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Patient-Reported Outcome Measures for Assessing Health-Related Quality of Life in Patients With Polyneuropathies, Focusing on Guillain-Barré Syndrome and Chronic Inflammatory Demyelinating Polyneuropathy: A Systematic Review of Measurement Properties

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ABSTRACT

Guillain-Barre syndrome (GBS) and chronic inflammatory demyelinating polyneuropathy (CIDP) are immune-mediated peripheral neuropathies. Despite treatment, patients may report residual deficits, pain, and fatigue with considerable impact on quality of life. A systematic review was conducted of the methodological quality of current patient-reported outcome measures (PROMs) for measuring health-related quality of life (HRQoL) in patients with GBS and CIDP. A literature search was conducted in EMBASE, MEDLINE, Web of Science, and Google Scholar. PROMs developed to measure (aspects of) HRQoL in patients with polyneuropathy were classified using the Wilson and Cleary model. Measurement properties were evaluated in accordance with Consensus-based Standards for selection of health Measurement Instruments (COSMIN) guideline. A total of 57 articles identified 31 unique PROMs that are used for measuring HRQoL in patients with polyneuropathies. Of these, 22 measured symptom status, 19 functional status, and 4 general health perception. Eight PROMs were developed or validated in patients with GBS/CIDP. None of the PROMs demonstrated sufficient content validity for recommendation in this population. Only the Rasch-built Fatigue Severity Scale (R-FSS) performed sufficiently across all other measurement properties. The Inflammatory Rasch-built Overall Disability Scale (I-RODS) and IN-QoL are not recommended for use because of insufficient construct validity. GBS Patient Experience Questionnaire, Chronic Acquired Polyneuropathy Patient-Reported Index (CAP-PRI), Fatigue Severity Scale (FSS), R-FSS, Rotterdam Handicap Scale (RHS) and the 36-Item Short Form Health Survey (SF-36) need further validation. PROMs of good quality assessing all relevant aspects of HRQoL are required for better insight in HRQoL in patients with GBS and CIDP.

1 | Introduction

Guillain-Barré syndrome (GBS) and chronic inflammatory demyelinating polyneuropathy (CIDP) are immune-mediated polyradiculoneuropathies with a significant impact on the lives of patients [1–3]. Both disorders are characterized by a progressive muscle weakness and sensory deficits of the limbs. GBS often has an acute monophasic course while CIDP has a more protracted and chronic course [4, 5]. In the acute stage, it may not be possible to distinguish between GBS and CIDP, and 5%–10% of patients initially diagnosed with GBS may have (acute-onset) CIDP [6]. Both disorders respond to immune-modulatory treatment, specifically intravenous immunoglobulin (IVIg) and plasma exchange (PE), with corticosteroids also used for treatment of CIDP. Patients with GBS only require induction treatment in the acute stage of the disease, while most patients with CIDP require additional maintenance treatment for years.

Most patients with GBS or CIDP respond to treatment, but a considerable proportion have residual complaints and disabilities that may have a significant and long-lasting impact on daily life, which may persist for years or even life-long [7–9]. The most commonly reported residual complaints are pain and fatigue, which can limit patients' ability to participate in daily activities and affect their quality of life [10–12]. Furthermore, patients may experience anxiety, depression, or psychosocial distress as a result of their condition [13–15]. The unpredictability of the disease progression and the possibility of relapse can also lead to feelings of uncertainty and anxiety [16, 17].

The multidimensional concept of health-related quality of life (HRQoL) captures an individual's personal evaluation of how a particular disease and its treatment affect the physical, psychological, and social aspects of their health [18]. Given the profound impact that GBS and CIDP can have on patients' daily lives, it is important to measure their HRQoL accurately. Patient-reported outcome measures (PROMs) are self-administered questionnaires that allow patients to report aspects of HRQoL from their own perspective [19]. PROMs provide valuable insights into how patients experience the impact of their condition and help health care professionals to evaluate the effect of treatments in clinical trials and to deliver value-based health care [20, 21].

To date, several PROMs have been used in patients with GBS and CIDP to assess multiple constructs related to HRQoL, such as the Inflammatory Rasch Overall Disability Scale (I-RODS) for measuring daily activity and social participation and the (Rasch-built) Fatigue Severity Scale ((R)-FSS) for measuring fatigue. However, consensus on the most relevant patient-reported outcomes (PROs) and PROMs for GBS and CIDP is lacking. To create a relevant and comprehensive PROM set, an overview of the currently available PROMs assessing HRQoL for patients with these polyneuropathies and their quality is needed. Recently, a scoping review on PROMs in neuromuscular disorders was published [22]. While this review identified and evaluated the measurement properties of the available PROMs, it did not consider the quality of the studies from which the data were derived, nor was the assessment conducted at the subscale level. Furthermore, the previous review did not distinguish among the nine measurement properties but was limited to an evaluation of the overall domain levels—namely validity, reliability, and responsiveness. Moreover, no evidence synthesis was performed. These requirements are considered to be essential for a high-quality systematic review of PROMs [23], which prompted us to conduct the current study.

This review is part of a larger project that aims to develop a comprehensive PROM set for GBS and CIDP specifically. Apart from PROMs validated for GBS and CIDP, we also considered available PROMs validated for other types of polyneuropathies as they could potentially generate valuable information for developing a comprehensive PROM set for GBS and CIDP. Therefore, this systematic review aimed to (1) identify all existing PROMs assessing (aspects of) HRQoL that have been validated to at least some extent in patients with polyneuropathies, (2) systematically describe and classify their content based on the Wilson and Cleary model [24], and (3) evaluate the measurement properties of PROMs assessing (aspects of) HRQoL in patients with GBS and CIDP, in order to provide recommendations for use in these patients.

2 | Methods and Materials

2.1 | Design

This systematic review was conducted in accordance with the Consensus-based Standards for the selection of health status Measurement Instruments (COSMIN) methodology and consists of two distinct parts [25]. The first part provides a comprehensive overview and description of the content of the available PROMs for patients with polyneuropathies. The aim of the second part was to evaluate the measurement properties of PROMs specifically developed or validated in patients with GBS and/or CIDP. The protocol was registered in the PROSPERO database on July 1, 2022 (registration number CRD42022340475) [26].

2.2 | Literature Search

A comprehensive literature search was performed to identify relevant studies that met the inclusion criteria. For this review, the following databases were searched from the date of inception to June 5th, 2022: MEDLINE, EMBASE, Google Scholar, and Web of Science. The search was updated prior to the final analyzes on July 26, 2024, to identify recent studies.

The search strategy was developed collaboratively with a clinical librarian from the Erasmus Medical Center and consisted of three blocks. The first block included terms referring to the population of interest, specifically, patients with polyneuropathies. The second block included terms referring to the type of instrument: PROMs, using an adapted version of a comprehensive PROM filter developed by the University of Oxford, available on the COSMIN website. The third block included terms referring to the measurement properties using an adapted version of a validated search filter for measurement properties [27].

An exclusion filter was used to exclude less relevant references such as case reports and conference abstracts. No time or language restrictions were imposed on our search, ensuring the inclusion of studies from all languages and years. In addition

to the database searches, a reference search of all included papers was conducted to identify any additional relevant studies. Appendix A provides the complete search strategy.

2.3 | Study Selection

Titles, abstracts, and selected full text papers identified through the literature search were independently screened by two out of three researchers (F.P., A.E., and N.P.) to determine their eligibility for inclusion. Following the initial abstract screening process, full-text articles of relevant studies or those we were uncertain of were obtained and screened for final inclusion in the systematic review. One researcher (F.P.) checked the references of the included studies for additional relevant studies. Discrepancies or uncertainties were resolved by discussion or consultation with a third reviewer (C.B.T.) if necessary. Endnote was used for documentation of the screening process. The described study selection process was documented in a PRISMA flowchart.

The study selection process was conducted based on predefined eligibility criteria: (1) the study aim should be the development or evaluation of one or more measurement properties or interpretability (e.g., floor/ceiling effects, minimal important change values) of a PROM, (2) the questionnaire was completed by the patient (in self-report form or interview form), (3) the questionnaire should measure aspects of (health-related) quality of life, including symptom status, functional status, and general health perceptions, (4) at least 50% of the study population or reported subgroups should consist of patients with a form of poly(radiculo)neuropathy, (5) full-text papers, and (6) articles in all languages. The evaluation of measurement properties of PROMs was confined to English-language articles.

Studies were excluded if any of the criteria were met: (1) not developing a PROM or evaluating the measurement properties of the PROM, (2) the questionnaire not completed by patients themselves, (3) studies in which the PROM is only used as a comparison instrument in a validation study of another instrument, (4) diagnostic measures used for screening purposes, and (5) review articles.

2.4 | PART I: Overview of PROMs Validated in Patients With Polyneuropathies

2.4.1 | Data Extraction

The data extraction process for the first part of this systematic review entails information on the characteristics of the included PROMs. Specific information extracted and described included the name of the (sub)scales, the number of items per (sub)scale, the construct(s) being measured, the target population for which the PROM was developed, the mode of administration, the language in which the PROM was developed, the recall period, and available translations. This information was primarily obtained from the papers under review. Studies where information was not readily available in the papers, PROMs, or manuals were obtained through a Google search. If relevant information remained unavailable, the authors were contacted for clarification. Data extraction was performed by one researcher (F.P.) and then checked by one out of two other researchers to ensure accuracy and completeness.

The subscales of all included PROMs were classified by HRQoL constructs according to the Wilson and Clearly model [24]. This classification was based on both the names of the subscales and the questions included in the PROMs.

2.5 | PART II: Measurement Properties of PROMs Validated for GBS and CIDP

2.5.1 | Data Extraction

For PROMs specifically developed for GBS and/or CIDP or validated in patients with GBS and/or CIDP, the following measurement properties were evaluated: content validity, structural validity, internal consistency, cross-cultural validity/measurement invariance, reliability, measurement error, criterion validity, construct validity, and responsiveness. Alongside content validity, the PROM development was also evaluated. Information on the study populations and results of the measurement properties was extracted from studies performed in patients with GBS and/or CIDP. Additionally, information on the feasibility and interpretability of the PROMs was extracted from included papers and manuals, if available.

2.5.2 | Evaluation of Measurement Properties

For each study, the 2018 COSMIN Risk of Bias checklist was used to assess the methodological quality of the included studies with respect to a specific measurement property [28]. Each study on a measurement property was evaluated separately and rated as 'very good', 'adequate', 'doubtful', or 'inadequate'. The overall quality of each study concerning a measurement property was determined by applying the worst-score counts principle, which assumes the lowest rating on a standard as the reference. The risk of bias was rated by two reviewers independently (F.P., N.P.). Discrepancies are resolved by discussion and/or consultation of a third reviewer (C.B.T.).

The results of the included studies (the measurement properties) were then rated against the criteria for good measurement properties, leading to ratings of sufficient ('+'), insufficient ('−'), or indeterminate ('?') [25]. Subsequently, the results for each measurement property per PROM were quantitatively summarized or pooled, and again compared to the criteria for good measurement properties. Finally, a modified GRADE approach was used to grade the quality of evidence, resulting in a classification of 'high', 'moderate', 'low,' or 'very low' quality [25].

2.5.3 | Formulation of Recommendations

Recommendations for suitable PROMs for GBS and CIDP were formulated based on the evidence for the measurement properties and considering interpretability and feasibility aspects.

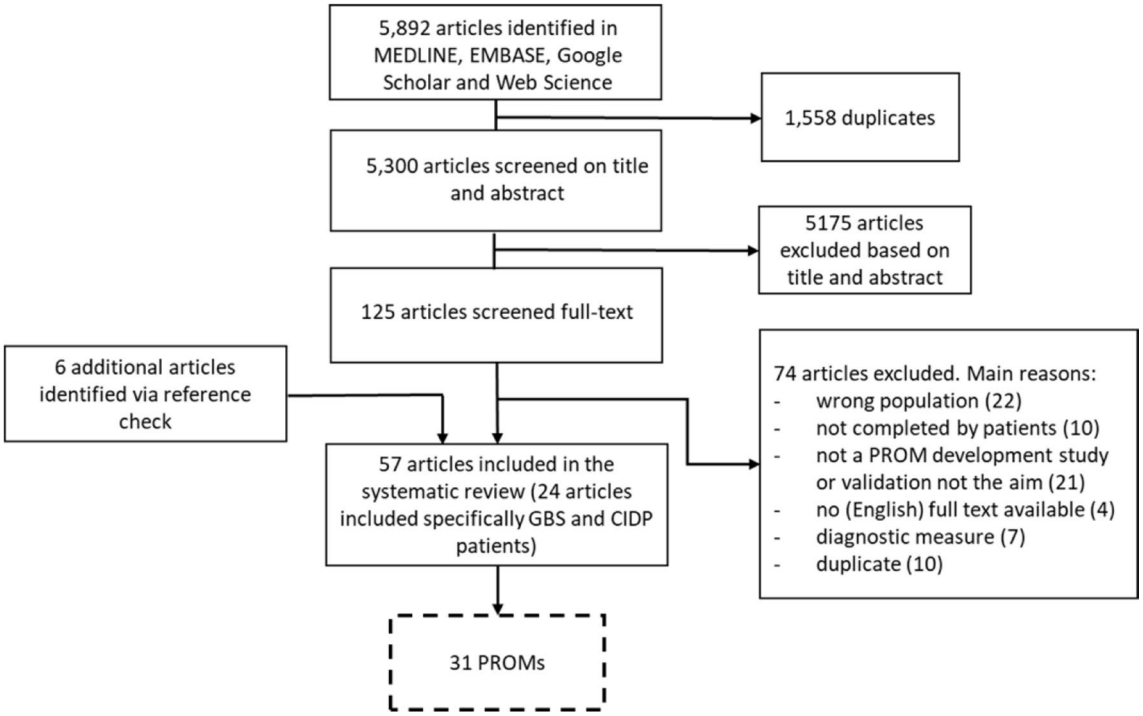

FIGURE 1 | PRISMA flowchart of selection of published articles and PROMs.

This was achieved by classifying the included PROMs for GBS and CIDP into three groups: (A) PROMs that have the potential to be recommended as the most suitable PROM for the construct and study population of interest (i.e., PROMs that have evidence supporting sufficient content validity (any level of evidence) and a minimum of low evidence for sufficient internal consistency); (B) PROMs that have the potential to be recommended but require further validation (PROMs not classified in A or C); (C) PROMs that are not recommended (i.e., PROMs with high quality evidence of insufficient measurement properties) [25].

3 | Results

3.1 | Study Selection and Literature Search

After removing duplicates from the initial search results, 5892 articles were identified. Of these, 125 articles underwent full-text review, and 53 articles were included. See Figure 1 for PRISMA flowchart and reason for exclusion. Following reference checking, an additional six articles were included, resulting in a total of 59 articles that developed or validated PROMs that measure (aspects of) HRQoL in patients with polyneuropathies.

3.2 | PART I: Overview of PROMs Validated in Patients With Polyneuropathies

3.2.1 | Characteristics of the PROMs

In total, 31 PROMs were included, of which six (19%) were specifically developed for immune-mediated polyneuropathies, including GBS and CIDP (Table 1). The SF-36 and FSS were validated in GBS/CIDP patients but were originally developed for the general and chronic illness population, respectively. The number of subscales per PROM varies from 1 to 16, and most PROMs contain more than 10 items. The majority of the PROMs were developed in English (71%).

3.2.2 | Aspects of HRQoL Measured

Table 2 presents the classification of HRQoL based on the Wilson and Cleary model for each included PROM. Among the 31 PROMs analyzed, 22 subscales focused on symptom status, 19 on functional status, and 4 on general health perception. For symptom status, 9 out of 22 subscales addressed symptoms related to polyneuropathy, such as tingling, numbness, strength endurance, and weakness. Furthermore, 17 out of 22 subscales measured physical symptoms, including pain, fatigue, and sleep, while 7 out of 22 measured mental symptoms, including distress, anxiety, and depression. Regarding functional status, 19 out of 19 measured physical function, covering aspects such as daily activities and sexual function. Furthermore, 7 out of 19 focused on psychological function, and 9 out of 19 examined social role functioning. In addition, one PROM measured overall quality of life. Two PROMs also included items on individual and environmental characteristics and patient-reported experience measures (PREMs), incorporating aspects such as work status and satisfaction with treatment and hospital care. Specifically, the GBS Patient Experience Questionnaire included demographic information as part of its assessment. Finally, only 5 out of the 31 HRQoL PROMs addressed all aspects of HRQoL as outlined in the Wilson and Cleary model. These include the GBS Patient Experience Questionnaire, Health-Related Quality of Life Measure for Peripheral Neuropathy, SF-36, PROMIS-29 Profile v2.0 and IN-QoL.

TABLE 1 | Characteristics of the included HRQoL PROMs.

Reference	PROM	Target population	Construct(s) being measured	Name of (sub)scales	Number of items per (sub)scale	Mode of administration	Recall period	Development language	Available translations
Bozovic et al. [29] Merkies et al. [30] Merkies et al. [31] **Ware et al.** [32]	36-Item Short Form Health Survey (SF-36)[a]	General (patient) population	Generic health concepts and Health-related quality of life	1. Physical functioning 2. Physical role functioning 3. Bodily pain 4. General Health 5. Vitality 6. Social functioning 7. Emotional role functioning 8. Mental Health 9. Perceived change in health	1. 10 items 2. 2. 4 items 3. 2 items 4. 5 items 5. 4 items 6. 2 items 7. 3 items 8. 5 items 9. 1 item 36 items in total	Self-report	4 weeks; past year	English	SF-36/SF-36v2|SF-36 Health Survey described in ePROVIDE
Batcho et al. [33] **vanderVelde et al.** [34]	ACTIVLIM	Patients with neuromuscular diseases (NMD)	Activity limitations	1. Common activities 2. Activities for children 3. Activities for adults	4. 14 items 5. 2. 4 items 6. 3. 4 items 22 items in total	Self-report or proxy	NR	French and Dutch	English, Spanish and Norwegian
Zelman et al. [35]	Brief Pain Inventory for painful diabetic peripheral neuropathy (BPI-DPN)	Patients with painful diabetic peripheral neuropathy	Severity of pain and its interference with daily function	1. Pain severity 2. Pain interference	3. 4 items 4. 7 items 11 items in total	Self-report	24 h	English	
Bjelica et al. [36] Englezou et al. [37] Sadjadi et al. [38] Gwathmey et al. [39] **Gwathmey et al.** [40]	Chronic Acquired Polyneuropathy Patient-Reported Index (CAP-PRI)[a]	Patients with Chronic inflammatory demyelinating polyneuropathy (CIDP)	Health related quality of life	1. Social functioning 2. Emotional well-being 3. Physical functioning 4. Pain	15 items in total	Self-report	Few weeks	English	Serbian
Vernon et al. [41]	Daily Sleep Interference Diary (DSIS)	Patients with Diabetic Neuropathies, neuralgia, sleep disorders and chronic pain	Sleep interference	Sleep interference due to pain	Single item	Self-report	24 h	English	DSIS or DSIRS|Daily Sleep Interference Scale or Daily Sleep Interference Rating Scale described in ePROVIDE
Brod et al. [42]	Diabetic Peripheral Neuropathic Pain Impact (DPNPI)	Patients with Diabetic Peripheral Neuropathy (DPN)	Disease impact	1. Physical functioning/ mobility 2. Sleep 3. Daily activities	1. 8 items 2. 5 items 3. 5 items 18 items in total	Self-report	1 week	English	

(Continues)

TABLE 1 | (Continued)

Reference	PROM	Target population	Construct(s) being measured	Name of (sub)scales	Number of items per (sub)scale	Mode of administration	Recall period	Development language	Available translations
Pruppers et al. [43]	Familial Amyloid Polyneuropathy Rasch-built Overall Disability Scale (FAP-RODS)	Patients with Val30Met Familial Amyloid Polyneuropathy	Activity and Participation	Activity and Participation	34 items in total	Self-report	NR	Portuguese	English
Merkies et al. [44] **Krupp et al.** [45] Van Nes et al. [46]	Fatigue Severity Scale (FSS)[a]	Chronic illness population	Fatigue	Fatigue	9 items in total	Self-report	NR	English	FSS|Fatigue Severity Scale described in ePROVIDE
Calhoun et al. [47] McCray et al. [48]	Functional Assessment of Cancer Therapy/ Gynecologic Oncology Group Neurotoxicity (Fact/GOG-Ntx)	Patients with chemotherapy-induced neuropathy	Health related quality of life	1. Sensory neuropathy 2. Motor neuropathy 3. Auditory neuropathy 4. Dysfunction associated with neuropathy	1. 4 items 2. 3 items 3. 2 items 4. 2 items 11 items in total	Self-report	7days	English	FACT-GOG-NTX|Functional Assessment of Cancer Therapy – Gynecologic Oncology Group-Neurotoxicity described in ePROVIDE
Siriwardena et al. [49]	GBS Patient Experience Questionnaire[a]	Patients with Guillain-Barré Syndrome (GBS)	Symptoms and experiences	1. *Symptoms* Peripheral nerve symptoms Cranial nerve/respiratory symptoms Psychological symptoms 2. *Factors affecting recovery* Positive social interactions Work support Changes at work Changes at home Physical activity Therapy Other 3. *Information provided* Specialists Non-specialists 4. *Care received* In hospital After	40 items in total	Self-report	NR	English	

(Continues)

TABLE 1 | (Continued)

Reference	PROM	Target population	Construct(s) being measured	Name of (sub)scales	Number of items per (sub)scale	Mode of administration	Recall period	Development language	Available translations
Vickrey et al. [50]	Health Related Quality of Life Measure for Peripheral Neuropathy	Patients with peripheral neuropathies	Health related quality of life	Physical health 1. Physical Functioning 2. Role limitations 3. Pain 4. Energy/Fatigue 5. Upper Extremities 6. Balance 7. Sleep 8. Social Functioning 9. General Health Perception Mental health 10. Self-esteem 11. Emotional well-being 12. Stigma 13. Cognitive Functioning 14. Role Limitation 15. Health Distress 16. Sexual Function	Physical Health 1. 11 items 2. 6 items 3. 7 items 4. 5 items 5. 6 items 6. 8 items 7. 5 items 8. 9 items 9. 7 item Mental Health 10. 6 items 11. 7 items 12. 3 items 13. 3 items 14. 3 items 15. 3 items 16. 2 items 6 single items 97 items in total	Self-report	NR	English	
Draak et al. [51]	IN-QoL[a]	Patients with Inflammatory Neuropathy	Quality of life	1. Mental subset 2. Functional subset	1. 55 items 2. 18 items 73 items in total	Self-report	Today	English	
Draak et al. [52] Draak et al. [53] Keh et al. [54] Peric et al. [55] Rajabally et al. [56] Rajabally et al. [57] Stojanov et al. [58] VanHoutte et al. [59] **Van Nes et al.** [60] van Veen et al. [61] White et al. [62]	Inflammatory Rasch-built Overall Disability Scale (I-RODS)[a]	Patients with immune mediated polyneuropathies: GBS, CIDP and MGUSP	Activity and social participation limitations	Disability and social participation	24 items in total	Self-report	NR	Dutch	I-RODS|Inflammatory Rasch-built Overall Disability Scale described in ePROVIDE

(Continues)

TABLE 1 | (Continued)

Reference	PROM	Target population	Construct(s) being measured	Name of (sub)scales	Number of items per (sub)scale	Mode of administration	Recall period	Development language	Available translations
Binkley et al. [63] Galantino et al. [64]	Lower Extremity Functional Scale (LEFS)	Patients with lower-extremity orthopedic conditions	Lower extremity function	Functional status	20 items in total	Self-report	Today	English	LEFS|Lower Extremity Functional Scale described in ePROVIDE
Gabel et al. [65]	Lower Limb Functional Index (LLFI)	Patients with lower limb condition	Lower extremity function	Functional status	25 items in total	Self-report	Few days	English	Official LLFI|Lower Limb Functional Index distributed by Mapi Research Trust|ePROVIDE
Komelyagina et al. [66] Saraf et al. [67] **Vileikyte et al.** [68] Xavier et al. [69]	Neuropathy – and Foot Ulcer – Specific Quality of Life instrument (NeuroQol)	Patients with Diabetic Peripheral Neuropathy	Quality of life	Physical symptoms 1. Pain 2. Reduced feeling 3. Diffuse sensory motor Psychosocial symptoms 1. Interpersonal/emotional burden 2. Activity limitations Overall quality of life	Physical symptoms 1. 7 items 2. 3 items 3. 3 items Psychosocial symptoms 1. 11 items 2. 3 items 3. 1 item 28 items in total	Self-report	4 weeks	English	Portuguese (Brazil) and Russian
Boyd et al. [70] Vinik et al. [71] **Vinik et al.** [72] Yarlas et al. [73]	Norfolk Quality of Life-Diabetic Neuropathy (QOL-DN)	Patients with Diabetic Neuropathy	Quality of life	1. Activities of Daily Living (ADL) 2. Symptoms 3. Small-fiber neuropathy 4. Physical functioning/ large-fiber 5. Autonomic neuropathy	47 items in total	Self-report	4 weeks	English	German and Romanian
Farrar et al. [74]	The Numeric Rating Scale-Pain Intensity (NRS-PI)	General patient population	Pain	Pain intensity	Single item	Self-report	24 h/7 days	English	
Tolle et al. [75]	PainPREDICT	Patients with neuropathic pain (NeP)	Pain	1. Pain intensity 2. Course of pain 3. Location of pain 4. Sensory symptoms	1. 2 items 2. 1 item 3. 1 item 4. 16 items 20 items in total	Self-report	1 week	English, French and German	

(Continues)

TABLE 1 | (Continued)

Reference	PROM	Target population	Construct(s) being measured	Name of (sub)scales	Number of items per (sub)scale	Mode of administration	Recall period	Development language	Available translations
Geelen et al. [76]	Painful Diabetic Neuropathy Anxiety Rasch Transformed Questionnaire (PART-Q30)	Patients with Painful Diabetic Neuropathy (PDN)	PDN related fears and anxiety	Disabling fears and anxiety 1. Worries about low blood sugar 2. Fears about pain and its consequences in daily life 3. Fears about your pain 4. Worries about falling 5. Worries about fatigue and negative evaluation	1. 3 items 2. 13 items 3. 5 items 4. 6 items 5. 3 items 30 items in total	Self-report	4 weeks or no recall period	Dutch	English, Spanish and Norwegian
Keh et al. [77]	POEMS-RODS	Patients with POEMS	Activity limitation	Disability	23 items in total	Self-report	NR	English	
D′ Souza et al. [78] **Hays et al.** [79]	PROMIS Global Health v1.2	General (patient) population	Global health	1. Physical Health 2. Mental health 3. Social Health	1. 5 items 2. 3 items 3. 2 items 10 items in total	Self-report	7 days or no recall period	English	Available Translations
Cella et al. [80] D′ Souza et al. [78]	PROMIS-29 Profile v2.0	General (patient) population	Health related quality of life	1. Anxiety 2. Depression 3. Fatigue 4. Pain Interference 5. Physical function 6. Sleep Disturbance 7. Ability to Participate in Social Roles and Activities 8. Pain Intensity	1. 4 items 2. 4 items 3. 4 items 4. 4 items 5. 4 items 6. 4 items 7. 4 items 8. 4 items 9. 1 item 29 items in total	Self-report	7 days or no recall period	English	Available Translations
D′ Souza et al. [78] **Lai et al.** [81]	PROMIS Short Form Fatigue 8a v1.0	General (patient) population	Fatigue	Intensity and impact of fatigue	8 items in total	Self-report	7 days	English	Available Translations
Van Nes et al. [46]	The Rasch-built Fatigue Severity Scale (R-FSS)[a]	Patients with immune-mediated polyneuropathies	Fatigue	Fatigue	7 items in total	Self-report	NR	Dutch	English
Keh et al. [54] **VanHoutte et al.** [82]	Rasch-built Overall Disability Scale for Multifocal Motor Neuropathy (MMN-RODS)	Patients with Multifocal Motor Neuropathy (MMN)	Activity limitations	Activity limitations	25 items in total	Self-report	NR	Dutch, French and Italian	MMN-RODS|Rasch-built Overall Disability Scale for Multifocal Motor Neuropathy described in ePROVIDE

(Continues)

TABLE 1 | (Continued)

Reference	PROM	Target population	Construct(s) being measured	Name of (sub)scales	Number of items per (sub)scale	Mode of administration	Recall period	Development language	Available translations
Merkies et al. [83] Merkies et al. [30]	Rotterdam Handicap Scale (RHS)[a]	Patients with immune-mediated polyneuropathies	Functional ability and level of handicap	Physical independence Occupation Social integration	9 items in total	Self-report	NR	Dutch	English
Abraham et al. [84]	Single item PROM	Patients with non-diabetic polyneuropathy	Disease severity		Single item	Self-report	NR	English	
Treister et al. [85]	The Small-Fiber Symptom Survey (SSS)	Patients with Small-Fiber Polyneuropathy (SFPN)	Symptoms of SFPN	1. Gastrointestinal symptoms 2. Somatosensory symptoms 3. Miscellaneous symptoms 4. Vascular symptoms 5. Urological symptoms	1. 5 items 2. 4 items 3. 5 items 4. 5 items 5. 3 items 33 items in total	Self-report	1 week	English	
Zilliox et al. [86]	Survey of Autonomic Symptoms (SAS)	Patients with (mild) neuropathy	Autonomic neuropathy	Autonomic symptoms	12 items in total (men) 11 items in total (women)	Self-report	6 months	English	Korean
Hays et al. [87] Viala-Danten et al. [88]	The Medical Outcomes Study Sleep Scale (MOS-Sleep)	General (patient) population	Sleep quality	1. Sleep disturbance 2. Somnolence 3. Sleep adequacy 4. Snoring 5. Awaken short of breath or headache 6. Sleep quantity	1. 4 items 2. 3 items 3. 2 items 4. 1 item 5. 1 item 6. 1 item 12 items in total	Self-report	4 weeks	English	MOS Sleep|Medical Outcomes Study Sleep scale described in ePROVIDE

Note: **Bold** represents the development paper of the PROM.
[a]PROMs developed or validated in GBS or CIDP patients.

TABLE 2 | Classification of HRQoL based on the Wilson and Cleary model.

	Health-related quality of life												Other		
	Symptom status							Functional status					General health perception	Overall quality of life	
		Physical symptoms			Mental symptoms			Physical function		Psychological function	Social function		Overall health	Overall quality of life	
PROM	Polyneuropathy related symptoms	Pain	Energy/ fatigue	Sleep	Distress	Anxiety/ worry	Depression	Activities of daily living	Sexual function	Emotional function/ cognition	Social function/ participation		General health perception, self-rated health	Overall quality of life/ well-being	Characteristics of individual/ environment or PREM
36-Item Short Form Health Survey (SF-36)		•	•					•		•	•		•		
ACTIVLIM								•							
Brief Pain Inventory for painful diabetic peripheral neuropathy (BPI-DPN)		•						•							
Chronic Acquired Polyneuropathy Patient-Reported Index (CAP-PRI)	•	•	•	•		•	•	•		•	•				
Daily Sleep Interference Diary (DSIS)				•											
Diabetic Peripheral Neuropathic Pain Impact (DPNPI)				•				•							
Familial Amyloid Polyneuropathy Rasch-built Overall Disability Scale (FAP-RODS)								•			•				

(Continues)

TABLE 2 | (Continued)

	Health-related quality of life													Other	
	Symptom status							Functional status				General health perception	Overall quality of life		
		Physical symptoms			Mental symptoms			Physical function		Psychological function	Social function	Overall health	Overall quality of life		
PROM	Polyneuropathy related symptoms	Pain	Energy/ fatigue	Sleep	Distress	Anxiety/ worry	Depression	Activities of daily living	Sexual function	Emotional function/ cognition	Social function/ participation	General health perception, self-rated health	Overall quality of life/ well-being	Characteristics of individual/ environment or PREM	
Fatigue Severity Scale (FSS)			•												
Functional Assessment of Cancer Therapy/ Gynecologic Oncology Group Neurotoxicity (Fact/ GOG-Ntx)	•														
GBS Patient Experience Questionnaire	•	•	•	•		•	•	•		•	•				
Health Related Quality of Life Measure for Peripheral Neuropathy		•	•	•	•				•	•	•	•			
Inflammatory Rasch-built Overall Disability Scale (I-RODS)								•			•				
IN-QoL		•	•	•	•	•	•	•	•	•	•		•		
Lower Extremity Functional Scale (LEFS)								•							
Lower Limb Functional Index (LLFI)								•							

(Continues)

TABLE 2 | (Continued)

	Health-related quality of life												Other		
	Symptom status							Functional status					General health perception	Overall quality of life	
		Physical symptoms			Mental symptoms			Physical function		Psychological function	Social function		Overall health	Overall quality of life	
PROM	Polyneuropathy related symptoms	Pain	Energy/ fatigue	Sleep	Distress	Anxiety/ worry	Depression	Activities of daily living	Sexual function	Emotional function/ cognition	Social function/ participation		General health perception, self-rated health	Overall quality of life/ well-being	Characteristics of individual/ environment or PREM
Neuropathy – and Foot Ulcer – Specific Quality of Life instrument (NeuroQol)	•	•			•	•	•	•		•	•				
Norfolk Quality of Life-Diabetic Neuropathy (QOL-DN)	•							•							
The Numeric Rating Scale-Pain Intensity(NRS-PI)		•													
PainPREDICT	•	•													
Painful Diabetic Neuropathy Anxiety Rasch Transformed Questionnaire (PART-Q30)						•									
POEMS-RODS								•							
PROMIS Global Healthv1.2													•		
PROMIS-29 Profile v2.		•	•	•		•	•	•			•		•		
PROMIS Short Form Fatigue 8a v1.0			•												
The Rasch-built Fatigue Severity Scale (R-FSS)			•												

(Continues)

TABLE 2 | (Continued)

	Health-related quality of life												Other		
	Symptom status							Functional status					General health perception	Overall quality of life	
		Physical symptoms			Mental symptoms			Physical function		Psychological function	Social function		Overall health	Overall quality of life	
PROM	Polyneuropathy related symptoms	Pain	Energy/ fatigue	Sleep	Distress	Anxiety/ worry	Depression	Activities of daily living	Sexual function	Emotional function/ cognition	Social function/ participation		General health perception, self-rated health	Overall quality of life/ well-being	Characteristics of individual/ environment or PREM
Rasch-built Overall Disability Scale for Multifocal Motor Neuropathy (MMN-RODS)								•							
Rotterdam Handicap Scale (RHS)								•							
Single item PROM	•													•	
The Small-Fiber Symptom Survey (SSS)	•	•	•						•	•					
Survey of Autonomic Symptoms (SAS)	•														
The Medical Outcomes Study Sleep Scale (MOS-Sleep)				•											

3.3 | PART II: Measurement Properties of PROMs Validated for GBS and CIDP

3.3.1 | Quality of the Studies

Information on the study populations involved in the studies on measurement properties is provided in Table S1. The ratings on the quality of the PROM development and content validity studies of the eight PROMs that were specifically developed or validated for GBS or CIDP are provided in Table 3. The PROM development of almost all included PROMs was rated as inadequate. Only the GBS Patient Experience Questionnaire development was of doubtful quality. The main reason for the inadequate quality of the PROM development studies is the lack of pilot testing of the PROMs and no involvement of patients. However, for all PROMs, a clear definition of the target population and construct was given except for CAP-PRI and IN-QoL, which development was rated as inadequate because a clear construct of interest was lacking. Only two studies evaluated (aspects of) content validity. For the I-RODS, relevance and comprehensibility were assessed in studies rated to be of inadequate and doubtful quality, respectively. For CAP-PRI, comprehensibility was assessed in a study of inadequate quality.

The quality ratings of each study on the measurement properties can be found in Table 4. Structural validity was assessed in patients with GBS or CIDP for all PROMs except the RHS and SF-36, with the quality of the studies ranging from inadequate to very good. Internal consistency was assessed for all PROMs, with the majority of studies having ratings of very good quality. Cross-cultural validity was assessed for the I-RODS, CAP-PRI, IN-QoL, FSS, and R-FSS, with all studies rated to be of inadequate quality except for one study on the I-RODS that was rated as doubtful. Reliability was evaluated for the I-RODS, FSS, R-FSS, and RHS, with all studies rated to be of adequate quality except for one study on the R-FSS that was rated as very good. Measurement error was assessed for the I-RODS, RHS, and SF-36 Physical Component Summary (PCS) and Mental Component Summary (MCS). The studies were rated as doubtful quality for the I-RODS and inadequate quality for the RHS and SF-36 PCS and MCS. Construct validity was assessed for all PROMs except the GBS Patient Experience Questionnaire, with the majority of studies having ratings of adequate or very good quality. Responsiveness was assessed for the I-RODS, CAP-PRI, IN-QoL, RHS, and SF-36, including the PCS and MCS, with all studies rated as adequate or very good quality.

3.4 | Quality of the PROMs

3.4.1 | Content Validity

The overall ratings and quality of evidence on measurement properties are provided in Table 5. Because of the very few content validity studies and the inadequate PROM development studies, the ratings for the relevance, comprehensiveness, and comprehensibility of the PROMs were primarily based on the subjective assessments of the reviewers (F.P., N.P., and B.J.) and led to low and very low-quality evidence for inconsistent content validity. It should be noted that one of the reviewers (B.J.) is a neurologist and professor in peripheral neuropathies with expertise in treating patients with GBS and CIDP.

3.4.2 | Internal Structure

For most PROMs, except for the FSS and R-FSS, the assessment of structural validity was incomplete, leading to an undetermined overall rating. The FSS demonstrated insufficient structural validity as the scale was not unidimensional, with moderate-quality evidence. In contrast, the R-FSS showed sufficient structural validity as the scale was shown to be unidimensional, supported by moderate-quality evidence. Due to the lack of evidence for unidimensionality of most PROMs, the internal consistency was rated as indeterminate for these PROMs, despite the Cronbach's alphas being >0.70, with no level of evidence assigned. The R-FSS demonstrated sufficient internal consistency with moderate-quality evidence.

3.4.3 | Cross-Cultural Validity/ Measurement Invariance

Sufficient cross-cultural validity was found for CAP-PRI, IN-QoL, and R-FSS, while the I-RODS and FSS demonstrated insufficient cross-cultural validity. However, the evidence supporting these findings was of low to very low quality.

3.4.4 | Reliability

Test–retest reliability was evaluated for the I-RODS, FSS, R-FSS, and RHS with the ICC and was found to be sufficient across all four PROMs. However, only the results for the R-FSS were supported by high-quality evidence.

3.4.5 | Measurement Error

Measurement error was found to be insufficient across all three PROMs for which this was assessed: I-RODS, RHS, and SF-36 PCS and MCS, for the use of the PROMs in individual patients. The main reason for this insufficiency is that the smallest detectable change is larger than the minimal important change. However, the evidence supporting these findings was of low to very low quality.

3.4.6 | Construct Validity

Construct validity was evaluated against predefined hypotheses set by the reviewers (Table S5). Inconsistent construct validity was found for the I-RODS in patients with CIDP, but insufficient validity was found in patients with GBS. The R-FSS, RHS, and SF-36, including the PCS, demonstrated sufficient construct validity, while CAPPRI and FSS showed inconsistent validity and IN-QoL (including mental and functional subset) insufficient construct validity. These evaluations were primarily based on correlations between instruments. The evidence supporting these findings was generally

TABLE 3 | Quality of the PROM development and content validity studies.

	General design requirements							Cognitive interview (CI) study[b]		
								General design requirements		
PROM	Clear construct	Clear origin of construct	Clear target population for which the PROM was developed	Clear context of use	PROM developed in sample representing the target population	Concept elicitation[a]	Total PROM design	CI study performed in sample representing the target population	Comprehensibility	Total CI study
CAP-PRI	Inadequate	Doubtful	Very good	Very good	Very good	Doubtful	Inadequate			
FSS	Very good	Doubtful	Very good	Very good	Very good	Doubtful	Doubtful			
GBS Patient Experience Questionnaire	Very good	Doubtful	Very good	Very good	Very good	Doubtful	Doubtful	Very good	Doubtful	Doubtful
IN-QoL	Inadequate	Doubtful	Very good	Doubtful	Very good	Doubtful	Inadequate			
I-RODS	Very good	Very good	Very good	Very good	Adequate	Inadequate	Inadequate			
R-FSS	Very good	Doubtful	Very good	Doubtful	Very good	Doubtful	Doubtful			
RHS	Very good	Very good	Very good	Doubtful	Very good	Doubtful	Doubtful	Inadequate	Inadequate	
SF-36	Very good	Very good	Adequate	Very good	Inadequate	Inadequate	Inadequate			

		Content validity				
		Asking patients			Asking experts	
PROM	TOTAL PROM DEVELOPMENT	Relevance	Comprehensiveness	Comprehensibility	Relevance	Comprehensiveness
CAP-PRI	Inadequate			Inadequate		
FSS	Inadequate					
GBS Patient Experience Questionnaire	Doubtful					
IN-QoL	Inadequate					
I-RODS	Inadequate	Inadequate		Doubtful		
R-FSS	Inadequate					
RHS	Inadequate					
SF-36	Inadequate					

Abbreviation: PROM = Patient Reported Outcome Measure.

[a]When the PROM was not developed in a sample representing the target population, the concept elicitation was not further rated.

[b]Empty cells indicate that a CI or content validity study (or part of it) was not performed 1 W.

TABLE 4 | Quality of studies on measurement properties.

							Construct validity		Responsiveness			
PROM (Reference)	**Structural validity**	**Internal consistency**	**Cross-cultural validity**	**Reliability**	**Measurement error**	**Criterion validity**	**Convergent validity**	**Known groups validity**	**Comparison with gold standard**	**Comparison with other instruments**	**Comparison between subgroups**	**Comparison before and after intervention**
CAP-PRI [51]	Doubtful		Inadequate							Very good	Adequate	
CAP-PRI [37]	Adequate	Very good	Inadequate				Adequate					
CAP-PRI [39]		Very good					Adequate					
CAP-PRI [41]	Inadequate	Very good	Inadequate				Adequate					
FSS [60]	Adequate	Very good	Inadequate									
FSS [45]		Very good		Adequate			Adequate					
GBS Patient Experience Questionnaire [50]	Inadequate	Very good										
IN-QoL [89]	Very good	Very good	Inadequate				Very good				Adequate	
IN-QoL Mental [89]	Very good	Very good					Very good				Adequate	
IN-QoL Functional [89]	Very good	Very good					Very good				Adequate	
I-RODS [38]	Very good	Very good	Doubtful	Adequate			Inadequate					
I-RODS [53]			Inadequate									
I-RODS [54]							Adequate					
I-RODS [56]		Very good					Very good					
I-RODS [57]									Inadequate			
I-RODS [58]							Adequate			Doubtful		
I-RODS [59]											Adequate	
I-RODS [61]							Very good				Adequate	
I-RODS [62]					Doubtful						Adequate	
R-FSS [60]	Adequate	Very good	Inadequate	Adequate			Doubtful					
RHS [31]		Doubtful			Inadequate							
RHS [81]				Adequate			Adequate	Very good				Very good
SF-36 [29]							Doubtful				Very good	

(Continues)

TABLE 4 | (Continued)

PROM (Reference)	Structural validity	Internal consistency	Cross-cultural validity	Reliability	Measurement error	Criterion validity	Construct validity		Responsiveness			
							Convergent validity	Known groups validity	Comparison with gold standard	Comparison with other instruments	Comparison between subgroups	Comparison before and after intervention
SF-36 Physical [30]							Doubtful				Very good	
SF-36 Physical [31]		Doubtful			Inadequate							
SF-36 Physical [32]		Very good					Very good				Adequate	
SF-36 Mental [30]											Very good	
SF-36 Mental [31]		Doubtful			Inadequate							
SF-36 Mental [32]		Very good									Adequate	

Abbreviation: PROM = Patient Reported Outcome Measure.

of moderate to high quality, except for the R-FSS, which had low-quality evidence.

3.4.7 | Responsiveness

Responsiveness was evaluated against predefined hypotheses set by the reviewers. Sufficient responsiveness was found for all PROMs for which this was assessed, with moderate quality of evidence for CAP-PRI, IN-QoL including mental and functional subset, and SF-36 including the PCS and MCS; high quality of evidence for the I-RODS; and low quality of evidence for the RHS. A comprehensive table of all the results of studies on the measurement properties is provided in Table S2.

3.5 | Recommendations

The R-FSS demonstrated moderate evidence for sufficient internal consistency for measuring fatigue. However, content validity was not formally assessed. Reviewers rated the relevance and comprehensibility as inconsistent and comprehensiveness as insufficient. Since the ratings were based on reviewer assessments, the evidence is considered to be of very low quality. Because of the inconsistent results for content validity, the R-FSS does not meet the criteria for recommendation A.

The I-RODS showed high-quality evidence for insufficient construct validity in patients with GBS for measuring limitations in daily activity and social participation. Similarly, IN-QoL, including the mental and functional subsets, showed high-quality evidence of insufficient construct validity for measuring quality of life and is therefore not recommended for use (recommendation C). The remaining PROMs (GBS Patient Experience Questionnaire, CAP-PRI, FSS, R-FSS, RHS and SF-36 including the PCS and MCS) are categorized under recommendation B.

In terms of interpretability, there was limited and inconsistent information of the PROMs. However, the score distribution of the study population for most PROMs and floor and ceiling effects has been reported for the I-RODS, CAP-PRI, and FSS (Table S3). Additionally, there are some inconclusive findings regarding the MIC and MID. In terms of feasibility, the FSS appears generally feasible, as it consists of a minimal number of questions and is easy to score by calculating a sum score (Table S4).

4 | Discussion

This systematic review identified 31 PROMs measuring (aspects of) HRQoL that were validated at least to some extent in patients with polyneuropathies, including eight PROMs in patients with GBS or CIDP. We reviewed the evidence on the measurement properties of these specific PROMs in accordance with the COSMIN guideline. Most studies were of poor or doubtful quality, and none of the PROMs scored sufficiently across all measurement properties. None of the PROMs met all criteria that are recommended for use.

The classification of PROMs based on the Wilson and Cleary model indicated that most of the identified PROMs primarily

TABLE 5 | Overall ratings and quality of evidence on measurement properties.

	CAP-PRI		FSS		GBS patient experience questionnaire		IN-QoL		IN-QoL functional		IN-QoL mental	
	Overall rating	**Quality of evidence**	**Overall rating**	**Quality of evidence**	**Overall rating**	**Quality of evidence**	**Overall rating**	**Quality of evidence**	**Overall rating**	**Quality of evidence**	**Overall rating**	**Quality of evidence**
	+/−/?/±	**High, moderate, low, very low**	**+/−/?/±**	**High, moderate, low, very low**	**+/−/?/±**	**High, moderate, low, very low**	**+/−/?/±**	**High, moderate, low, very low**	**+/−/?/±**	**High, moderate, low, very low**	**+/−/?/±**	**High, moderate, low, very low**
Content validity	±	Very low	±	Very low	±	Very low	±	Very low	±	Very low	±	Very low
Relevance	±	Very low	±	Very low	−	Very low	±	Very low	±	Very low	±	Very low
Comprehensiveness	−	Very low	−	Very low	±	Very low	±	Very low	±	Very low	±	Very low
Comprehensibility	+	Low	±	Very low	±	Very low	±	Very low	±	Very low	±	Very low
Structural validity	?		−	Moderate	?		?		?		?	
Internal consistency	?		?		?		?		?		?	
Cross-cultural validity	+	Low	−	Very low			+	Very low				
Reliability			+	Moderate								
Measurement error												
Criterion validity												
Construct validity	±	Moderate	GBS± CIDP ±	Moderate			−	High	−	High	−	High
Responsiveness	+	Moderate					+	Moderate	+	Moderate	+	Moderate

(Continues)

TABLE 5 | (Continued)

	I-RODS		R-FSS		RHS		SF-36		SF-36 Physical		SF-36 Mental	
	Overall rating	**Quality of evidence**	**Overall rating**	**Quality of evidence**	**Overall rating**	**Quality of evidence**	**Overall rating**	**Quality of evidence**	**Overall rating**	**Quality of evidence**	**Overall rating**	**Quality of evidence**
	+/−/?/±	**High, moderate, low, very low**	**+/−/?/±**	**High, moderate, low, very low**	**+/−/?/±**	**High, moderate, low, very low**	**+/−/?/±**	**High, moderate, low, very low**	**+/−/?/±**	**High, moderate, low, very low**	**+/−/?/±**	**High, moderate, low, very low**
Content validity	±	Low	±	Very low			±	Very low	±	Very low	±	Very low
Relevance	±	Very low	±	Very low	±	Very low	+	Very low	+	Very low	+	Very low
Comprehensiveness	−	Very low	−	Very low	−	Very low	−	Very low	−	Very low	−	Very low
Comprehensibility	+	Low	±	Very low	±	Very low	+	Very low	+	Very low	+	Very low
Structural validity	?		+	Moderate								
Internal consistency	?		+	Moderate	?				?		?	
Cross-cultural validity	−	Low	+	Very low								
Reliability	+	Moderate	+	High	+	Low						
Measurement error	−	Very low			−	Very low			−	Low	−	Low
Criterion validity												
Construct validity	GBS—CIDP ±	High	+	Low	+	High	+	Moderate	+	Moderate		
Responsiveness	+	High			+	Low	+	Moderate	+	Moderate	+	Moderate

focus on symptom and functional status, instead of general health perceptions. Only five PROMs (GBS Patient Experience Questionnaire, SF-36, Health-Related Quality of Life Measure for Peripheral Neuropathy, PROMIS-29 Profile v2.0, and IN-QoL) address all aspects of HRQoL. These findings indicate a gap in the comprehensive assessment of the impact of polyneuropathies in patients.

Our evaluation of measurement properties of PROMs in GBS and CIDP showed that the majority of PROMs were developed without appropriate pilot testing or patient involvement that likely undermines their content validity. Only two studies provided formal evaluations of content validity, with results indicating inconsistent relevance, insufficient comprehensiveness, but sufficient comprehensibility for the I-RODS and CAP-PRI. These results are likely due to the lack of patient involvement in the development process, which would ensure alignment with the intended construct and target population.

The R-FSS is the only PROM for which evidence was found for sufficient structural validity, internal consistency, construct validity, reliability, and cross-cultural validity. The R-FSS is a PROM that measures fatigue, which was developed as an improved version of the original FSS, specifically for use in patients with immune-mediated polyneuropathies [46]. However, the development of the R-FSS was inadequate because concept elicitation was not properly performed and pilot testing was not done. Additionally, no content validity study was available. Review ratings indicated that the scale's comprehensiveness was insufficient, but because of very low-quality evidence, more research on content validity is needed before recommendation A or C can be given.

These findings also suggest that further studies on the measurement properties of the current PROMs for patients with GBS and CIDP are needed, particularly for those with reasonable content validity. For instance, the SF-36 initially showed sufficient internal consistency for both the PCS and MCS. However, structural validity, cross-cultural validity, and reliability have not yet been evaluated in patients with GBS and CIDP, although these properties have been studied in many other patient populations. Cross-cultural validity assessments, in particular, were limited to a few PROMs [46–51]. Therefore, more validation studies are needed in diverse cultural contexts, especially given the global prevalence of polyneuropathies. Additionally, we found that only a few studies adequately assessed unidimensionality, suggesting there is a lack of clear evidence for structural validity across many PROMs. Because of this, internal consistency results could not be interpreted, even when acceptable values (e.g., >0.70) were reported. There may also be other PROMs that could be suitable for GBS and CIDP but have not yet been validated in these patient groups. A promising example would be the Patient-Reported Outcomes Measurement Information System (PROMIS). This system includes PROMs for measuring relevant constructs for patients with GBS and CIDP, such as fatigue, physical function, and the ability to participate in social roles and activities that have been validated in many patient populations and translated into more than 70 languages [89].

A strength of this review is the use of the COSMIN guideline, which allowed for a systematic and standardized evaluation of the measurement properties. The comprehensive inclusion of PROMs specific to polyneuropathies provides insights into the current state of HRQoL assessment in this patient population. There are also several limitations. The review is limited by the overall inadequate quality of the PROM development studies, which restricted our ability to fully assess the measurement properties of the PROMs. Furthermore, the lack of formal content validity studies implicated that reviewers had to rely on subjective opinions, increasing the risk of bias. Another limitation is that we have not considered evidence of the included PROMs from other populations such as evidence for the measurement properties of the SF-36 and PROMIS in other patient populations.

In conclusion, this systematic review revealed shortcomings in many of the current PROMs used to assess HRQoL in patients with GBS and CIDP, as well as a lack of evidence on their measurement properties. This review did not identify any PROMs that met the recommendations for use. Although the R-FSS has shown promise for measuring fatigue, its inconsistent content validity limits its clinical application and therefore did not meet the criteria for recommendation for use. Two PROMs are recommended not to be used: I-RODS and IN-QoL, and for the remaining PROMs, further validation is needed before a recommendation can be made.

To develop a comprehensive PROM set for GBS and CIDP, we recommend first establishing consensus on the relevant PROs. Once these have been clearly defined, promising PROMs to measure these outcomes should be further validated in patients with GBS and CIDP. Rather than relying on a single PROM, a combination of PROMs may be necessary to comprehensively capture all relevant aspects of HRQoL for patients with GBS and CIDP.

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Conflicts of Interest

C.B.T. is one of the founders of COSMIN, past president of the PROMIS Health Organization, and head of the Dutch-Flemish PROMIS National Center. The other authors declare that they have no competing interests.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.

Appendix A

Search Strategy

Embase.com

('polyneuropathy'/de OR 'acute inflammatory demyelinating polyneuropathy'/de OR 'chronic inflammatory demyelinating polyneuropathy'/exp OR 'motor neuropathy'/de OR 'diabetic neuropathy'/de OR 'polyradiculoneuropathy'/exp OR 'demyelinating neuropathy'/de OR 'AL amyloidosis'/de OR (polyneuropath* OR ((multifocal-motor* OR paraprotein* OR myelin-associated-glycoprotein* OR MAG OR demyelinat* OR Chronic-ataxic* OR monoclonal-gammopath*) NEAR/3 (neuropath*)) OR ((multifocal OR multi-focal*) NEAR/6 (motor*) NEAR/3 (neuropath*)) OR (Guillain* NEXT/2 Barre*) OR Fisher-syndrome* OR CIDP OR GBS OR radiculoneuropath* OR polyradiculoneuropath* OR (acute-motor* NEAR/3 neuropath*) OR Pharyngeal-cervical-brachial-variant* OR (Bickerstaff* NEAR/4 encephalitis) OR Asymmetric-sensorimotor-variant* OR Lewis-Sumner* OR CASPR1 OR CNTN1 OR NF140 OR NF155 OR NF186 OR ((IgG4 OR Immunogloblin-g4 OR immunoglobulin-g-4 OR Ig-G4 OR Ig-G-4) NEAR/3 (nodal* OR paranodal*) NEAR/3 (antibod*)) OR CANOMAD OR POEMS OR ((Amyloid OR AL OR primary) NEAR/3 (amyloidos*)) OR AIDP OR AMAN OR AMSAN OR PCB OR BBE OR MADSAM):ab,ti,kw) **AND** ('patient-reported outcome'/de OR 'quality of life'/de OR (((patient* OR self*) AND (report* OR rated OR rating* OR based OR assess*) NEAR/3 (outcome* OR index OR indices OR instrument* OR measure* OR questionnaire* OR profile* OR scale* OR score* OR status* OR survey*)) OR ((disabilit* OR function* OR subjective* OR utilit* OR wellbeing* OR well-being*) NEAR/3 (outcome* OR index OR indices OR instrument* OR measure* OR questionnaire* OR profile* OR scale* OR score* OR status* OR survey*)) OR PROM OR PROMs OR (qualit* NEAR/3 life*) OR QoL OR HRQoL OR HRQL):ab,ti,kw) **AND** ('intermethod comparison'/exp OR 'data collection method'/exp OR 'validation study'/exp OR 'feasibility study'/exp OR 'pilot study'/exp OR 'reproducibility'/exp OR 'psychometry'/exp OR 'observer variation'/exp OR 'discriminant analysis'/exp OR 'validity'/exp OR (reproducib* OR audit* OR psychometr* OR clinimetr* OR clinometr* OR observer-variation* OR reliab* OR valid* OR coefficient* OR internal-consistenc* OR (cronbach* NEAR/3 alpha*) OR (item NEAR/3 (correlation* OR selection* OR reduction*)) OR agreement* OR precision* OR imprecision* OR precise-value* OR (test NEAR/3 retest*) OR stability OR ((inter OR intra) NEAR/3 (rater* OR tester* OR observ* OR technician* OR examiner* OR assay* OR individual* OR participant*)) OR interrater* OR intrarater* OR intertester* OR intratester* OR interobeserv* OR intraobserv* OR intraobserver OR intertechnician* OR intratechnician* OR interexaminer* OR intraexaminer* OR interassay* OR intraassay* OR interindividual* OR intraindividual* OR interparticipant* OR intraparticipant* OR kappa* OR coefficient-of-variation* OR repeatab* OR replicab* OR (repeat* NEAR/3 (measure* OR finding* OR result* OR test*)) OR generaliza* OR generalisa* OR concordance* OR (intraclass* NEAR/3 correlation*) OR discriminative* OR known-group* OR factor-analys* OR factor-structure* OR dimensionality* OR subscale* OR multitrait-scaling-analys* OR item-discriminant* OR interscale-correlation* OR (error* NEAR/3 (measure* OR correlat* OR evaluat* OR accurac* OR accurate* OR precision* OR mean)) OR ((individual*l OR interval*l OR rate*) NEXT/1 variabilit*) OR Variabilit*-analys* OR (uncertain* NEAR/3 measure*) OR standard-error-of-measurement* OR sensitiv* OR responsive* OR (limit* NEAR/3 detection*) OR minimal-detectable-concentration* OR interpretab* OR (small* NEAR/6 (real* OR detectable*) NEAR/6 (change* OR difference*)) OR ((minimal*) NEAR/6 (importan* OR detect* OR real*) NEAR/6 (change* OR differen*)) OR meaningful-change* OR ceiling-effect* OR floor-effect* OR item-response-model* OR IRT OR rasch* OR differential-item-function* OR DIF OR computer-adaptive-test* OR item-bank* OR cross-cultural-equivalen*):ab,ti,kw) NOT [conference abstract]/lim.

Medline (Ovid)

(Polyneuropathies/OR "Hereditary Sensory and Motor Neuropathy"/OR Diabetic Neuropathies/OR exp Polyradiculoneuropathy/OR Immunoglobulin Light-chain Amyloidosis/OR (polyneuropath* OR ((multifocal-motor* OR paraprotein* OR myelin-associated-glycoprotein* OR MAG OR demyelinat* OR Chronic-ataxic* OR monoclonal-gammopath*) ADJ3 (neuropath*)) OR ((multifocal OR multi-focal*) ADJ6 (motor*) ADJ3 (neuropath*)) OR (Guillain* ADJ2 Barre*) OR Fisher-syndrome* OR CIDP OR GBS OR radiculoneuropath* OR polyradiculoneuropath* OR (acute-motor* ADJ3 neuropath*) OR Pharyngeal-cervical-brachial-variant* OR (Bickerstaff* ADJ4 encephalitis) OR Asymmetric-sensorimotor-variant* OR Lewis-Sumner* OR CASPR1 OR CNTN1 OR NF140 OR NF155 OR NF186 OR ((IgG4 OR Immunogloblin-g4 OR immunoglobulin-g-4 OR Ig-G4 OR Ig-G-4) ADJ3 (nodal* OR paranodal*) ADJ3 (antibod*)) OR CANOMAD OR POEMS OR ((Amyloid OR AL OR primary) ADJ3 (amyloidos*)) OR AIDP OR AMAN OR AMSAN OR PCB OR BBE OR MADSAM).ab,ti,kf.) **AND** (Patient Reported Outcome Measures/OR Quality of Life/OR (((patient* OR self*) AND (report* OR rated OR rating* OR based OR assess*) ADJ3 (outcome* OR index OR indices OR instrument* OR measure* OR questionnaire* OR profile* OR scale* OR score* OR status* OR survey*)) OR ((disabilit* OR function* OR subjective* OR utilit* OR wellbeing* OR well-being*) ADJ3 (outcome* OR index OR indices OR instrument* OR measure* OR questionnaire* OR profile* OR scale* OR score* OR status* OR survey*)) OR PROM OR PROMs OR (qualit* ADJ3 life*) OR QoL OR HRQoL OR HRQL).ab,ti,kf.) **AND** (instrumentation.fs. OR methods.fs. OR Validation Study.pt. OR Comparative Study.pt. OR exp Psychometrics/OR exp Outcome Assessment, Health Care/ OR exp Observer Variation/OR exp Health Status Indicators/OR exp Reproducibility of Results/OR exp Discriminant Analysis/OR (reproducib* OR audit* OR psychometr* OR clinimetr* OR clinometr* OR observer-variation* OR reliab* OR valid* OR coefficient* OR internal-consistenc* OR (cronbach* ADJ3 alpha*) OR (item ADJ3 (correlation* OR selection* OR reduction*)) OR agreement* OR precision* OR imprecision* OR precise-value* OR (test ADJ3 retest*) OR stability OR ((inter OR intra) ADJ3 (rater* OR tester* OR observ* OR technician* OR examiner* OR assay* OR individual* OR participant*)) OR interrater* OR intrarater* OR intertester* OR intratester* OR interobeserv* OR intraobserv* OR intraobserver OR intertechnician* OR intratechnician* OR interexaminer* OR intraexaminer* OR interassay* OR intraassay* OR interindividual* OR intraindividual* OR interparticipant* OR intraparticipant* OR kappa* OR coefficient-of-variation* OR repeatab* OR replicab* OR (repeat* ADJ3 (measure* OR finding* OR result* OR test*)) OR generaliza* OR generalisa* OR concordance* OR (intraclass* ADJ3 correlation*) OR discriminative* OR known-group* OR factor-analys* OR factor-structure* OR dimensionality* OR subscale* OR multitrait-scaling-analys* OR item-discriminant* OR interscale-correlation* OR (error* ADJ3 (measure* OR correlat* OR evaluat* OR accurac* OR accurate* OR precision* OR mean)) OR ((individual*l OR interval*l OR rate*) ADJ variabilit*) OR Variabilit*-analys* OR (uncertain* ADJ3 measure*) OR standard-error-of-measurement* OR sensitiv* OR responsive* OR (limit* ADJ3 detection*) OR minimal-detectable-concentration* OR interpretab* OR (small* ADJ6 (real* OR detectable*) ADJ6 (change* OR difference*)) OR ((minimal*) ADJ6 (importan* OR detect* OR real*) ADJ6 (change* OR differen*)) OR meaningful-change* OR ceiling-effect* OR floor-effect* OR item-response-model* OR IRT OR rasch* OR differential-item-function* OR DIF OR computer-adaptive-test* OR item-bank* OR cross-cultural-equivalen*).ab,ti,kf.) NOT (news OR congres* OR abstract* OR book* OR chapter* OR dissertation abstract*).pt.

Web of Science

TS=(((polyneuropath* OR ((multifocal-motor* OR paraprotein* OR myelin-associated-glycoprotein* OR MAG OR demyelinat* OR Chronic-ataxic* OR monoclonal-gammopath*) NEAR/2 (neuropath*)) OR ((multifocal OR multi-focal*) NEAR/5 (motor*) NEAR/2 (neuropath*)) OR (Guillain* NEAR/2 Barre*) OR Fisher-syndrome* OR CIDP OR GBS OR radiculoneuropath* OR polyradiculoneuropath* OR (acute-motor* NEAR/2 neuropath*) OR Pharyngeal-cervical-brachial-variant* OR (Bickerstaff* NEAR/3 encephalitis) OR Asymmetric-sensorimotor-variant* OR Lewis-Sumner* OR CASPR1 OR CNTN1 OR NF140 OR NF155 OR NF186 OR ((IgG4 OR Immunogloblin-g4 OR immunoglobulin-g-4 OR Ig-G4 OR Ig-G-4) NEAR/2 (nodal* OR

paranodal*) NEAR/2 (antibod*)) OR CANOMAD OR POEMS OR ((Amyloid OR AL OR primary) NEAR/2 (amyloidos*)) OR AIDP OR AMAN OR AMSAN OR PCB OR BBE OR MADSAM)) **AND** ((((patient* OR self*) AND (report* OR rated OR rating* OR based OR assess*) NEAR/2 (outcome* OR index OR indices OR instrument* OR measure* OR questionnaire* OR profile* OR scale* OR score* OR status* OR survey*)) OR ((disabilit* OR function* OR subjective* OR utilit* OR wellbeing* OR well-being*) NEAR/2 (outcome* OR index OR indices OR instrument* OR measure* OR questionnaire* OR profile* OR scale* OR score* OR status* OR survey*)) OR PROM OR PROMs OR (qualit* NEAR/2 life*) OR QoL OR HRQoL OR HRQL)) **AND** ((reproducib* OR audit* OR psychometr* OR clinimetr* OR clinometr* OR observer-variation* OR reliab* OR valid* OR coefficient* OR internal-consistenc* OR (cronbach* NEAR/2 alpha*) OR (item NEAR/2 (correlation* OR selection* OR reduction*)) OR agreement* OR precision* OR imprecision* OR precise-value* OR (test NEAR/2 retest*) OR stability OR ((inter OR intra) NEAR/2 (rater* OR tester* OR observ* OR technician* OR examiner* OR assay* OR individual* OR participant*)) OR interrater* OR intrarater* OR intertester* OR intratester* OR interobeserv* OR intraobserv* OR intraobserver OR intertechnician* OR intratechnician* OR interexaminer* OR intraexaminer* OR interassay* OR intraassay* OR interindividual* OR intraindividual* OR interparticipant* OR intraparticipant* OR kappa* OR coefficient-of-variation* OR repeatab* OR replicab* OR (repeat* NEAR/2 (measure* OR finding* OR result* OR test*)) OR generaliza* OR generalisa* OR concordance* OR (intraclass* NEAR/2 correlation*) OR discriminative* OR known-group* OR factor-analys* OR factor-structure* OR dimensionality* OR subscale* OR multitrait-scaling-analys* OR item-discriminant* OR interscale-correlation* OR (error* NEAR/2 (measure* OR correlat* OR evaluat* OR accurac* OR accurate* OR precision* OR mean)) OR ((individual*l OR interval*l OR rate*) NEAR/1 variabilit*) OR Variabilit*-analys* OR (uncertain* NEAR/2 measure*) OR standard-error-of-measurement* OR sensitiv* OR responsive* OR (limit* NEAR/2 detection*) OR minimal-detectable-concentration* OR interpretab* OR (small* NEAR/5 (real* OR detectable*) NEAR/5 (change* OR difference*)) OR ((minimal*) NEAR/5 (importan* OR detect* OR real*) NEAR/5 (change* OR differen*)) OR meaningful-change* OR ceiling-effect* OR floor-effect* OR item-response-model* OR IRT OR rasch* OR differential-item-function* OR DIF OR computer-adaptive-test* OR item-bank* OR cross-cultural-equivalen*))) AND DT=(Article OR Review OR Early Access OR Letter).

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Polyneuropathy|polyneuropathies|'multifocal motor|paraprotein neuropathy|neuropathies'|'Guillain Barre' 'patient|self reported|rated|rating|based outcome|outcomes|index|indices|instrument|measure'|PROM|PROMs validation.