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Patient-reported impact of myasthenia gravis in the real world: findings from a digital observational survey-based study (MyRealWorld MG)

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ABSTRACT

Objectives This study aims to explore the impact of myasthenia gravis (MG) — in terms of treatments, side effects, comorbidities, psychological health and work or study— in the real world from a patient perspective.

Design and participants This is a prospective, observational, digital, longitudinal study. Adults diagnosed with MG residing in the USA, Japan, Germany, the UK, Italy, Spain or Canada were eligible to participate in the study. There were no other exclusion criteria. Participants used a bespoke smartphone application to confirm eligibility, provide consent and enter data about their MG into a profile, a tracker to record MG-related events and a series of patient-reported outcome instruments. 1693 participants completed at least 1 survey and were included in this analysis.

Results Results are presented as a percentage of respondents to each survey question. The study population was largely female (69% of 1586 respondents), with an average age of 49.9 years (SD 14.8). In the previous 12 months, 83.7% of 1412 respondents confirmed that they had received one or more routine treatments for MG, and 67.1% of 255 respondents confirmed that they had experienced a side effect in the previous month. Commonly experienced comorbidities reported by 966 respondents were thyroid problems, hypertension and anxiety, experienced by 37.5%, 31.4% and 28.0% of respondents, respectively.

According to 889 respondents to the Hospital Anxiety and Depression Scale survey, 52.7% and 43.2% had a score indicative of at least mild anxiety and mild depression, respectively. Of 257 respondents, 33.0% reported experiencing a work or study impact in the past month.

Conclusions This analysis of baseline characteristics of the MyRealWorld MG study population indicates that, despite current treatments, patients experience notable burden. Further scheduled analyses will develop a longitudinal picture of MG burden.

Trial registration number NCT04176211.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Collecting data directly from participants will enable people with myasthenia gravis (MG) to share their own experiences of living with the condition.
⇒ Allowing participants to self-enrol and document/report data using a digital application should enable a large and diverse group of people with MG to take part.
⇒ However, selection bias could impact on the generalisability of findings.
⇒ Remote self-entry of data by participants rather than by trained study researchers may increase the risk of incorrect or poor quality data entering the study database.
⇒ The absence of direct contact and follow-up with a clinician or member of the study team increases the challenge of retaining and engaging participants.

INTRODUCTION

Myasthenia gravis (MG) is a rare, IgG-mediated autoimmune disorder characterised by fluctuating muscle weakness and resulting from the presence of autoantibodies against components of the neuromuscular junction membrane.[1 2] In most instances, IgGs against the acetylcholine receptor (AChR) can be found. The underpinnings of the disease are complex and multifactorial.[2 3]

The cardinal feature of MG is fluctuating skeletal muscle weakness that commonly affects control of the eyes and eyelids, facial expressions, chewing, swallowing and speaking.[4 5] While patients typically present with ocular symptoms, over 80% of these cases will eventually progress to generalised disease, in which peripheral skeletal muscles are affected.[1] Fatigable muscle weakness can impair the ability of individuals to perform daily activities, result in the need for regular care by family members and impact the ability to work, thus imposing a financial burden on patients and their families.[6 7] Respiratory muscles are affected in the most severe and

potentially life-threatening cases; patients in this state of 'myasthenic crisis' will require intubation and mechanical ventilation.[8] While MG is a treatable disease, the health-related quality of life (HRQoL) of patients may still be affected by residual symptoms, refractory disease and episodes of symptom exacerbation and myasthenic crisis, as well as the debilitating side effects of available treatment options.[7 8]

As with many other rare conditions, there is a lack of data about the disease and treatment burden of MG, which is critical for informed decision-making on disease management.[9 10] Direct reports from patients can provide unique and in-depth perspectives on disease burden and impact of treatment. To date, most of such patient-reported outcome (PRO) data has been generated in the clinical trial setting.[11]

In rare diseases, where small patient populations are geographically dispersed, there is value in collecting more granular, longer-term real-world evidence (RWE) from a broader patient population than is typical in clinical trials.[12 13] Furthermore, symptoms in MG can fluctuate frequently, and actual disease severity and burden may escape medical examination at a given time point, meaning that an RWE study, in which participants can provide data regularly, may be especially valuable.

MyRealWorld MG (Vitaccess, Oxford, UK) is an ongoing international, digital, observational study, exploring the burden of MG from the patient perspective. This analysis presents first-entered data by study participants recruited up to and including 31 October 2021, thus describing the baseline characteristics of the patient population.

Objectives

To evaluate real-world management and symptom burden of MG, as well as HRQoL of individuals with MG, in the USA, Japan, Germany, the UK, Italy, Spain and Canada.

METHODS

Patient and public involvement

Patient and public involvement in the design of this study has been previously described.[14] Briefly, the study's Scientific Advisory Board includes at least one clinician with expertise in the field of MG and one patient advocacy group (PAG) representative from each study country. Clinicians and disease experts provide guidance on data acquisition, ethics and compliance, evaluating project implementation and data generation. PAG representatives provided input during conceptualisation and design of the study, as well as feedback on key study materials and the MyRealWorld MG study application (app).

Study design

The study design has been described elsewhere.[14] This is a prospective, longitudinal, observational, PRO study. Adults diagnosed with MG residing in one of the seven participating countries—the USA, Japan, Germany, the UK, Italy, Spain and Canada—were eligible to participate in the study. There were no other exclusion criteria. Participants use a bespoke smartphone app, MyRealWorld MG, to enrol in the study and regularly enter data about MG management and disease burden. Participants self-identify their diagnosis at the enrolment stage. Data collected between 1 December 2019 and 31 October 2021 are presented in this analysis of the baseline characteristics of study participants.

Data collection

Data collection began once participants gave informed consent and enrolled in the study. At study enrolment, participants completed their profile, consisting of information that was not expected to change frequently over the course of the study (eg, demographic data); the profile could be updated at any time. Once every month, participants entered data into the tracker concerning events that had taken place in the past month (eg, treatment changes, healthcare visits); the tracker could not be updated at other times. Finally, a range of PRO instruments were used to capture reports directly from participants regarding the status of their health. The administration of PRO surveys varied from monthly to 6 monthly, depending on the instrument. The instruments from which the baseline characteristics of participants were derived are described below.

PRO measures

MG activities of daily living scale

The MG Activities of Daily Living (MG-ADL) scale is an MG-specific questionnaire that assesses the severity of the following symptoms: talking, chewing, swallowing, breathing, impairment of ability to brush teeth/comb hair, impairment of ability to rise from a chair, double vision and eyelid droop. There are four response options for each symptom, ranging from 0 to 3. The total score ranges from 0 (no impact) to 24 (severe impact) on daily living.[15 16]

MG Quality Of Life 15-item Revised Scale

The MG Quality Of Life 15-item Revised Scale (MG-QOL15r) is an MG-specific HRQoL questionnaire that assesses the impact of MG on the following domains: emotions, physical health, self-care, social life and role. There are three response options for each item, ranging from 0 to 2. The maximum score of 30 represents the largest impact on HRQoL and is calculated by taking the sum of the item scores.[17 18]

Hospital Anxiety and Depression Scale

The Hospital Anxiety and Depression Scale (HADS) is a tool developed to assess psychological distress in non-psychiatric patients. Both the anxiety and depression subscales consist of seven items, which are each scored on a scale from 0 to 3. The total score for each subscale, therefore, ranges from 0 to 21, where scores from 8 to 10 represent mild anxiety or depression, scores from 11 to 14 represent moderate anxiety or depression, and scores ≥15 represent severe anxiety or depression.[19]

Statistical analysis

Data analysis followed a predefined statistical analysis plan. All analyses were descriptive and no hypotheses were tested. Descriptive distribution statistics for each PRO instrument score, or domain score, are presented for baseline (first data-entry time point).

Note that participants were not required to complete all surveys, or to respond to all questions within a single survey. Thus, in this analysis, results for a particular survey question are presented as a percentage of the number of participants responding to that specific question, while the tables additionally show results as a percentage of the total study population.

RESULTS

The following are 'first-entered data', equivalent to the baseline, providing a snapshot of the study population.

Participants

As at 31 October 2021, 1806 participants had registered for the study; 1693 participants were included in the data set for analysis having met the criteria of both registering and entering some data across any survey.

Demographics and disease profile

Demographic and clinical characteristics of participants are presented in table 1.

The majority of participants were female (69% of 1586). The average participant age was 49.9 years (n=1563; SD 14.8) and Italy was the most common country of residence (38.7% of 1693). Of participants who reported their MG type (n=1520), the majority classified their MG as generalised (88.5%), whilst a smaller proportion classified their MG as ocular (11.5%). Sixty-eight per cent of reporting participants (n=1520) indicated their antibody status as MG antibody positive, vs approximately one-third indicating their antibody status as negative (31.2%). Additionally, 13.6% of the total study population confirmed that they had been tested but could not remember the result. The largest proportion of reporting participants further indicated their antibody type as AChR (87.8% of 826).

Of participants reporting their Myasthenia Gravis Foundation of America (MGFA) disease classification at the time of survey completion (n=1520), the highest proportion reported Class III (36.9%), whereas the lowest proportion reported class V (1.4%). Participants had been living with MG for an average of approximately 9 years (n=1444).

Use of routine and rescue treatments

Results for reported use of routine and rescue treatments in the 12 months prior to study registration are shown in figures 1 and 2, respectively. Note that, in both figures, categories are non-exclusive and sum to greater than 100. The majority of respondents (83.7% of 1412) confirmed that they had received at least 1 routine treatment for MG in the 12 months prior to study registration, with the prevalent form of treatment used being acetylcholinesterase inhibitors (AChEIs) (80.9%), followed by steroids (65.4%) and non-steroidal immunosuppressive therapies (NSISTs) (48.1%). Of 129 participants who reported the type of NSIST that they had received in the 12 months prior to study registration, over one-third (34.9%) reported receiving azathioprine. This was followed by mycophenolate and tacrolimus, reported by 30.2% and 22.5% of respondents, respectively.

Participants were subsequently asked whether they had used any rescue treatments for MG in the 12 months prior to study registration. Of 1376 respondents overall, 30.8% confirmed that they had received 1 or more rescue treatments. The most commonly used rescue treatment was steroids (58.0% of 424 respondents).

Symptoms attributed to side effects

Overall, 171 of 255 responding participants reported that they experienced a symptom attributed to a side effect in the 30 days prior to study registration. The number of participants reporting each symptom and the proportion of participants reporting the different levels of severity (mild, moderate, severe or life-threatening) are shown in figure 3. The most frequently reported symptom attributed to a side effect by participants was tiredness (65.5%), followed by muscle twitches (52.0%), weight gain (48.5%) and mood swings (46.8%). Over one-third of participants additionally reported experiencing headaches, sweating and diarrhoea. The grade of severity most often reported was grade 2 (moderate severity).

Comorbidities

The proportion of participants that reported experiencing additional medical conditions is presented in figure 4. The majority (64.6% of 1495 respondents) reported experiencing at least one additional medical condition and the most commonly selected comorbidities were thyroid problems (37.5%), high blood pressure (31.4%) and anxiety (28.0%). Additionally, 36.0% selected the answer option 'other', meaning that the additional medical condition(s) that they experienced were not on the option list provided.

PRO measures

MG-specific PRO

The mean (SD) total MG-ADL score (n=880 reporting) was 5.7 (4.0). Of the 880 respondents, 41.7% had an MG-ADL score of less than 5, 26.9% had a score between 5 and 7, 12.0% had a score between 8 and 9, and 19.0% had a score equal to or greater than 10.

The mean (SD) total MG-QOL15r score (n=895 reporting) was 11.9 (7.4).

Hospital Anxiety and Depression Scale

The mean (SD) total HADS (n=889 reporting) anxiety subscale score was 8.3 (4.4), with 22.5%, 20.3% and 9.9% of respondents reporting mild, moderate and severe anxiety, respectively, and 47.4% reporting non-case

Table 1 Summary baseline statistics

Characteristic	Result	% of total study population (n=1693)	% of those reporting*
Age at enrolment, years (mean (SD)): 1563 reporting	49.9 (14.8)		
Gender, n: 1586 reporting			
Male	485	28.6	30.8
Female	1086	64.1	69.0
Other	4	0.2	0.3
Prefer not to answer	11	0.6	
Country of residence, n: 1693 reporting			
Canada	19	1.1	
Germany	89	5.3	
Spain	191	11.3	
Italy	656	38.7	
Japan	116	6.9	
UK	56	3.3	
USA	566	33.4	
MG type, n: 1520 reporting			
Generalised	1311	77.4	88.5
Ocular	170	10.0	11.5
Unknown	37	2.2	
Prefer not to answer	2	0.1	
Antibody status, n: 1520 reporting			
MG antibody positive	826	48.8	68.8
MG antibody negative	374	22.1	31.2
Unknown (haven't been tested)	71	4.2	
Unknown (can't remember test result)	230	13.6	
Prefer not to answer	19	1.1	
Antibody type, n: 826 reporting			
Acetylcholine receptor	659	38.9	87.8
Lipoprotein-related protein 4	18	1.1	2.4
Muscle-specific kinase	62	3.7	8.3
Other	12	0.7	1.6
Unknown	75	4.4	
MGFA disease classification at time of survey completion, n: 1520 reporting			
Class I	224	13.2	15.3
Class II	426	25.2	29.0
Class III	542	32.0	36.9
Class IV	254	15.0	17.3
Class V	21	1.2	1.4
Prefer not to answer	53	3.1	
Age at symptom start, years (mean (SD)): 1508 reporting	40.1 (17.4)		
Age first sought medical care, years (mean (SD)): 1504 reporting	40.4 (17.1)		
Age diagnosed with MG, years (mean (SD)): 1503 reporting	41.3 (17.0)		
Duration of MG, years (mean (SD)): 1444 reporting	8.7 (10.1)		

*Results for reporting participants who did not select the following answer options: 'prefer not to answer' or 'unknown'.
MG, myasthenia gravis; MGFA, Myasthenia Gravis Foundation of America.

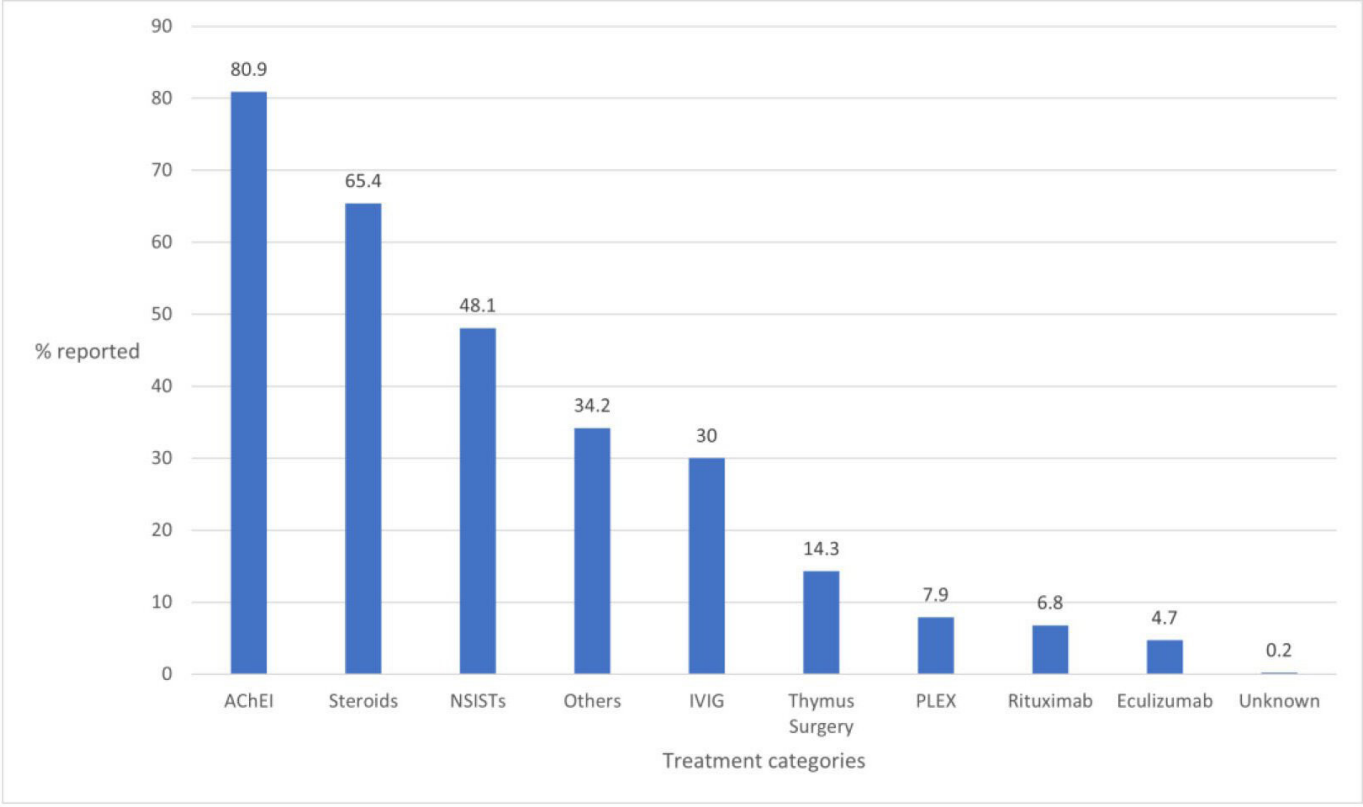

Figure 1 Routine treatment regimens in the 12 months prior to study registration (% of 1412 responding participants—note that participants could select more than one treatment). AChEI, acetylcholinesterase inhibitor; NSISTs, non-steroidal immunosuppressive therapies.

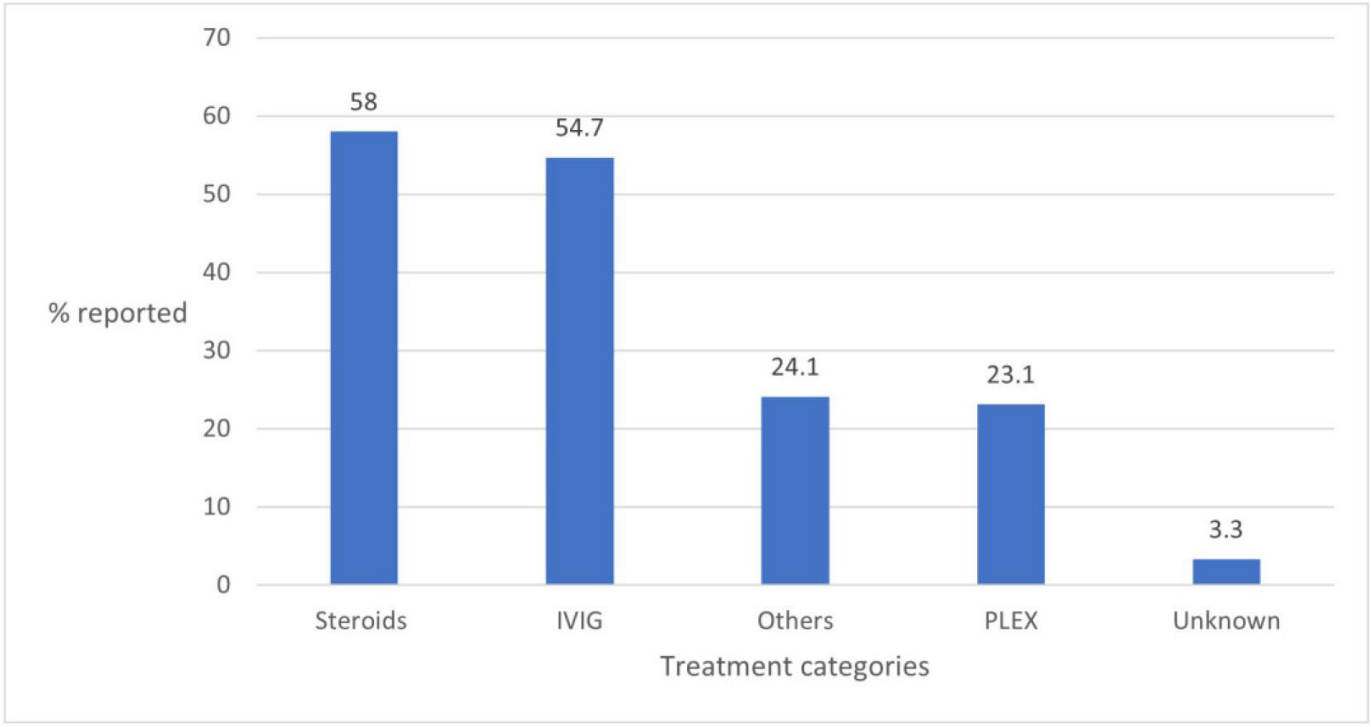

Figure 2 Rescue treatment regimens in the 12 months prior to study registration (% of 1376 responding participants—note that participants could select more than one treatment). IVIG, intravenous immunoglobulin; PLEX, plasma exchange.

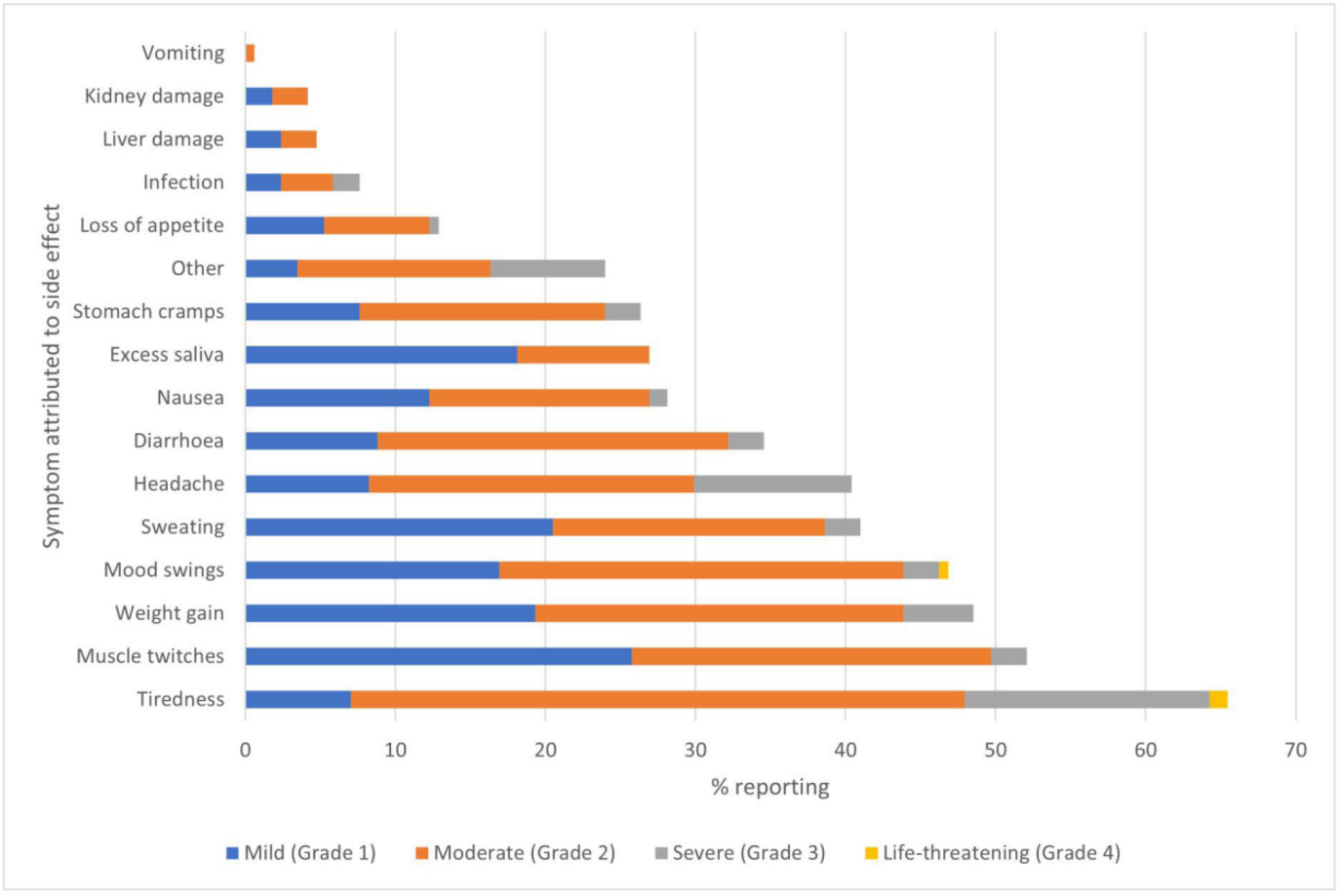

Figure 3 Symptoms attributed to side effects in the 30 days prior to study registration (% of 171 responding participants—note that participants could select more than one symptom).

anxiety. The mean (SD) total HADS depression subscale score was 6.8 (4.2), with 24.5%, 14.5% and 4.2% of respondents reporting mild, moderate and severe depression, respectively, and 56.8% reporting non-case depression.

Of 166 participants with a HADS depression score of 11 or above (ie, reporting at least moderate depression), 69.3% reported experiencing additional medical conditions to MG; of 268 participants with a HADS anxiety score of 11 or above (ie, reporting at least moderate anxiety), 64.6% reported experiencing additional medical conditions to MG (see online supplemental table 1). The most commonly reported comorbidities (excluding depression) by the former cohort (n=115 participants reporting at least moderate depression as well as additional medical conditions to MG) were anxiety (50.4%), high blood pressure (33.9%), gastrointestinal problems (21.7%) and respiratory problems (28.7%). The most commonly reported comorbidities (excluding anxiety) by the latter cohort (n=173 participants reporting at least moderate anxiety as well as additional medical conditions to MG) were depression (41.6%), gastrointestinal problems (31.8%), respiratory problems (25.4%) and high blood pressure (24.3%). Additionally, 44.3% of the former cohort and 44.5% of the latter cohort selected the answer option 'other', meaning that the additional medical condition(s) that they experienced were not on the option list provided.

Work/study impacts

Of 86 respondents who indicated whether they had or had not experienced a work or study impact in the last 30 days—in other words, not skipping the question or indicating that they preferred not to answer—all confirmed an impact to their work or study. Of 61 respondents reporting the reason for not working or studying in the last 30 days, the majority (57.4%) indicated MG as the reason for this impact, and a smaller proportion (31.1%) indicated retirement (not because of MG) as the reason for this impact. The mean (SD) number of days taken off work or study, according to reports from 83 respondents, was 13.1 (11.9) days.

Of 85 participants reporting a work or study impact who also reported whether they were experiencing additional medical conditions to MG, the majority (72.9%) confirmed the presence of comorbidities (see online supplemental table 2). The most commonly reported comorbidities by this cohort (n=62) were respiratory problems (27.4%), high cholesterol (25.8%), high blood pressure (22.6%), thyroid disorder (19.4%) and thyroid problems (17.8%). Additionally, 40.3% of this cohort

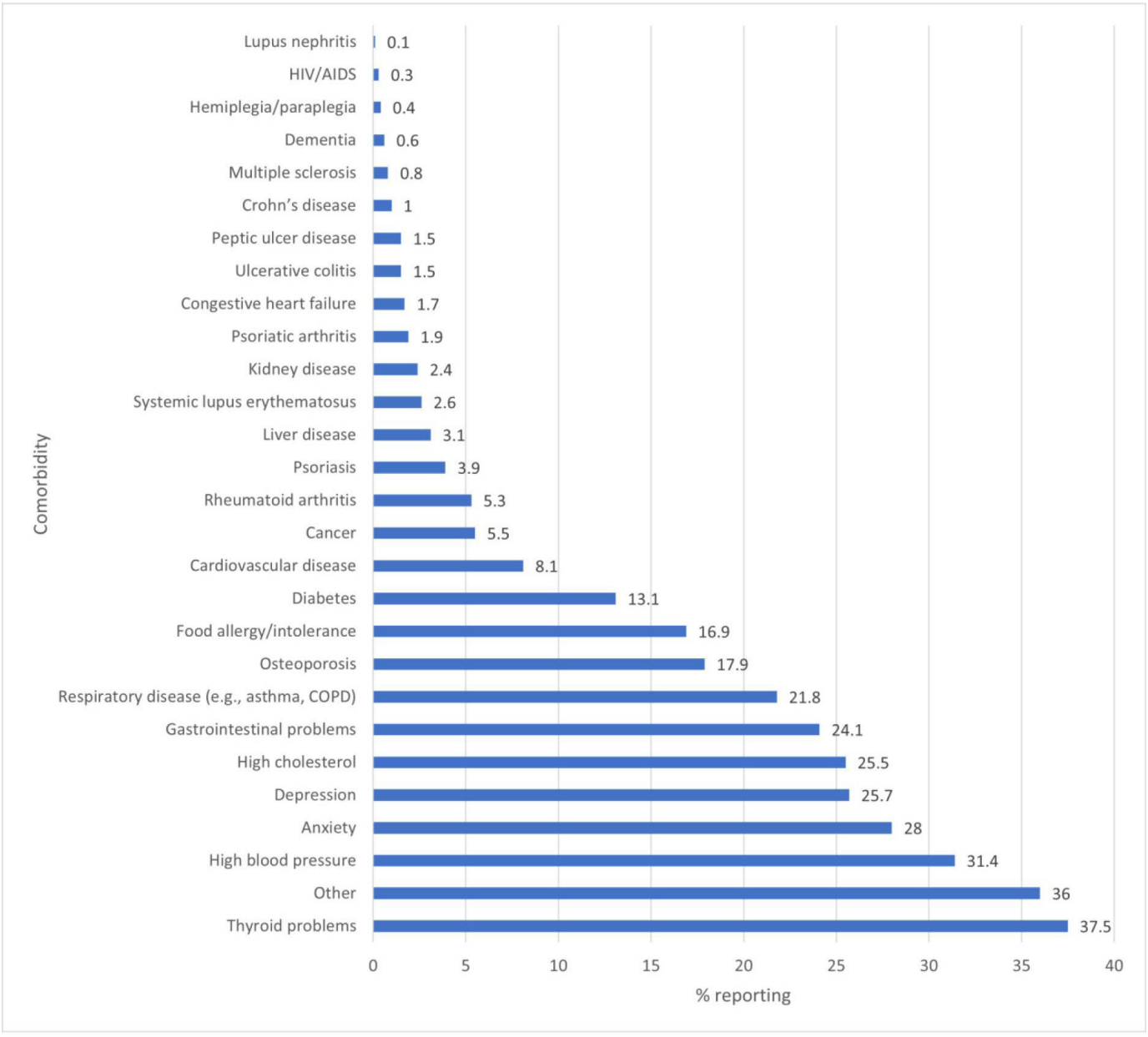

Figure 4 Comorbid conditions reported at study registration (% of 1495 responding participants—note that participants could select more than one condition). COPD, chronic obstructive pulmonary disease.

selected the answer option 'other', meaning that the additional medical condition(s) that they experienced were not on the option list provided.

DISCUSSION

This analysis of baseline data from 1693 adults living with MG across seven countries revealed a moderate participant-reported burden, despite effective treatment being actively received. Reporting participants were likely to experience at least one of a wide range of comorbidities, alongside symptoms attributed to side effects such as tiredness and muscle twitches. According to the PRO data, around one-half of reporting participants met the HADS definition for anxiety, with 43.2% meeting it for depression, and all participants who reported on their work or study experiences confirmed that they had been impacted.

Various therapies—typically AChEIs, steroids and NSISTs—are available to patients for disease management.[20] Of participants reporting their use of such treatments, 83.7% confirmed that they had received at least 1 routine treatment for MG in the past 12 months; the predominance of AChEIs, steroids and NSISTs as the treatments received for management of MG corroborates prior literature.[20 21] Alongside symptomatic treatment with AChEIs, chronic autoimmune conditions such as MG often necessitate long-term immunosuppression. Azathioprine, an NSIST, is commonly the first-choice long-term immunosuppressive therapy for MG[22] and was reported by over one-third of responding participants.

Furthermore, mycophenolate and tacrolimus, NSISTs which are considered in patients who are unresponsive or intolerant to azathioprine,[22] were reported by 30.2% and 22.5% of respondents, respectively. On top of routine therapies, acute exacerbations often require additional treatment[23]—the use of at least one rescue treatment in the past year was confirmed by over 30% of responding participants.

Side effects resulting from MG therapies are not only likely to impact patients' adherence to treatment, but also their HRQoL. In our study, while treatments received were not explicitly linked to patients' reported side effects, 171 responding participants reported a wide range of symptoms that they attributed to side effects, most notably tiredness, muscle twitches, weight gain and mood swings. Considering the prevalence of tiredness as a symptom in this cohort, it is worth noting the difficulty in differentiating between tiredness as a side effect of treatment and as a symptom of MG. Over one-third of participants additionally reported experiencing headaches, sweating and diarrhoea, consistent with prior literature.[24 25]

Almost 65% of responding participants reported experiencing at least one additional medical condition alongside MG—this is in line with literature indicating that 65%–73% of MG patients experience comorbidities.[26] Consistent with literature reporting thyroid disease as the most common autoimmune disorder associated with MG,[27] 37.5% of reporting participants in this study indicated thyroid problems as an additional medical condition. 31.4% of respondents reported experiencing hypertension—while prior research has also found hypertension to be the single most common comorbidity among MG patients,[28] it should be noted that the incidence among participants is similar to that of the general population.[29] Further to this, anxiety and depression were directly reported by 28.0% and 25.7% of respondents, respectively; however, results for 889 participants responding to the HADS survey indicate that 52.7% and 43.2% qualified for at least mild anxiety and depression, respectively. In a 2020 review of psychiatric comorbidity in MG, an association between MG and mood disorders was found in the majority of 32 assessed studies.[30] The global incidence of anxiety and depression in the general population has been estimated at 3.6% and 4.4%, respectively[31]; a higher incidence in MG patient populations is expected considering the chronic and unpredictable nature of the illness.[32 33] It is also worth noting that the proportions of participants qualifying for at least moderate anxiety or moderate depression according to the HADS survey who also reported experiencing one or more additional medical condition(s) to MG were similar to the proportion of the overall study population reporting comorbidities. Despite the complexity in understanding the interaction between MG and emotional/psychological comorbidities,[32–34] the prevalence of the latter in our study population is noteworthy and warrants further investigation.

Additional PRO instruments were used to demonstrate the HRQoL impact experienced by participants as a result of living with MG. Of 880 participants who completed the MG-ADL survey, close to one-fifth had a total score equal to or greater than 10, where higher scores on a scale of 24 indicate greater severity of symptoms. Considering that the majority of the study population had received some form of routine treatment for MG in the past year, and further that the range of treatments received was widespread, this proportion of respondents falling in the more severe subcategory according to the MG-ADL scale is noteworthy.

All of 86 responding participants confirmed that they had experienced an impact to their work or study in the past month, and 60.3% of 61 respondents indicated MG as the reason for this impact. Prior literature has indicated wide heterogeneity in levels of employment across MG patient populations, with the proportion of employed patients in one review of 19 studies varying between 28% and 82%.[35] This impact is not surprising: the employment rate of patients with chronic disease is considerably lower than that of a population with no chronic disease.[36] It is interesting to note that thyroid problems and/or disorder were reported by close to 20% of participants confirming a work or study impact in both instances; the fact that thyroid disease often presents with fatigue or restlessness[37] could account to some extent for the work or study impact experienced by this cohort, and is worth further exploration. The number of participants responding to the work and study questionnaire was low; the reason for this is not clear, however, it is possible that non-responding participants were simply not working or studying at the time of enrolment and therefore did not consider the survey relevant to them. It should be additionally considered that since the study was conducted during the COVID-19 pandemic, work commitments and the nature of work could have been affected; the reported figures may, therefore, represent a slight underestimate of actual disability.

Future research

Planned expansion of the study to additional target countries will encourage recruitment of a broader and more representative patient population. Adding a cohort from, for instance, an outpatient clinic to contribute registry-based data on disease severity and demographics could be considered as a means of validating the prevalence of reported burden. Implementation of a rewards scheme—specifically, completion of surveys triggering monetary donations to PAGs in countries where this is permitted—will incentivise participants to contribute a more complete set of data. Further to this, multivariable analysis could be used to explore which of the factors included in the study surveys are causing the greatest impact to HRQoL, or data could be segmented according to the MGFA classes of participants, for instance, to explore the relationship of different MGFA classes to HADS scores and delineate

further the interaction between psychological and physical impacts experienced by participants.

Strengths and weaknesses of the study

This study aims to build a repository of data relating to the real-world impact of MG, for which its digital, app-based approach—as opposed to the in-person, site-based approach of clinical studies—is particularly effective. The ability to reach patients globally, who can enter data at their own convenience and over an extended period of time, is especially advantageous in the case of a rare disease such as MG.

Methodological limitations of this study have been discussed elsewhere.[14] While digital real-world studies are valuable in evidencing the generalisability of clinical trial findings, certain types of bias necessarily exist in their design which can impact on the applicability of results to the average patient. For instance, the study population was limited to technologically competent participants, meaning that the demographics recorded reflect those of smartphone users. It should also be taken into consideration that there may be some degree of recruitment bias, in that patients with greater severity of disease may be more inclined to enrol, or equally may have more time to contribute data as a result of greater limitations in the ability to work or study. This is reflected in the fact that close to one third of responding participants reported the use of rescue treatments in the past year, which may not represent the experience of the average MG patient. Further, remote self-enrolment carries the risk that people who are ineligible for the study may register; the fact that the study is community recruited, where participants often become aware of the study through PAGs that are likely to be associated with genuine patients, alongside eligibility questions asked before study enrolment, does mitigate this risk to a certain extent. The self-reporting of data additionally introduces validation challenges. Moreover, some survey questions are associated with a low response rate; this is an unavoidable component of this study design, as participants are not required to complete all surveys or all questions in any one survey. Methods of encouraging engagement could be considered to account for this as the study progresses.

Conclusion

This analysis of the MyRealWorld MG study indicates that, despite current treatments, patients still experience moderate burden. The results also indicate a considerable impact of emotional/psychological comorbidities, which warrants investigation. Further scheduled analyses over the course of the study will develop a more longitudinal picture of MG burden.

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Competing interests The principal investigator, ML is CEO and owner of Vitaccess, which has been commissioned by argenx BV to carry out the study. FA and CQ are employees of Vitaccess. JB, GP, FDR, JR and SP are employees of argenx BV, the sponsor of the study. SB-A is a consultant and receives honoraria from argenx BV for this study. AM has received speaker honoraria, consulting fees or financial research support from Alexion, argenx BV, Grifols, Hormosan Pharma, Janssen, Octapharma and UCB. He serves as Chairman of the medical advisory board of the German Myasthenia Gravis Society. KGC has received advisory board honoraria, speaker fees and funding for research from Alnylam Pharmaceuticals, Biogen, CSL Behring and Sanofi-Genzyme, and travel reimbursement from Sanofi-Genzyme. KGC holds the Emil von Behring Chair in Neuromuscular and Neurodegenerative Disorders, sponsored by CSL Behring. FS has received public-speaking honoraria from Almirall, Biogen, Mylan, Novartis, Roche, Sanofi and Teva Pharmaceuticals, and served on advisory boards for Almirall, argenx BV, AveXis, Biogen, Forward Pharma, Lexeo Therapeutics, Merck, Novartis, Novatek Pharmaceuticals, Pomona, Roche, Sanofi and Takeda.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval Ethics approval was granted by Salus IRB (protocol number 5105-08-2019; Salus IRB, Austin, Texas, USA) for residents in the USA, Germany and the UK; by Veritas IRB (protocol number ARG-MG-2019-01; Veritas IRB, Quebec, Canada) for participants resident in all Canadian provinces excluding Newfoundland and Labrador, for which approval was granted by Newfoundland and Labrador Health Research Ethics Board (protocol number 5105-08-2019; Newfoundland and Labrador HREB, Newfoundland and Labrador, Canada); by Istituto Neurologico Carlo Besta (INCB, Milan, Italy) for Italy; by Research Ethics Committees with Medicines Hospital de la Santa Creu I Sant Pau (protocol number ARG-MG-2019-01; CEIm HSCSP, Barcelona, Spain) for Spain; and by the Non-Profit Organisation MINS IRB (protocol number ARG-MG-2019-01, NPO MINS, Japan) for Japan. Participants provided informed consent through the MyRealWorld MG app on their smartphones or tablets prior to commencing the study. The study was performed in accordance with the Declaration of Helsinki.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. MyRealWorld MG is an international observational digital longitudinal study designed to understand the impact of living with MG. At September 2022, data are collected from participants from the USA, Japan, Germany, the UK, France, Italy, Spain, Canada, Denmark and Belgium. The MyRealWorld MG dataset is available to researchers who would like to further knowledge of MG and improve patient care. To apply for access to the study data, please complete the data access request form available at: https://vitaccess.com/myasthenia-gravis-dataset/. All applications will be reviewed by the SAB before access is granted. Once approved, Vitaccess will either provide: access to the study dashboards, containing interactive figures and summary tables, presenting anonymised, aggregated data for key variables, or; a quotation to provide the necessary data.

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