to discuss evaluation of the GCA patients' needs and input from all key informants. d) Item selection and reduction was achieved based on patients as well as an interdisciplinary group of physicians, nurses, and health educators, in addition to clinometric and psychometric methods. The latter included Rasch and internal consistency reliability analyses. Following a content analysis of the transcripts reflecting important patient-reported outcomes, the GCA-specific measures of impairment and health related quality of life were listed. Related themes were highlighted, grouped together and organised by conceptual categories [13–15]. The content analysis, category identification and linguistic evaluation was discussed between members of the development team and assessed for repetition and ambiguity. The information gathered was incorporated into the GCA-PROMs draft. The detailed methodology was described in a former publication [16].

Step II: development of the questionnaire

The questionnaire included 5 domains:

I. Health Related Quality of Life assessment questionnaire: include 10-items scale to assess a) functional ability, and 10-items to assess b) quality of life. Using Rasch analysis [17] for ordered response options, content analysis and semi structured group discussion, the questionnaire was developed. The patient should respond using one of the 4 standard response options: 0 = without any difficulty, 1 = with some difficulty, 2 = with much difficulty and 3 = unable to do. The mean score for each of the functional ability index as well as quality of life is calculated, and the total score ranged from 0 to 3 [18].

II. Disease activity parameters [19]: namely severity of temporal headache, severity of acute visual loss, patient global assessment, fatigue, memory affection and difficulty to concentrate, assessed using numeric rating "0–10-cm" horizontal visual analogue scales (VAS) that contains half units, where a score of 0 = no symptoms, and a score of 10 = very severe symptoms. The range is 0–10.

III-A. Assessment of the disease symptoms and systemic features (12-items check list): reflecting the patients' benefit and response to therapy, or relapse, using tick boxes.

III-B. Psychological impact of the disease/ Self-perception (6-items check list): reflecting the psychological changes that patient might have developed in response to the disease or its medical therapy.

IV-A. Self-reported risks associated with medical therapy (25 items check list). Reflecting risks associated with steroid management.

IV-B. Self- reported comorbidities (15 items): which help to stratify the patients according to their risk factors, using tick boxes.

IV-C. Falls risk assessment using Falls Risk Assessment Score (FRAS) [20]

V. Patient motivation score: to assess for the individual patient's motivation. The questionnaire includes 10-items questions and using numeric rating "0–10 cm" Visual Analogue Scale to score each item. A mean score is calculated across all items. The total score ranged from 0 to 10.

Step III: validation

The routine clinic was used as a setting for the questionnaire evaluation. 54 registered patients who meet the American College of Rheumatology/EULAR classification criteria for giant cell arteritis [12] were included in this step of the work. All patients were asked to complete the PROMs questionnaire while sitting in the waiting area before being examined by the treating physician. A supervising nurse was present to provide help, if needed. Assessment of the disease and medication associated risks: HbA1c, blood pressure both upper limbs,

body weight, lipid profile, DXA-scan and 10-year probability of fracture risk was carried out for every patient. Also, every patient had ultrasound scan for assessment of axial artery, common superficial temporal artery, and its parietal and frontal branches. The PROMs questionnaire was validated by comparing its yield to a group of other instruments' results that explore different disease activity parameters:

- Vascular deficit whether cranial or extracranial
- Acute visual deficit
- GCA outcome measures: Temporal headache, visual deficit, and patient global assessment.
- Laboratory assessment for inflammatory markers: (The erythrocyte sedimentation rate (ESR) measured using Westergren's method and CRP using ELISA technique.
- Falls risk assessment (FRAS) [20]
- In addition, each patient completed a copy of the Stanford HAQ [21] as well as European quality of life questionnaire- 5D [22]. The EQ-5D includes single item measures of: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each item is coded using 3-levels (1 = no problems; 2 = some problems; 3 = severe problems). The instrument includes a global rating of current health using a visual analogue scale (VAS) ranging from 0 (worst imaginable) to 100 (best imaginable). An additional single item measure of health change (better, much the same, worse) was included.

Reliability and comprehensibility

Test-retest reliability (reproducibility) was assessed by asking the patients to complete a second copy of the questionnaire 2-days after the initial visit to the rheumatology department when they completed the first copy. "Analysis of properties of the questionnaire" was set as a justification for completing the questionnaire for the second time. After completing the questionnaire for the first time, every patient was asked to rate the questionnaire out of 10 to assess for the comprehensibility.

Responsiveness

Responsiveness has been described as the ability of an instrument to measure clinically important change over time with change at present. Sensitivity to change of the PROMs questionnaire was assessed in 54 patients who received medical management as well as a patient education program. Patients completed the questionnaire at baseline assessment and 4-weeks as well as 12-weeks after treatment. Average percentage changes in disease severity parameters assessed by GCA-PROMs were assessed.

GCA medical management

All patients started steroid therapy according to the EULAR recommendations [5], however, patients were also stratified according to their associated comorbidities, such that a combination of steroids and methotrexate therapy was commenced for those patients precenting with acute GCA symptoms in association with diabetes mellitus, depression, or eye affection (cataract or glaucoma). Tocilizumab therapy was commenced in selected patients with GCA refractory, or relapsing disease, the presence or an increased risk of GC related adverse effects or complications: osteoporosis, diabetes, cardiovascular disease, or glaucoma.

Statistical analysis

Data collected regularly and statistical manipulation was performed using the 11th version of SPSS. Variables are summarized in the form of mean and standard deviation if continuous, and frequency distribution if categorical. Median and Inter-quartile range (IQR) was calculated for skewed data. Pearson correlation coefficient was used to figure out correlation between quantitative variables. Error bars and scatter diagram were used to illustrate deviations and correlation respectively of different variables. Changes in the PROMs questionnaire were calculated by subtracting the second record from the first record. Intraclass correlation coefficient for agreement (reliability) and consistency was calculated, and alpha statistic was calculated as an additional measure of reliability. Validation was tested by calculation of Spearman's correlation coefficient with the tested questionnaire and the selected confirmatory tests. P value is significant if less than 0.05.

Results

Fifty-four patients (18 males, 36 females, mean age 68.8 ± 7.8 years, mean disease duration 2.3 ± 1.9 weeks) who meet the American College of Rheumatology/EULAR classification criteria for giant cell arteritis [12] included in this work to assess for the validity and reliability of the GCA-PROMs questionnaire.

Applicability and feasibility of the PROMs: The mean time to complete the questionnaire was 5.16 + 0.28 min. The mean time to scan and score the patient answers 1.72 + 0.47 min. One hundred and 49 (90.7 %) assigned the PROMs questionnaire as comprehensive giving scores higher than or equal 8.5. Five patients (9.3 %) recorded a score of 7–8 out of 10. A mean score of 9.3 was reported by the interviewed patients (95 % CI 9.3–9.6)

Validity: To assess the validity of the GCA-PROMs questionnaire items were compared to the parameters of disease severity, Table 1 shows correlation of the GCA-PROMs items with the disease outcome measures as well as the inflammatory markers (ESR and CRP) in the GCA patients included in this work.

Both the functional ability and quality of life questionnaires had no misfitting items, correlated significantly ($p< 0.01$) with clinical parameters of disease activity, whereas Cronbach's alpha for functional ability was 0.947 and quality of life was 0.938. A significant correlation ($p< 0.01$) was observed in percentage changes of both functional ability score and quality of life score with those of the scores of GCA outcome measures including headache and acute visual deficit scores (Table 2).

Comparing the GCA-PROMs functional ability to the Stanford HAQ among GCA patients revealed a significant correlation with $r = 0.924$, $p <0.001$. Similarly, there was a significant correlation between GCA-PROMs Quality of life and EQ-5D score with $r = 0.891$ ($p< 0.001$) as well as EQ-5D VAS score with $r = 0.886$ ($p< 0.001$).

Reliability: Minimal changes ranging between −0.02 and 0.06 were noticed when repeating the GCA-PROMs for functional ability assessment while the quality-of-life score demonstrated changes ranging between 0.03 and 0.11 (Table 3). Standardized alpha as well as intraclass correlation coefficient (ICC) showed a high value for the functional impairment, quality of life as well as patient motivation scores.

Responsiveness: On studying the correlation of percentage changes in GCA-PROMs Functional disability and quality of life (QoL), motivation score as well as percentage of change of disease severity parameters, a statistically significant correlation ($p< 0.001$) was observed. Table 4 shows the average percentage of change was almost in the same range for the different instruments.

Stratification of the patients' management, helped to achieve significant improvement in 47 patients (87 %) by week-12. IV methylprednisolone therapy was administered in 25/54 (46.3 %) patients, whereas prednisolone monotherapy was recommended in 29/54 (53.7 %) patients. Combined prednisolone and methotrexate therapy at baseline was reported in 7/54 (13 %) patients, whereas methotrexate therapy was added to prednisolone by week-4 in 5/54 (9.3 %) patients. Tocilizumab was commenced in by week-8 in 8/54 (14.8 %) patients Assessment of benefit/risk ratio was positive reflecting good response to therapy in 37/54 (68.5 %) Patients whereas it was negative indicating poor response to therapy and development of steroid side effects in 17/54 (31.5 %) Of the patients.

Table 1
Giant Cell Arteritis: Correlation of the GCA-PROMs items with the disease activity parameters as well as the inflammatory markers (ESR and CRP) as Validating tools.

Items of the PROMsQ	Acute Temporal Headache	Acute Visual Deficit	Jaw Pain	EQ-5D	HAQ	ESR	CRP
Functional disability	0.752**	0.778*	0.692**	0.665**	0.946**	0.641**	0.628**
Quality of Life	0.764**	0.671**	0.763**	0.876**	0.581**	0.621**	0.751**
Patient Global Assessment	0.858**	0.674**	0.768**	0.569**	0.653**	0.632**	0.674**
Fatigue Score	0.869**	0.676**	0.748**	0.662**	0.596**	0.648**	0.687**
Trouble Thinking	0.846**	0.795**	0.573**	0.578**	0.558**	0.608**	0.572**
Motivation	-0.684**	-0.754**	-0.687**	-0.598**	-0.697**	-0.589**	-0.649**

Table 2
Correlation between GCA outcome measures and Functional Disability Score at Baseline, 4 weeks and 12 weeks follow up.

	Functional Disability					
	Baseline		At 4 weeks		At 12 weeks	
	r	P	r	P	r	P
Headache	.670**	.000	.902**	.000	.723**	.000
Vision	.660**	.000	.897**	.000	.917**	.000
ESR	.263*	.016	-0.329*	.015	-0.310*	.023
Patient GA	.540**	.000	.913**	.000	.847**	.000
Physician GA	.380**	.002	.811**	.000	.800**	.000

Table 3
Reproducibility of GCA-PROMs Questionnaire.

	First Measure *Mean (SD)*	Change *Mean (95 % CI)*	*Standardized Alpha*	*ICC (95 % CI)*
Functional Ability	2.7 (0.6)	0.01 (-0.02 – 0.06)	0.983	0.936 (0.914–0.956)
Quality of life	2.9 (0.9)	0.07 (0.03 – 0.11)	0.965	0.932 (0.913 – 0.948)
Acute Headache	8.9(0.8)	0.11 (0.05 – 0.13)	0.893	0.87 (0.82–0.86)
Acute visual deficit	7.06 (1.5)	0.1 (0.04 – 0.12)	0.932	0.86 (0.84–0.88)
Patient Global Assessment sleep	8.9 (0.63)	0.08 (0.03 – 0.14)	0.878	0.87 (0.83–0.86)
Fatigue	8.8 (0.61)	0.09 (0.02 – 0.13)	0.925	0.83 (0.82–0.88)
Motivation score	8.9 (0.42)	0.07 (0.05–0.08)	0.934	0.942 (0.943 – 0.956)

Table 4
Percentage Changes in GCA outcome measures at different points of follow up.

	Percentage Changes			*P* value
	Baseline – 4 wks (%)	Baseline – 12 wks (%)	4 wks – 12 wks (%)	
Headache	72.3 ± 10.9	87.1 ± 8.0	54.86 ± 17.9	<0.001
Vision	77.9 ± 11.3	88.8 ± 12.8	41.3 ± 78.2	<0.001
ESR	78.8 ± 6.4	86.8 ± 10.5	35.15 ± 40.2	<0.001
Patient GA	72.2 ± 10.2	82.4 ± 12.5	37.8 ± 74.1	<0.001
Quality of life	75.2 ± 9.4	81.7 ± 14.5	33.2 ± 87.2	<0.001
Functional ability	74.1 ± 8.9	74.1 ± 15.7	32.9 ± 34.8	<0.001

Discussion

By incorporating PROMs into routine clinical practice, healthcare professionals can better understand the unique needs and preferences of each patient with GCA. This information can be used to tailor treatment plans to individual patients and improve outcomes. This study was carried out to develop a disease-specific self-reported PROMs questionnaire for GCA; assess its validity, reliability as well as responsiveness to change.

The core set of domains and outcome measures for use in clinical trials in LVV published by the OMERACT Vasculitis Working Group in 2017 [9] highlighted the lack of a disease-specific PRO for people with GCA [7]. The OMERACT group proposed a draft core set of domains for both GCA and Takayasu arteritis "TAK", including "organ function, arterial function, biomarkers, fatigue, pain, and death and two additional preferred domains including psychosocial impact and physical function, plus separate additional GCA- and TAK- specific domains". The specific GCA-PROMs tool developed in this study was proved to be valid, reliable as well as responsive to change. It has also facilitated the incorporation of the individual patient's disease outcome measures, fatigue level, psychological status, preferences/perspectives as well as motivation into standard practice and evaluation. It has also incorporated health related quality of life, patient's associated comorbidities, as well as benefit/ratio into patient's evaluation. In addition, it helped in defining the disease activity status in addition to both the traditional biomarkers (sedimentation rate and C-reactive protein) and imaging outcomes for GCA.

Given the lack of international standards for measuring disease activity status in GCA, disease specific PROM for GCA is expected to play an important role in standard clinical practice as well as clinical trials. The devised GCA-PROMs has adopted the FDA-approved methodology and has involved patients in the different steps of development. Previously published specific measures of disease activity in LVV include the Birmingham Vasculitis Activity Score (BVAS) which has been validated as a tool for small and medium-vessel vasculitis. Birmingham Vasculitis Activity Score entails a list of multiple manifestations of vasculitis, arranged by organ systems on one page, hence it facilitates the recording of the absence or presence of evidence of active vasculitis. Although Birmingham Vasculitis Activity Score has been used widely in ANCA-associated vasculitis [granulomatosis with polyangiitis (Wegener's) and microscopic polyangiitis] therapeutic trials [23], it has been used in only a small number of studies of GCA [24,25], and has not been fully validated for use in clinical trials of LVV. The Disease Extent Index for Takayasu's arteritis (DEI.Tak) was developed based on the BVAS.

Recently, a disease-specific patient-reported outcome measure was developed to assess for patient perceptions of health-related quality of life in giant cell arteritis [8]. The developed tool included 40-item draft questionnaire to assess GCA symptoms and its impact on the patients' health-related quality of life. The items were split over 4 domains: Acute symptoms, activities of daily living, psychological and participation with a total score of 0–90. However, this has not yet been subject to psychometric testing. Furthermore, the questionnaire developed by Robson et al. needed to interview 36 patients, whereas in this work 12-patients were interviewed. This could be attributed to the factor that health related quality of life measures and disease outcome measures have been assessed previously in separate studies [18,19]. de Boysson et al. [26] published a single-center self-assessment study to assess the GCA impact and Its treatment on the patient's quality of life. The identified parameters are in agreement with the findings of this work. Results of this work also agrees with the findings of the work done by Jobard et al. [27] to assess the quality of life of GCA patients which showed significant improvement after high glucocorticoids dose. In concordance with the previously published research and the results of this work, Hellmann et al. [28] identified 20-items that were rated as

extremely important parameters for GCA patients. As expected, "losing sight in both eyes permanently, came on top of the 20 items. An important finding of this work was that the Short Form (SF-12) does not cover several domains important for GCA patients. Lastly, Boysson et al. [29] published a study assessing glucocorticoids tolerance in GCA patients using a self-evaluation questionnaire which concluded that careful monitoring of glucocorticoids-related adverse events and endorsed the use of sparing approaches in patients at high risk. The PROMs questionnaire developed in this work, included all the domains published in the earlier studies into one format which can be scored and used to monitor the GCA patients in the day-to-day standard practice.

Using disease specific PROMs within routine clinical care has been explored in other inflammatory arthritic conditions [16,31]. Qualitative analysis of the Remote Monitoring of RA smartphone app data over 4 weeks (Rheumatoid Arthritis (RA) patients were asked to complete the PROMs questionnaire over 4-weeks [patients reminded each day with a buzzer] with a rheumatologist review at the end of the 4 weeks), revealed that RA patients noted that their disease was "more visible" to clinicians who were able to capture the global image of their disease [32]. A yearlong European study evaluating the e-PROs use in RA patients, revealed that they were also acceptable to patients [33]. One of the challenges raised regarding implementing PROMs in standard practice was, given that GCA patients are usually among the older age groups, they may not prefer to complete the PROMs questionnaire. Our experience in this study and in previous studies revealed that the GCA patients were happy to complete the questionnaire as they felt it is relevant to their condition, hence the high comprehensibility score recorded in this work.

The 2018 EULAR recommendations for management of GCA [5] recommended one treatment approach of management for all the patients (considering IV methylprednisolone for patients presenting with visual affection/ ischemic complications and high oral steroids dose for the rest of the patients). EULAR suggested the empirical addition of DMARD therapy only to GCA patients who sustain a flare of their disease or at increased risk of steroid associated side effects. Considering the expected rapid progression of glucocorticoid-related and disease-related complications, the strategy of "one size fits all" is no more applicable in GCA management approach [34]. Early intervention, in a style similar to that adopted in inflammatory arthritis, early introduction of DMARD/-biologic therapy sounds logic and would be more appropriate strategy towards Treat to Target outcome. Results of this work, though was a secondary outcome, are in favor of this move towards therapy tailored to a stratified approach.

In conclusion, GCA is a multifaceted disorder which represents a challenge to its diagnosis as well as management in standard clinical practice. Generic PROMs, which can be used across a range of different diseases, may not always involve content specific enough for use in GCA. The GCA-PROMs is a specific multi-dimensional patient reported outcome measures questionnaire which is valid, reliable and sensitive to change tool for assessment and monitoring of GCA patients. Being short, rapid and comprehensive, this adds more to its applicability in standard clinical practice. The data support the value of completion of the patient self-reported questionnaire, which provides a quantitative written documented record by the patient, at each visit to the clinic. Stratification of the patients based on their associated comorbidities and/or risk factors and the regular evaluation of the benefit/risk ratio of medical therapy has facilitated the disease control and the timely use of DMARD/ biologic therapy.

Funding

No specific funding was received from any bodies in the public, commercial or not-for-profit sectors to carry out the work described in this article.

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Data availability

The data that support the findings of this study are available on request from the corresponding author.

Declarations

Ethics approval and consent to participate

Local ethical and methodological protocols for approval of the study were followed and accepted by the research ethical committee Tanta University (approval number 36264PR45/1/23). All the participants were kept anonymous, in compliance with data protection regulations. Written Informed consent from all participants was obtained in accordance with the local ethical committee.

Consent for publication

NA.

Availability of data and materials

The datasets used and/or analyzed during the current study available from the corresponding author on reasonable request.

Author contribution

All authors contributed to the study methodology, analysis, and interpretation of the data and outcomes as well as the manuscript writing, reading, and approval of the final version.

Declaration of Competing Interest

Authors declare no conflicts of interest.

Acknowledgment

NA.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.semarthrit.2023.152285.

References

[1] Petri H, Nevitt A, Sarsour K, Napalkov P, Collinson N. Incidence of giant cell arteritis and characteristics of patients: data-driven analysis of comorbidities. Arthritis Care Res 2015;67:390–5.
[2] van der Geest KSM, Sandovici M, van Sleen Y, et al. Review: what is the current evidence for disease subsets in giant cell arteritis? Arthritis Rheumatol 2018;70:1366–76.
[3] Salvarani C, Cimino L, Macchioni P, et al. Risk factors for visual loss in an Italian population-based cohort of patients with giant cell arteritis. Arthritis Rheum 2005;53:293–7.
[4] Salvarani C, Pipitone N, Versari A, Hunder GG. Clinical features of polymyalgia rheumatica and giant cell arteritis. Nat Rev Rheumatol 2012;8:509–21.
[5] Hellmich B, Agueda A, Monti S, et al. 2018 Update of the EULAR recommendations for the management of large vessel vasculitis. Ann Rheum Dis 2020;79:19–30.
[6] Kirwan JR, Hewlett SE, Heiberg T, et al. Incorporating the patient perspective into outcome assessment in rheumatoid arthritis—progress at OMERACT 7. J Rheumatol 2005;32:2250–6.
[7] Aydin SZ, Direskeneli H, Sreih A, et al. Update on outcome measure development for large vessel vasculitis: report from OMERACT 12. J Rheumatol 2015;42:2465–9.
[8] Robson JC, Almeida C, Dawson J, Bromhead A, Dures E, Guly C, Hoon E, Mackie S, Ndosi M, Pauling J, Hill C. Patient perceptions of health-related quality of life in giant cell arteritis: international development of a disease-specific patient-reported outcome measure. Rheumatology 2021;60(10):4671–80 (Oxford).
[9] Sreih AG, Alibaz-Oner F, Kermani TA, Aydin SZ, Cronholm PF, Davis T, Easley E, Gul A, Mahr A, McAlear CA, Milman N, Robson JC, Tomasson G, Direskeneli H,

Merkel PA. Development of a core set of outcome measures for large-vessel vasculitis: report from OMERACT 2016. J Rheumatol 2017;44(12):1933–7.
[10] U.S. Department of Health and Human Services FDA Center for Drug Evaluation and Research, U.S. Department of Health and Human Services FDA Center for Biologics Evaluation and Research, U.S. Department of Health and Human Services FDA Center for Devices and Radiological Health. Guidance for industry: patient reported outcome measures: use in medical product development to support labelling claims: draft guidance. Health Qual Life Outcomes 2006;4:79.
[11] Aydin SZ, Robson JC, Sreih AG, Hill C, Alibaz-Oner F, Mackie S, Beard S, Gul A, Hatemi G, Kermani TA, Mahr A, Meara A, Milman N, Shea B, Tómasson G, Tugwell P, Direskeneli H, Merkel PA. Update on outcome measure development in large-vessel vasculitis: report from OMERACT 2018. J Rheumatol 2019;46(9):1198–201.
[12] Ponte C, Grayson PC, Robson JC, et al. 2022 American college of rheumatology/EULAR classification criteria for giant cell arteritis. Ann Rheum Dis 2022;81:1647–53.
[13] Ruta DA, Garratt AM, Russell IT. Patient centered assessment of quality of life for patients with four common conditions. Qual Health Care 1999;8:22–9.
[14] Bowling A. Research methods in health. Investigating health and health services. Buckingham, UK: Open University Press; 1997.
[15] Garratt AM, Ruta DA. The patient generated index. JOYCE CRB, O'BOYLE CA, MCGEE HM. Individual quality of life: approaches to conceptualisation and assessment. Amsterdam Harwood Academic Publishers; 1999. p. 105–18.
[16] El Miedany Y, El Gaafary M, Youssef SS, Palmer D. Incorporating patient reported outcome measures in clinical practice: development and validation of a questionnaire for inflammatory arthritis. Clin Exp Rheumatol 2010;28(5):734–44.
[17] Linacre JM. Understanding Rash measurement: estimation methods for Rasch measures. J Outcome Meas 1999;3:382–405.
[18] El Miedany Y, Elgaafary M, Toth M, et al. POS0720 Measuring functional disability in giant cell arteritis: the validity, reliability and responsiveness of the GCA-disability index (GCA-DI). Ann Rheum Dis 2023;82:647–8.
[19] El Miedany Y, Elgaafary M, Toth M, Azim AA, Palmer D, Dolbear G, Abu-Zaid MH, Affam D, Hassan W, Elnady B, Tabra SA, Saber S. Development of outcome measures for giant cell arteritis for use in clinical trials and standard practice. Clin Rheumatol 2023;42(11):3049–57. https://doi.org/10.1007/s10067-023-06704-7.
[20] El Miedany Y, El Gaafary M, Toth M, et al. Falls risk assessment score (FRAS): time to rethink. J Clin Gerontol Geriatr 2011;2(1):21–6.
[21] Fries JF, Spitz P, Kraines RG, Holman HR. Measurement of patient outcomes in arthritis. Arthritis Rheum 1980;23:137–45.
[22] Parkin D, Rice N, Devlin N. Statistical analysis of EQ-5D profiles: does the use of value sets bias inference? Med Decis Mak 2010;30(5):556–65.
[23] Merkel PA, Aydin SZ, Boers M, Direskeneli H, Herlyn K, Seo P, et al. The OMERACT core set of outcome measures for use in clinical trials of ANCA-associated vasculitis. J Rheumatol 2011;38:1480–6.
[24] Both M, Ahmadi-Simab K, Reuter M, Dourvos O, Fritzer E, Ullrich S, et al. MRI and FDG-PET in the assessment of inflammatory aortic arch syndrome in complicated courses of giant cell arteritis. Ann Rheum Dis 2008;67:1030–3.
[25] Henes JC, Muller M, Krieger J, Balletshofer B, Pfannenberg AC, Kanz L, et al. [18F] FDG-PET/CT as a new and sensitive imaging method for the diagnosis of large vessel vasculitis. Clin Exp Rheumatol 2008;26(Suppl 49):S47–52.
[26] de Boysson H, Barakat C, Dumont A, Boutemy J, Martin Silva N, Maigné G, Nguyen A, Lavergne A, Castan P, Gallou S, Sultan A, Deshayes S, Aouba A. Impact of giant cell arteritis and its treatment on the patient's quality of life: a single-center self-assessment study. Front Med 2021;8:777310. https://doi.org/10.3389/fmed.2021.777310 (Lausanne).
[27] Jobard S, Magnant J, Blasco H, Ferreira-Maldent N, Griffoul I, Diot E, Maillot F. Quality of life of patients treated for giant cell arteritis: a case-control study. Clin Rheumatol 2017;36(9):2055–62. https://doi.org/10.1007/s10067-017-3619-4.
[28] Hellmann DB, Uhlfelder ML, Stone JH, Jenckes MW, Cid MC, Guillevin L, Moreland L, Dellaripa PF, Hoffman GS, Merkel PA, Spiera R, Brown L, Hernández-Rodríguez J, Rubin HR. Domains of health-related quality of life important to patients with giant cell arteritis. Arthritis Rheum 2003;49(6):819–25. https://doi.org/10.1002/art.11464.
[29] de Boysson H, Barakat C, Dumont A, Boutemy J, Silva NM, Maigné G, Nguyen A, Lavergne A, Castan P, Gallou S, Sultan A, Deshayes S, Aouba A. Tolerance of glucocorticoids in giant cell arteritis: a study of patient-reported adverse events. Rheumatology 2022;61(9):3567–75. https://doi.org/10.1093/rheumatology/keab921.
[30] El Miedany Y, El Gaafary M, Youssef S, Palmer D. Towards a multidimensional patient reported outcome measures assessment: development and validation of a questionnaire for patients with ankylosing spondylitis/spondyloarthritis. Joint Bone Spine 2010;77(6):575–81.
[31] Austin L, Sharp CA, van der Veer SN, Machin M, Humphreys J, Mellor P, McCarthy J, Ainsworth J, Sanders C, Dixon WG. Providing "the bigger picture": benefits and feasibility of integrating remote monitoring from smartphones into the electronic health record. Rheumatology 2020;59(2):367–78 (Oxford).
[32] Gossec L, Cantagrel A, Soubrier M, Berthelot JM, Joubert JM, Combe B, Czarlewski W, Wendling D, Dernis E, Grange L, Beauvais C, Perdriger A, Nataf H, Dougados M, Servy H. An e-health interactive self-assessment website (Sanoia ((R))) in rheumatoid arthritis. A 12-month randomized controlled trial in 320 patients. Joint Bone Spine 2018;85(6):709–14.
[33] Tomelleri A, van der Geest K, Sebastian A, van Sleen Y, Schmidt W, Dejaco C, et al. Disease stratification in giant cell arteritis to reduce relapses and prevent long-term vascular damage. Lancet Rheumatol 2021;3(12):886–95.