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ORIGINAL RESEARCH

Digital Monitoring of Patients with Generalized Myasthenia Gravis: A Prospective Pilot Study

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ABSTRACT

***Introduction*:** Monitoring patients with myasthenia gravis (MG) can be challenging due to the fluctuating nature of the disease. We aimed to test the reliability of using the MG Activities of Daily Living (MG-ADL) scale in the form of a smartphone application as a means for optimal patient monitoring and early exacerbation detection.

***Methods*:** We conducted an observational, prospective, single-center study including patients with generalized MG at risk of clinical worsening. Follow-up was based on routine outpatient visits, remote monitoring via weekly self-completion of the MG-ADL scale, and home visits by specialist nurses.

***Results*:** Thirty-one patients were included [41.9% female; mean (SD) age 59 (15) years], 87.1% seropositive for anti-AChR antibodies. MG-ADL scores reported by the patient via the application showed excellent agreement with healthcare provider scores (ICC = 0.92, $P < 0.01$),

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moderate correlation with the MG Composite scale (ρ = 0.595, $P < 0.01$), and weak correlation with the Quantitative MG scale (ρ = 0.328, $P < 0.01$). Over the 15-month follow-up period, compared to 23 exacerbations detected during routine outpatient visits, the application detected 38 exacerbations in 14 patients, 20 of which led to therapeutic modifications.
Conclusion: This study demonstrates the reliability of MG-ADL scale data obtained via a smartphone application in reflecting clinical status and in detecting deterioration episodes sometimes missed during routine outpatient visits.

Keywords: Myasthenia gravis; Exacerbation; Smartphone application; Remote monitoring; Patient-reported outcomes; Myasthenia gravis activities of daily living scale

Key Summary Points

Why carry out this study?

Muscle weakness in patients with myasthenia gravis (MG) is fluctuating, making accurate follow-up difficult.

We evaluated a smartphone application based on self-assessed patient-reported outcomes to improve monitoring of patients with MG.

What was learned from this study?

This application provides reliable information and helps detect exacerbations that might otherwise go unnoticed.Remote monitoring may be useful for monitoring adult patients with generalized MG.

INTRODUCTION

Myasthenia gravis (MG) is a chronic autoimmune disease mediated by antibodies against proteins at the neuromuscular junction, resulting in a weakening of skeletal muscles that typically worsens with exertion [1, 2]. Monitoring these patients can be challenging due to several factors: disease symptoms can fluctuate, even within the same day, potentially resulting in a strictly normal physical examination at the time of consultation [2]; and exacerbations—which may be triggered by factors such as infections, medications, changed medication or emotional stress—may also occur unpredictably and without an identifiable trigger in 24% of cases [3]. For this reason, routine follow-up in the form of consultations is often insufficient to monitor patient evolution, treatment response, and early exacerbation detection.

In recent decades, several efforts have been made to objectively monitor patient response and categorize their clinical status, focusing on the impact on activities of daily living and quality of life [4, 5]. Moreover, given the fluctuating nature of the disease, scales that provide a more comprehensive view of clinical status over a recent period have become popular [4]. In 1999, the Myasthenia Gravis Activities of Daily Living Scale (MG-ADL) was developed as an 8-item questionnaire on symptoms in the previous 7 days; it is administered by a healthcare provider but captures patient-reported outcomes without a clinician's interpretation of responses [6, 7]. Numerous studies have demonstrated good correlation between the MG-ADL and other MG scales [6–8], and, accordingly, it has come to be widely used in clinical trials and a useful tool for routine clinical practice in recent years [6].

The implementation of new digital technologies in medicine is an opportunity to develop tools that optimize MG follow-up. In 2012, Dr. Ted Burns, with support from the Myasthenia Gravis Foundation of America (MGFA), developed a smartphone application called *MyMG*, aimed at optimizing the follow-up of patients with MG [9]. However, to the best of our knowledge, the results of this study have not been formally published. In recent years, several smartphone application-based studies have evaluated different patient-reported outcomes [10, 11], with several telemedicine-based studies conducted during the COVID-19 pandemic demonstrating that data from remotely monitored patients with MG were strongly correlated with data collected in face-to-face settings [12–14]. In 2023, Dewilde et al. [15] opened the door to

using the MG-ADL scale for remote patient monitoring, by demonstrating excellent agreement overall and across all items between patient-reported and physician-reported scores.

With the goal of improving MG follow-up, our aim was to test the reliability of a smartphone MG-ADL application in terms of correlation between patient-reported scores and healthcare provider-reported scores.

METHODS

Study Design

A prospective, observational, longitudinal, single-center study of a cohort of patients with generalized MG (gMG) was conducted between July 2023 and December 2024. All patients were followed up for a minimum of 14 months, and all patients completed a satisfaction questionnaire regarding the tested smartphone application.

Patients

Inclusion criteria were patients aged over 18 years, diagnosed with gMG, and requiring close monitoring, defined as: (1) MG onset during the study inclusion period and eligible for treatment initiation; (2) patients experiencing an exacerbation during the study inclusion period; and (3) patients who, as part of routine care, were undergoing modifications to their treatment regimens, due either to down excursions of immunosuppressants or medication withdrawal due to adverse effects. The exclusion criteria were not owning or not knowing how to use a smartphone.

Evaluations

Included patients were monitored through a triple strategy as follows:

1. Routine visits within regular clinical practice, with a periodicity as determined by the treating physician.
2. Home-based assessments by a nurse specifically trained in MG scales administration, in once-monthly visits except when patients resided in distant locations, when frequency was every 2 or 3 months as determined by the treating physician.
3. Weekly monitoring through a smartphone application in which patients self-completed the MG-ADL scale (Fig. 1). Overall and itemized results were reported to the patient's neurologist. To encourage adherence in use of the application, patients received quarterly reminders.

The weekly application data were shared with the patient's neurologist for review aimed at identifying potential deterioration. Exacerbations were defined as a $\geq$ 2-point increase in MG-ADL scores compared to previously reported values. Additionally, any deterioration detected by nursing staff was also reported to the neurology team, so that an in-person or remote visit could be scheduled to assess patient symptoms and decide if therapeutic intervention was necessary.

Clinical Characteristics

Demographic, clinical, immunological, and therapeutic data were collected during follow-up. During consultation with the neurologist, MG-ADL and Myasthenia Gravis Composite (MGC) scales and therapeutic changes were recorded. At each visit, nurses administered the MG-ADL, Quantitative Myasthenia Gravis (QMG), and MGC scales, as well as the 4-item Morisky–Green scale to evaluate therapeutic adherence.

Permission and the appropriate licenses were obtained for the use of the MG-ADL, QMG, MGC and Morisky scales during the study.

Calculated in addition to raw values were delta (Δ) values for the patient-reported and healthcare provider-reported MG-ADL, determined as the difference between the value at a visit compared to the baseline value, defined as the ones at the moment of recruitment. Δ-values reflected the patient's evolution over that period.

Recorded during the follow-up months were all exacerbations detected by the application, nurse, and neurologist; data on therapeutic

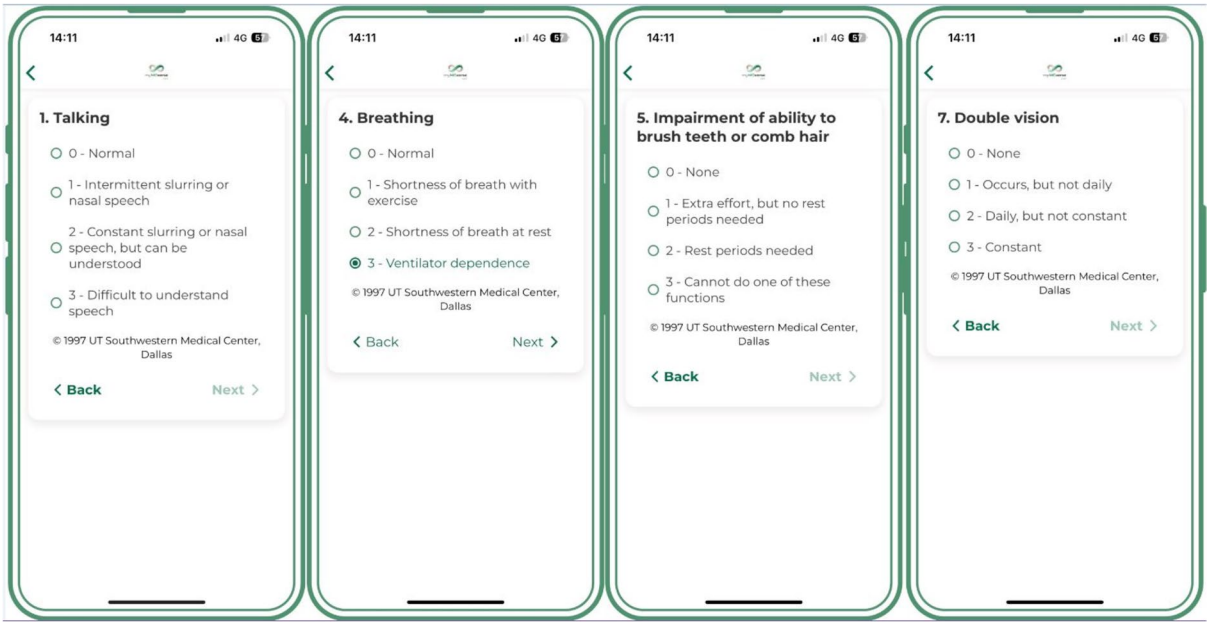

Fig. 1 Images of selected Myasthenia Gravis Activities of Daily Living (MG-ADL) items as they appear in the *MyMGVerse* app. For each item, severity is indicated on a scale from 0 to 3

interventions deriving from a deterioration; and the monthly number of patient-reported MG-ADL values, reflecting adherence to application use.

Statistical Analysis

Demographic, immunological, and clinical data were reported as means or medians, together with standard deviation (SD), interquartile range (IQR), and percentages when appropriate.

Depending on normality test results, between-variable correlations were analyzed using either Pearson's or Spearman's correlation tests, for a 95% confidence interval (CI). Based on previous studies [15], correlations were rated as follows: non-existent (0–0.2), weak (0.21–0.4), moderate (0.41–0.6), strong (0.61–0.8), or excellent (>0.8).

MG-ADL scoring agreement between different administrators was assessed using the intraclass correlation coefficient (ICC), and was classified as follows: poor (<0.5), moderate (0.51–0.75), good (0.76–0.90), or excellent (>0.90) [15].

To avoid measurement frequency bias in the above comparisons, we used healthcare provider-reported MG-ADL values (whether recorded by the neurologist or the specialist nurse) that were closest in time to the patient-reported MG-ADL values. Excluded from the correlation studies were patient-reported MG-ADL values separated by more than 7 days from those reported by healthcare providers.

We also evaluated a possible tendency to over- or underestimate MG-ADL values by patients compared to healthcare providers, using a paired *t* test with a 95% CI.

A two-tailed *P* value of <0.05 was considered significant. Data processing and statistical analysis were performed using IBM SPSS Statistics v29.

Ethical Approval

This study was conducted in accordance with the principles of the Declaration of Helsinki (1964) and its subsequent amendments and has been approved by the Ethics Committee of the Hospital de la Santa Creu i Sant Pau (code IIBSP-MIA-2023–03). All participants signed an informed consent for participation in the study

and for the publication of anonymized data prior to their inclusion.

The *myMGverse* app is a medical device with CE marking in accordance with the Medical Devices Directive (MDD, 93/42/EEC).

RESULTS

Patient Characteristics

Of the 34 patients recruited for the study, 3 patients withdrew during follow-up as unable to comply with the required activities. The characteristics of the remaining 31 patients included in the analysis are summarized in Table 1. Mean follow-up was 15 months (range 14–18).

Table 1 Clinical and demographic characteristics of the 31 included patients

Sex (*n*, %)	
Women	13 (41.9%)
Men	18 (58.1%)
Age (mean (SD), years)	59 (15)
Antibodies (*n*, %)	
Anti-AChR	27 (87.1%)
Anti-MuSK	3 (9.7%)
Anti-LRP4	0
Seronegative	1 (3.2%)
Reason for inclusion (*n*, %)	
Exacerbation	11 (35.5%)
Disease onset	1 (3.2%)
Immunosuppressant tapering	19 (61.3%)

AChR acetilcoline receptor, *MuSK* muscle-specific tirosin kinase, *LRP4* low-density lipoprotein receptor-related protein 4, *SD* standard deviation

Smartphone Application

During the entire follow-up period, 2 patients, women aged 20 and 79 year, did not use the application at any point, stating that they had problems remembering to use the application. Therefore, 29 patients reported usable data which are included in the following analysis. Throughout the follow-up period, the patients reported a total of 1126 MG-ADL scale scores, for an average of 39 scores per patient (range 0–65). The mean MG-ADL value reported was 1.51 (range 0–12) (see Table 2).

It was observed that the proportion of patients submitting data decreased progressively throughout the follow-up period, with adherence of above 85% in the first 5 months dropping to between 55 and 71% in the last 5 months (Fig. 2).

Regarding satisfaction with the application, 82.2% scored the application between 8 and 10 out of a maximum of 10.

Nurse Visits

A total of 308 nurse visits were conducted, for an average of 10 visits per patient. MG-ADL, MGC, and QMG scale scores were recorded at

Table 2 Smartphone application and nurse visit scores recorded on various scales

Scale	Mean score	Standard deviation	Range
Patient-reported MG-ADL	1.5	2.4	0–12
Healthcare provider-reported MG-ADL	1.5	2.3	0–11
QMG	6.6	3.9	0–20
MGC	3.5	4.2	0–21
Morisky–Green	3	0	3

MG-ADL myasthenia gravis activities of daily living, *MGC* myasthenia gravis composite, *QMG* quantitative myasthenia gravis

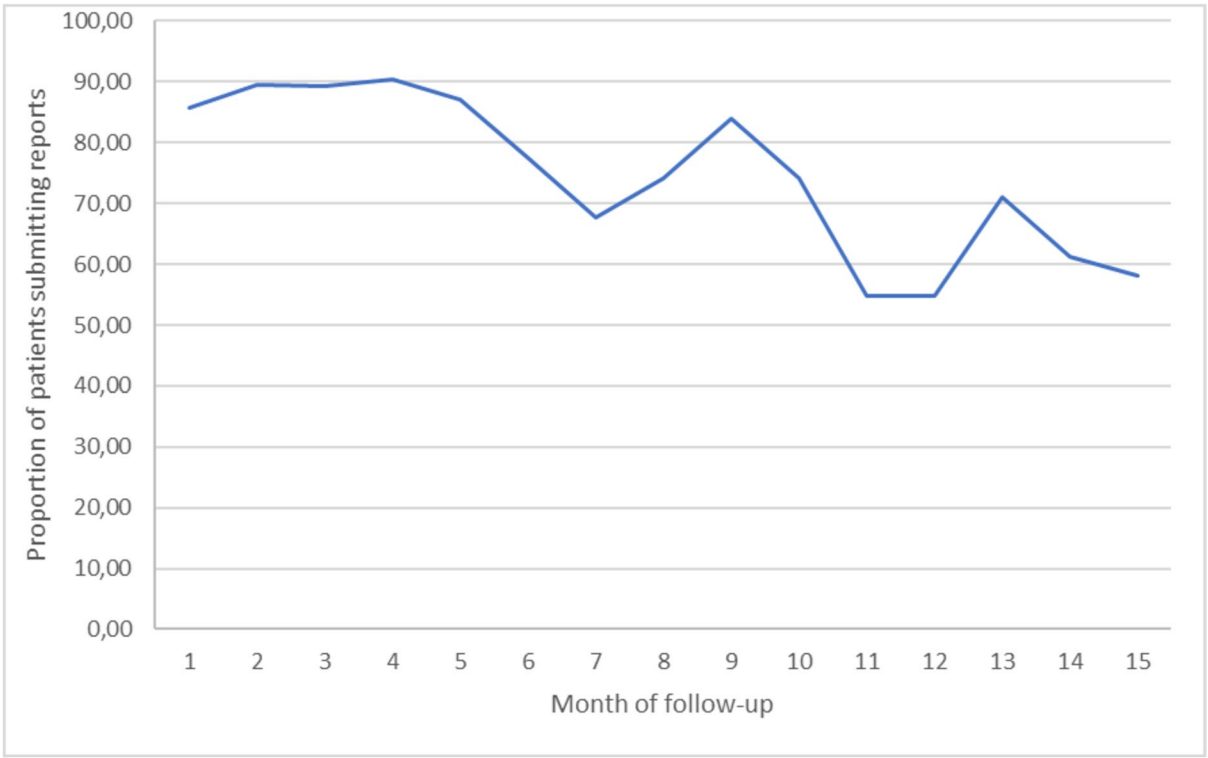

Fig. 2 Proportion of patients reporting Myasthenia Gravis Activities of Daily Living (MG-ADL) scores during follow-up

each visit, resulting in the average values shown in Table 2. Patients at all visits scored 3 on the Morisky–Green scale, indicating the highest possible adherence to medication.

Between-Scale Correlations

As confirmed by Fig. 3, patient-reported MG-ADL scores showed excellent correlation with healthcare provider-reported MG-ADL scores ($\rho = 0.857$, $P < 0.01$) and moderate correlation with the MGC scores ($\rho = 0.595$, $P < 0.01$), but were only weakly correlated with the QMG scores ($\rho = 0.328$, $P < 0.01$).

A strong correlation was also evident between patient-reported ΔMG-ADL and healthcare provider-reported ΔMG-ADL scores ($\rho = 0.713$, $P < 0.01$).

The inter-administration agreement was excellent between patient-reported MG-ADL scores and healthcare provider-reported MG-ADL scores (ICC = 0.92, $P < 0.01$). Furthermore, no systematic tendency to over- or underestimate scores by patients relative to healthcare providers was evident (mean (SD) = 0.036 (0.928); $t(277) = 0.642$, $P = 0.521$) (Fig. 3).

Exacerbations

Throughout follow-up, the application detected 38 deterioration episodes in 14 patients. The mean magnitude of the recorded fluctuations was 2.6 points on the MG-ADL scale compared with the previous value (range 2–8).

Of these 38 exacerbations, treatment was modified in 20 patients (Table 3). Among these 20 worsening episodes that required treatment adjustment, 13 were also identified during routine outpatient visits, whereas 7 were detected exclusively through the app. All exacerbations detected through the app were subsequently confirmed by means of a telephone or in-person visit.

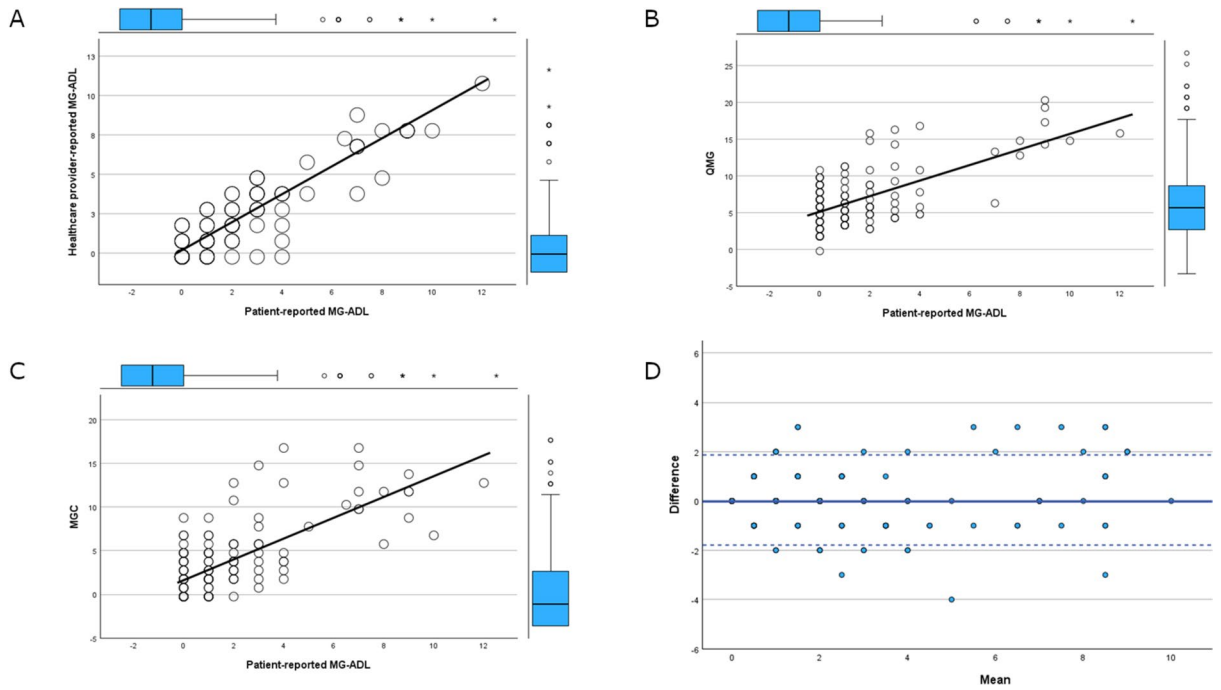

Fig. 3 **A** Correlation between patient-reported MG-ADL scores and healthcare provider reported MG-ADL scores. **B** Correlation between patient-reported MG-ADL scores and the QMG scale scores. **C** Correlation between patient-reported MG-ADL scores and the MGC scale scores. **D** Bland–Altman plot showing differences between patient-reported MG-ADL mean scores and healthcare provider-reported MG-ADL mean scores. The *solid line* represents the mean difference between the two observers, and the *dashed lines* reflect the limits of agreement (mean ± 1.96 SD). *MG-ADL* myasthenia gravis activities of daily living, *MGC* myasthenia gravis composite, *QMG* quantitative myasthenia gravis

Table 3 Therapeutic interventions in patients who experienced exacerbations ($n = 20$) during follow-up

Therapeutic intervention	Patients, *n*
Increased pyridostigmine dose	2
Increased corticosteroid dose	6
Initiation of immunosuppressive treatment	
Azathioprine	2
Mycophenolate	1
Rituximab	1
Cyclosporine dose escalation	1
Intravenous immunoglobulin	5
Efgartigimod	2

In addition, seven other exacerbations detected through the app corresponded to clinical worsening during the intercycle period of efgartigimod, leading to the initiation of a new treatment cycle. All of these cases were also identified through routine follow-up.

Among the 18 exacerbations that did not result in treatment modification, these consisted of mild worsening, self-limited fluctuations, or episodes occurring in patients without alternative therapeutic options or who declined changes in medication. Of these, only 3 were detected in routine consultation.

DISCUSSION

Follow-up of patients with MG is compromised by the fluctuating nature of MG and acute and

often unpredictable exacerbations. In this study, we demonstrate the reliability of a smartphone application for patient-reported MG-ADL scores as a means of monitoring patients with MG. Our results show excellent agreement between patient- and healthcare provider-reported outcomes. Furthermore, the fact that 38 exacerbations were detected by the application compared to 23 in routine consultations would suggest that standard follow-up of patients with MG fails to reliably capture disease fluctuations.

The reliability of the application was validated by the excellent agreement in MG-ADL scores between patients and healthcare providers. We also confirmed that patient-reported scores were not systematically over- or underestimated relative to the healthcare provider-reported scores, and that correlation between ΔMG-ADL values reflected a good capacity to detect changes and exacerbations.

With respect to other MG scales, we found MG-ADL to be moderately correlated with MGC but weakly correlated with QMG. Previous correlation studies of these scales observed moderate correlation between MG-ADL and QMG [7, 16]. However, weaker correlations for raw baseline values compared to changes in scores from baseline had been observed in other trials [16–18], suggesting that MG-ADL may be more sensitive than QMG in reflecting changes rather than clinical status at a given moment in time. Furthermore, MG-ADL and MGC both include a subjective component in the patient-reported items that is absent in QMG.

Remote monitoring detected more exacerbations than standard follow-up in outpatient visits, and some of those exacerbations required early therapeutic adjustments. We tentatively hypothesize that early intervention may prevent progressive worsening to potentially severe situations or avoid the need for rescue therapies. However, more robust conclusions in this regard are precluded by the small number of recruited patients in our study and the absence of a control group.

Besides, mild and self-limited fluctuations were also identified through the application. For this reason, in our opinion, remote monitoring applications are useful as screening tools; but exacerbations should always be confirmed by healthcare professionals and assessed with caution in order to avoid overdiagnosis and overtreatment of clinical changes that are part of the inherently fluctuating nature of this disease.

However, when appropriately implemented, these tools may help identify a subset of patients whose disease may be considered well-controlled based on routine clinical visits, but who experience frequent symptom fluctuations that, although mild, may significantly impact their daily functioning and quality of life.

In contemporary healthcare models, the active involvement of patients in condition management and self-care is becoming increasingly relevant [19, 20]. Digital tools empower patients by encouraging them to actively monitor their own clinical status and manage their disease. Additionally, a direct communication channel with the neurologist may enhance the physician–patient relationship and contribute to a greater sense of control over the disease. Our satisfaction survey results support this notion, as 82.2% of our patients evaluated the application as quite or very useful, and, when asked about the features found most beneficial, respondents primarily highlighted the direct communication pathway with their physician.

However, a crucial consideration in the practical application of digital tools is the large volume of data they generate, potentially requiring a significant time investment in data management and review by healthcare providers. To facilitate this task, our smartphone application includes a dashboard allowing classification of patients based on a color-coded system, whereby MG-ADL scores ≥ 2 or scores higher than the previous recorded ones are flagged, orange for mild cases and red for more severe cases. In this context, the specialist nurse plays a key role. Management of patients with MG requires a multidisciplinary approach, and nursing care is crucial to both case management and care continuity. This is especially so when new therapies are being introduced, as patient education regarding medication and periodic assessment of scales will become increasingly necessary [21]. In our opinion, nurses could also be crucial to the clinical implementation of remote MG monitoring, as they can instruct patients on application use and scale completion, manage dashboard

data, identify patients requiring closer monitoring, and even serve as the first point of contact for a patient with worsening symptoms.

Another practical aspect of using remote monitoring applications is adherence to use. Of the 34 patients recruited, 3 withdrew due to their inability to comply with the required activities, and 2 did not report any data through the app. Additionally, we observed a decrease over time in the proportion of patients regularly using our MG-ADL application. This likely reflects a limitation in the app's universal applicability, highlighting the need to identify and target the patient populations most likely to benefit from its use. For this reason, we suggest that remote monitoring, rather than a means of chronic monitoring of stable patients, is more useful for patients with uncontrolled MG, newly diagnosed patients, and patients experiencing exacerbations.

As limitations of our study, the number of exacerbations detected through consultations is likely overestimated, as early visits may have resulted from patients having established means of contacting their neurologist that they may have used in parallel with the application. Additionally, the small number of recruited patients and the absence of a control group do not allow us to draw conclusions as to whether remote monitoring enables earlier detection of exacerbations, potentially resulting in fewer hospital admissions and rescue therapy administrations. Further studies are needed to investigate these additional aspects.

CONCLUSIONS

The fluctuating nature of MG poses a challenge for patient monitoring, as assessment during a neurological consultation does not accurately reflect disease course over the previous months. Our study opens the door to optimized monitoring through the implementation of remote MG-ADL scale assessments, as it demonstrates that patient-reported MG-ADL scale scores obtained via a smartphone application yield reliable data on clinical status and, in detecting clinical deteriorations that may go unnoticed during routine follow-up visits, facilitating therapeutic interventions and adjustments.

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Author Contribution. Ana Vesperinas: Writing – review & editing, Writing – original draft. Visualization, Validation, Software, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. Josep Rocaspana-Codana: Writing – review & editing, Validation, Supervision, Conceptualization. David Reyes-Leiva: Writing – review & editing, Validation, Supervision, Conceptualization. Marta Caballero-Avila: Writing – review & editing, Validation, Supervision, Conceptualization. Alvaro Carbayo: Writing – review & editing, Validation, Supervision, Conceptualization. Roger Collet-Vidiella: Writing – review & editing, Validation, Supervision, Conceptualization. Laura Llanso: Writing – review & editing, Validation, Supervision, Conceptualization. Eduard Gallardo: Writing – review & editing, Validation, Supervision, Conceptualization. Joana Turon-Sans: Writing – review & editing, Validation, Supervision, Conceptualization. Ricard Rojas-García: Writing – review & editing, Validation, Supervision, Conceptualization. Elena Cortes-Vicente: Writing – review &

editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. All authors listed have made substantial contributions to the conception, design, analysis, and interpretation of the work; have drafted or critically revised the manuscript; have approved the final version for publication; and agree to be accountable for all aspects of the work, in accordance with the ICMJE authorship guidelines.

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Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of interest. Ana Vesperinas has received public speaking honoraria and compensation for advisory boards and consultation fees from argenx, UCB, Bial and Alexion. Elena Cortés-Vicente has received public speaking honoraria and compensation for advisory boards and consultation fees from UCB, argenx, Alexion, Johnson and Johnson, Amgen and Lundbeck. Josep Rocaspana-Codana, David Reyes-Leiva, Marta Caballero-Ávila, Alvaro Carbayo, Roger Collet-Vidiella, Laura Llansó, Eduard Gallardo, Joana Turon-Sans and Ricard Rojas-García have nothing to disclose.

Ethical Approval. This study was conducted in accordance with the principles of the Declaration of Helsinki (1964) and its subsequent amendments and has been approved by the Ethics Committee of the Hospital de la Santa Creu i Sant Pau (code IIBSP-MIA-2023–03). All participants signed an informed consent for participation in the study and for the publication of anonymized data prior to their inclusion. The myMGverse APP is a medical device with CE marking in accordance with the Medical Devices Directive (MDD, 93/42/EEC).

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