

Validation study of the Malay version of the Myasthenia Gravis Quality of Life (MGQOL)15 and Myasthenia Gravis Activities of Daily Living (MGADL) questionnaires

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Abstract

Myasthenia gravis (MG) is an immune mediated neuromuscular disease causing fatigability, which can influence quality of life (QOL). MG disease status can be established with Myasthenia Gravis Quality of Life (MGQOL) 15 and Myasthenia Gravis Activities of Daily Living (MGADL) questionnaires to measure patients' perception of MG-related dysfunction. This study aims to validate the translated Malay versions of the MGQOL15 and MGADL for use in Malay-speaking MG patients. By using the cross cultural adaptation process, both questionnaires were translated into Malay language. Two sets of MGQOL15 Malay version and MGADL Malay version were distributed to MG patients during their routine follow-up to be filled up one week apart. A total of 38 patients were recruited during this study comprising predominantly females compared to males (71% vs 29%) and Malays compared to non-Malays (60% vs 40%). The mean age was 52.5 years; with most of the patients in the 60-69 years old category (37%). The Spearman's correlation coefficient was 0.987 for MGQOL-15 Malay version and 0.976 for MGADL Malay version, while the internal consistency for MGQOL15 Malay version was 0.952-0.957, and 0.677-0.694 for MGADL Malay version. The MGQOL15 Malay version and MGADL Malay version are reliable and valid instruments for the measurement of quality of life in MG patients in the local setting.

INTRODUCTION

In Malaysia, the prevalence of MG has not been well known until 30 years ago after a clinical survey was performed which reported a total of 62 cases seen from 1968 to 1979 at the Kuala Lumpur General Hospital, giving an average of 5.16 new cases every year.¹

A study in 2010 have suggested that different ethnic groups may have different clinical presentations.² In 2014, a retrospective analysis reported a significant difference in the age of disease onset between the races.³ So far there are only demographics and descriptive data of MG patients in Malaysia and none reported on

the quality of life of the local MG patients.

Patient-derived quality of life, as assessed by questionnaires has proven to be an essential outcome measures when used in conjunction with clinical examination.⁴ MG disease status can be established with Myasthenia Gravis Quality of Life (MGQOL) 15⁵ and Myasthenia Gravis Activities of Daily Living (MGADL)⁶ questionnaires to measure patients' perception of MG-related dysfunction. Till date, MGQOL15 and MGADL has only been validated in the Japanese language.⁷ There are no validated MG-specific quality of life scale in Malay language.

In view of the lack of available data among

the local population, we embark on this study to produce a validated version of MGQOL15 and MGADL in the Malay language.

METHODS

Patient selection

This validation study was conducted at the Universiti Kebangsaan Malaysia Medical Centre (UKMMC), a tertiary health centre. We included MG patients who attended the Neurology Outpatient clinic at UKMMC, and able to converse in Malay language proficiently. Those who had diseases mimicking MG, such as Lambert Eaton disease were excluded. We enrolled 38 patients with various stages of illness over a duration of 6 months in a single center study. Table 1 shows the demographics data of our subjects, while Table 2 shows their clinical characteristics. Twenty-seven (71%) were females and 11 (29%) were males. The majority of patients were Malays (23 patients, 60%), followed by Chinese (14 patients, 37%), and Indian (1 patient, 3%). The mean age was 52.5 years old, with most of the patients in the 60-69 years old category (37%). The majority of our subjects have at least a secondary level education

(45%), followed by tertiary level education (18%).

All clinical information were obtained after provision of informed consent, and the study protocols were approved by the ethics committee of the UKMMC.

Translation of original MGQOL15 into Malay

For the purpose of translation of the MGQOL15 and MGADL into Malay, the cross-cultural adaptation process as proposed by Bombardier *et al*⁸ was used as a reference. After a final consensus was reached regarding the equivalence of the final Malay version to the original English version, a finalized draft version of both questionnaires were tested on MG patients at the Neurology outpatient clinic. Another questionnaire was completed within 7 days and returned by mail.

Statistical analysis

As the MGQOL15 had 15 questions, they were grouped together to measure a single underlying construct. Three scales were created – QT1 (mobility), QT2 (symptoms) and QT3 (emotions and general contentment).

Table 1: Patient demographics data of myasthenia gravis subjects involved

Demography	Characteristics	Number	Percent
Gender	Male	11	29
	Female	27	71
Age (years)	< 40	10	26
	40-49	2	5
	50-59	9	24
	60-69	14	37
	>70	3	8
Race	Malay	23	60
	Chinese	14	37
	Indian	1	3
Age at onset	< 40	13	34%
	40-49	6	16%
	50-59	7	18%
	60-69	5	13.5%
	>70	2	5%
	Unknown	5	13.5%
Education level	Unknown		32%
	Nil formal education		5%
	Secondary		45%
	Tertiary		18%

Table 2: Clinical characteristics of myasthenia gravis subjects involved

Clinical factor	Characteristics	Number	Percent
Crisis	Yes	13	34
	No	22	58
Thymectomy	Yes	20	53
	No	16	42
Thymic enlargement	Yes	8	21
	Absent	25	66
	Not done	5	13
MGFA classification	I	17	45
	II-V	19	50
AChR-Ab positivity	Positive	24	63
	Negative	4	11
SM-Ab positivity	Positive	4	11
	Negative	10	26
Repetitive nerve stimulation test	Positive	11	29
	Negative	9	24
Single fibre electromyogram	Positive	14	37
	Negative	2	5
Histopathology	Normal	1	3
	Thymic hyperplasia	6	16
	Thymoma	5	13
Thymectomy	Done	16	42
	Not Done	19	50

RESULTS*Reliability & internal consistency of the MGQOL15 Malay version*

Internal consistency scored 0.952 in total for the test questionnaire. Within each of the three scales involved, the mobility scale scored the highest

Cronbach alpha value at 0.986, followed by the emotion and general contentment scale at 0.726 and the emotion scale at 0.715. The fact that Cronbach's alpha in MGQOL15 Malay version (MGQOL15-M) was more than 0.7 indicated excellent internal consistency, comparable with the Japanese validation study⁷, which was 0.930.

Table 3: Internal consistency & reliability test-retest at baseline and at 1 week of MGQOL15-M

Scale	r_s value Spearman's coefficient	Test Cronbach's alpha	Scale	Retest Cronbach's alpha
QT1	0.983	0.986	QrT1	0.966
QT2	0.935	0.715	QrT2	0.713
QT3	0.907	0.726	QrT3	0.767
Total		0.952		0.957

QT, questions for MGQOL15 sub-categories, QrT, retest questions for MGQOL15 subcategories

Table 4: Internal consistency and reliability test-retest at baseline and at one week of the MGADL-M, with the median scores of each item

Items	Test		Retest		Median
	Spearman's coefficient	Cronbach's alpha	Cronbach's alpha	Wilcoxon signed rank	
1. Bercakap	0.825	0.671*	0.649*	<i>p</i> = 1.0, <i>z</i> = 0.0	1.00
2. Mengunyah	0.864	0.628*	0.623*	<i>p</i> = 0.157, <i>z</i> = -0.414	1.00
3. Menelan	0.927	0.643*	0.619*	<i>p</i> = 0.317 <i>z</i> = -1.00	1.00
4. Pernafasan	0.900	0.634*	0.598*	<i>p</i> = 0.157 <i>z</i> = -0.414	1.00
5. Ketidakupayaan memberus gigi atau menyikat rambut	0.919	0.651*	0.622*	<i>p</i> = 1.0 <i>z</i> = 0.00	1.00
6. Ketidakupayaan untuk bangun dari kerusi	0.964	0.708*	0.651*	<i>p</i> = 0.564 <i>z</i> = -0.577	1.50
7. Penglihatan berlapis	0.952	0.720*	0.743*	<i>p</i> = 0.564 <i>z</i> = -0.577	1.00
8. Kelopak mata jatuh	0.906	0.666*	0.666*	<i>p</i> = 0.180 <i>z</i> = -1.342	2.00
	0.976	0.694	0.677		

*Cronbach's alpha coefficient when each item was excluded from the set of all items
QT, items for MGADL-M, QrT, retest items for MGADL-M

The positive Spearman's correlation coefficient suggests a reasonably strong relationship for the test-retest questionnaire in MGQOL15-M. The highest value of r_s value was 0.983 in the mobility scale QT1, followed by the symptoms scale 0.935 and the emotions and general contentment scale at 0.907.

MGQOL15 Malay version, MGADL Malay version and median scores

The median scores for MGQOL15-M among the subjects ranged from 0 to 2 in both the test and retest studies. Item 4 which represents social activity had the highest median score of 2. Total calculated median score for MGQOL15-M for the 38 subjects in this study was 12. The median scores for MGADL Malay version (MGADL-M) among the subjects ranged from 1 to 2 in both the test and retest studies. Item 8 which represents

droopy eye lids had the highest median score of 2. Total calculated median score for MGADL-M for the 38 subjects in this study was 9.5

Quality of life among genders and ethnic origin

There was a statistically significant difference in MGQOL15-M total median scores between males and females, $z = -2.1$, $p = 0.034$. However, there was no statistically significant difference in MGQOL15-M scores between the Malays and Chinese, $z = -0.479$, $p = 0.650$.

DISCUSSION

In this study, there were more female patients compared to males (71% vs 29%). The fact that the majority of patients involved in this study were in the age range of 60–69 years of age along with other medical co-morbidities, it may also play a

factor in influencing perception to the disease as well. Other factors such as social background, family support and depressive states, which are not included in the demographics here, should be included as they are important in making a more holistic approach for the patient's quality of life and activities of daily living.

In MGQOL15-M, only item 10 had several participants who did not respond, as they were not drivers and do not own a car. No alternative has been found to be equivalent to driving and hence the statement remains unchanged. Despite of no response, a high level of internal consistency and repeatability was still maintained, even if the item was excluded from the rest of the study.

In general, the MGQOL15-M internal consistency was high for the items in MG-QOL15, signifying that there was a high level of homogeneity among the items. The median total score of 12 (out of a max of 60) in MGQOL15-M among our subjects suggests that the patients have a fairly good QOL with a good satisfaction for their state of health. Item 4 involving restriction of social activities had the highest median score of all the items, suggesting that most of the subjects experience difficulty with social activities and interactions due to MG.

In MGADL-M, internal reliability for the items of MGADL-M was acceptable. Item 7 "Penglihatan berlapis" which was translated from "double vision" had a marked increase in the Cronbach alpha value when it was excluded from the set of all items in the MGADL-M. Almost half of the patients involved in this study were in Class I of the Myasthenia Gravis Foundation of America (MGFA) classification which has purely ocular involvement. A possible explanation would be that for some participants, the degree or severity of double vision can vary markedly within a short period of time.

In conclusion, we found that the items translated to Malay in the MGQOL15-M and MGADL-M exhibit adequate internal reliability and test-retest repeatability as in the original English MGQOL15 and MGADL.

In this study however, social factors linked to clinical variables were not included to be analyzed in association with the MGQOL15 and MGADL. This may be a limiting factor as it was found by Twork *et al.* that employment, financial status, the status, stability and severity of illness as well as mental conditions are determinants of quality of life in MG.⁹ Hence, the overall value of the questionnaires as well as any clinical assessment should be individualized.

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The study was approved by the Ethics Committee of the UKMMC and the permission to use the MGQOL15 and MGADL tools were granted by the Muscle Study Group USA.

DISCLOSURE

Conflict of interest: None

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Appendix A: Validated Malay version of the MG-QOL15

Sila tandakan betapa benar setiap kenyataan di bawah (selama beberapa minggu kebelakangan ini)

Nama :

Tarikh :

Nombor Daftar:

	Tidak benar sama sekali	Sedikit sahaja benar	Agak benar	Sangat benar	Amat benar sekali
	0	1	2	3	4
1. Saya berasa kecewa dengan MG saya					
2. Saya mengalami masalah penglihatan					
3. Saya mengalami masalah untuk makan kerana MG					
4. Saya telah menghadkan aktiviti sosial saya kerana MG					
5. MG saya menghadkan kemampuan saya untuk menikmati hobi dan aktiviti-aktiviti yang menyeronokkan					
6. Saya menghadapi masalah memenuhi keperluan keluarga saya oleh sebab MG saya					
7. Saya perlu mengambil kira MG saya dalam membuat perancangan					
8. Kemahiran bekerja dan status pekerjaan saya telah terjejas akibat MG					
9. Saya mengalami masalah bercakap kerana MG					
10. Saya mengalami masalah memandu kerana MG					
	Tidak benar sama sekali	Sedikit sahaja benar	Agak benar	Sangat benar	Amat benar sekali
	0	1	2	3	4
11. Saya berasa murung tentang MG saya					
12. Saya mengalami masalah berjalan kerana MG					
13. Saya mengalami masalah berjalan di tempat awam oleh kerana MG saya					
14. Saya berasa lemas oleh MG saya					
15. Saya mengalami masalah merapikan diri sendiri					

MG-QOL15

Muscle and Nerve 2008;38:957-63.
Muscle and Nerve 2010;41:219-26.
Muscle and Nerve 2011;43:14-8.

Jumlah mata MG-QOL15

Appendix B: Validated Malay version of the MG-ADL

Gred	0	1	2	3	Skor
1. Bercakap	Normal	Tidak jelas/sengau sekali sekala	Sentiasa tidak jelas, tetapi boleh difahami	Susah difahami	
2. Mengunyah	Normal	Penat apabila kunyah makanan pejal	Penat bila kunyah makanan lembut	Guna tiub gastrik	
3. Menelan	Normal	Jarang tercekik	Kerap tercekik hingga perlu ubah diet	Guna tiub gastrik	
4. Pernafasan	Normal	Sukar bernafas semasa aktiviti fizikal	Sukar bernafas ketika berehat	Bergantung pada alat pernafasan	
5. Ketidak-upayaan memberus gigi/menyikat rambut	Tiada	Perlu usaha lebih, tak perlu masa rehat	Perlu masa rehat	Tidak boleh lakukan satu daripadanya	
6. Ketidak-upayaan bangun dari kerusi	Tiada	Sedikit, kadangkala gunakan tangan	Sederhana,selalu gunakan tangan	Teruk, perlu pertolongan	
7. Penglihatan berlapis	Tiada	Berlaku,bukan setiap hari	Setiap hari, bukan sepanjang masa	Sepanjang masa	
8. Kelopak mata jatuh	Tiada	Berlaku, bukan setiap hari	Setiap hari, bukan sepanjang masa	Sepanjang masa	