DOI: *http://dx.doi.org/10.18502/cjn.v22i1.12615*

Current Journal of Neurology

Original Paper

Curr J Neurol 2023; 22(1): 35-43

Stability monitoring of patients with myasthenia gravis using a mobile-based application

Received: 07 Sep. 2022
Accepted: 12 Nov. 2022

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Keywords
Medical Informatics Applications; Monitoring; Myasthenia Gravis; Mobile Health; Mobile Applications; Neuromuscular Junction Diseases

Abstract

Background: Failure in early diagnosis of myasthenia gravis (MG) and the risks of taking certain medications and undergoing surgery and anesthesia can lead to severe respiratory disorders and death. However, there are therapeutic measures that significantly control the disease and improve individual's functionality.

Methods: First, an expert panel was formed, and a needs assessment questionnaire was prepared for the information elements and the capabilities required for the application and provided to neurologists with a subspecialty fellowship in neuromuscular diseases. Then, based on the analyzed results, the application was designed and created in 2 versions (physician and patient), and in 2 languages (Persian and English). Eventually, a questionnaire for user interaction and satisfaction was provided to 5 relevant physicians to evaluate the application.

Results: The results showed that neurologists considered all items of the needs assessment questionnaire to be 100% essential. The capabilities of the application included registering the medication name and dose, recording symptoms and complaints by the patient, completing standard questionnaires, online chat, medication reminder, sending alerts to the doctor when the patient is unwell, and providing a variety of reports. The usability evaluation showed that neurologists evaluated the application at a good level with the average score of 8.23 ± 0.47 (out of 9 points).

Conclusion: In the long run, using this technology can reduce costs, improve patients' quality of life (QOL) and health care, change health behaviors, and ultimately, improve individual's health.

How to cite this article: Alaei Tafti E, Ghazisaeedi M, Sarraf P. Stability monitoring of patients with myasthenia gravis using a mobile-based application. Curr J Neurol 2023; 22(1): 35-43.

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Introduction

Neuromuscular disorders, such as myasthenia gravis (MG), refer to all diseases that affect the nerves and muscles.[1] MG is a chronic autoimmune disease that develops at the junction of nerve and muscle at the postsynaptic level and impairs neuromuscular transmission, resulting in muscle weakness.[2] The cause of this disease is a decrease in the number of acetylcholine receptors accessible at the nerve and muscle junction, which occurs due to the attack of local antibodies.[3] The main feature of this disease is the weakness of the voluntary muscles,[4] especially after daily activity.[5] The initial complaint of patients is usually diplopia. Other clinical signs of the disease include difficulty swallowing (Dysphagia), chewing, and speaking, as well as ocular and pharyngeal weakness, and weakness of the proximal muscles of the limbs, which in some cases may lead to respiratory failure.[6] Today, MG is one of the most well-known neuromuscular diseases.[7]

The incidence of this disease in the world is 7.2 per 10000 people.[8] The prevalence of this disease in Iran has not been determine.[9] According to a report by Ebrahimi et al., the average annual incidence of this disease in Kerman Province, Iran, between 2009 and 2011 was estimated to be 5.9 per one million people.[10] MG is seen in all ages, from infancy to old age.[11] The incidence of this disease is higher in women than men and its ratio is 3:2.[8] The vast age distribution of this disease and the accompanying disability, which limits the functionality of the affected people, deprive the patient of activity for a period of 4-7 years.[12]

Over the past decade, with the rapid intervention of treatment and medicine, the quality of life (QOL) of patients has improved; however, the mortality rate of patients who are in a critical condition is still about 4%-8%.[13]

Unequal access to health services and low involvement of people in their health management are major threats to the sustainability of the health care system.[14] The best way for the reduction of medical costs and empowerment of community members is the prevention of chronic diseases and establishment of correct management of health measures.[15] Traditional healthcare technologies are limited to specific hospitals and treatment centers, which are often costly and not suitable for patient use and access.[16] Therefore, more effective technologies such as E-Health and M-Health are needed to help prevent and educate, reduce hospitalization, and ultimately, substitute for traditional technologies in critical conditions.[17]

The idea of a mobile platform for monitoring patients is a relatively brand-new concept that still needs to be evolved.[18] The popularity of the mobile phone is rapidly increasing in developing countries.[19,20] The tendency of people to have their cell phones everywhere has provided an excellent opportunity for the application of this technology in the field of health.[15] Over the last century there has been a rise in the prevalence of chronic diseases due to the increase in average human life expectancy; therefore, many patients require constant monitoring and medical supervision in order to ensure that their health conditions do not deteriorate and lead to emergency situations.[18]

The main life threatening events in MG are respiratory failure and dysphagia.[21] Consequently, MG can be a serious threat to people with respiratory failure.[22] Using mobile health technology, physicians will be able to monitor and be aware of their patient's condition at any time and place via cell phone.[23] Technology can be used as a tool to monitor symptoms, and hence, patients are given the opportunity to manage their chronic disease.[24]

Since the drugs used for MG have severe side effects and the condition of these patients can become critical in a short time, continuous monitoring seems necessary. The purpose of this study was to use M-Health technology for continuous monitoring of patients' symptoms, health status, and drug dose in order to improve QOL, and prevent possible emergencies and even death.

Materials and Methods

This study was conducted with an applied approach in the 3 stages of description, development, and evaluation. In the first stage, by forming a panel of experts including professors of health information technology (HIT) from the Faculty of Paramedical Sciences of Tehran University of Medical Sciences, Iran, and neurologists with a subspecialty fellowship degree in neuromuscular diseases nationwide, the information elements required for the application were extracted by studying and reviewing the National Myasthenia Gravis Disease Guideline and expert panel opinions. In addition, the capabilities of the application were identified through consultation with professors in the field of HIT and neurologists. Finally, a comprehensive checklist of information elements and capabilities was assembled.

Subsequently, a researcher-made questionnaire was prepared based on the checklist of the previous stage and was given to the neurologists for a survey to select and validate the chosen

information elements and capabilities of the application. The face validity of the questionnaire was confirmed based on the National Myasthenia Gravis Disease Guideline and the opinion of a number of neurologists.

This questionnaire was classified into two main axes. In addition, according to the content validity ratio (CVR) method, its scoring scale responses were determined to be necessary, useful but not necessary, and not necessary. The first axis of the questionnaire, including the necessary information elements for the application, was classified into the 6 sections of physician demographic information (10 questions), patient demographic information (30 questions), disease information (7 questions), medication information (7 questions), paraclinical information (27 questions), and symptoms and complaints (15 questions). The patient's demographic information was divided into the 3 sections of personal information, history, and lifestyle. The second axis of the questionnaire included the capabilities of the application (20 questions). An open-ended question was placed at the end of each section, so that the respondent could provide further information on the topic.

According to the CVR method, when we have 5 experts, each information element is confirmed if obtains at least CVR = 0.99. In our study, all elements obtained CVR = 1. Moreover, if a new data element was suggested by at least 40% of the participants in the open-ended question section of the questionnaire, the data element was used in the application. The study population included all neurologists in the country with a subspecialty fellowship in neuromuscular diseases, and experience and research in the field of MG. Due to the limited size of the population, sampling was not performed and all 5 physicians entered the study. The researcher-made questionnaire was provided to them in person. The obtained data were analyzed using descriptive statistics and frequency distribution report in SPSS software (version 16, SPSS Inc., Chicago, IL, USA).

In the second stage, first, the application was designed by drawing a logical and conceptual model, behavioral diagrams (use case, activity, and sequence), and a structural diagram (class) using Unified Modeling Language (UML) and Microsoft Visio Professional 2019 software. Then, the application was created bilingually (Persian and English) in two versions of patient and physician using Java in Android Studio software (version 4.1.1). Furthermore, MySQL database (version 8.0.22) was used to store and retrieve information.

In the third stage, after 1 week of use of the application by the physicians, the standard Questionnaire for User Interaction Satisfaction (QUIS) was distributed among them to evaluate the application. The validity of the QUIS has been confirmed in the study by Mehdizadeh et al.[25] and its reliability in another study by Mehdizadeh ($\alpha = 0.94$).[26] The QUIS contains 30 questions in 6 sections. The questions of the QUIS are scored on a 9-point Likert scale ranging from 0 to 9. A total QUIS score of 0-3, 3.1-6, and 6.1-9 suggests poor, medium, and high satisfaction, respectively.

Informed consent was obtained from all individuals participating in the study.

This research has been approved by the Research Ethics Committee of Tehran University of Medical Sciences (No.: IR.TUMS.SPH.REC.1399.290).

Results

The present study was conducted to design and create a mobile-based application for monitoring MG patients with the aim of increasing patients' QOL and facilitating patient-physician communication. This application was named MG to familiarize users with the name of this disease. First, the required data for this study were collected during a survey of relevant physicians, the results of which are presented in tables 1 and 2.

The results of the survey showed that all 96 information elements and 20 capabilities required for the application were approved by the neurologists with the maximum amount of CVR (CVR = 1) for use in designing and creating the application. In the next phase, the application was designed based on the results of the survey. For this purpose, 3 use case diagrams, 23 scenario tables, 18 sequence diagrams, 3 activity diagrams, and 1 class diagram were designed.

After being registered in the web panel by the admin, the physician and the patient will receive a specific username and password to enter the application. It is possible to change the language of the application on the login page. After installing and logging in, the physician will see the main page of the application. There are 4 sections at the bottom of this page: Home, Doctor Profile, Patient List, and About Us.

The physician can complete or edit the information by logging into his profile page. By entering the "Patients List" page, the physician can search any patient and see his/her profile.

Table 1. Identified capabilities for the Myasthenia Gravis (MG) application

Axis	Information elements with a CVR of 1
Physician demographic information	First name and last name
	Medical council code
	National code
	Specialty
	Hospital address
	Hospital telephone number
	Clinic schedule
	Office address
	Office telephone number
	Office schedule
Patient demographic information (individual)	First name and last name
	Father's name
	Date of birth
	Gender
	Weight
	Height
	Blood type
	National code
	Birth certificate No.
	Place of birth
	Marital status
	Employment status
	Pregnancy status (for women)
	Mobile No.
	Telephone No.
	Address
	Address and telephone No. in case of emergency
	Insurance type
	Insurance No.
	Attending physician's name
Patient demographic information (history)	Family history of MG
	History of other diseases
	History of hospitalization because of MG
	Date of onset of the disease (first diagnosis)
	Family relationship of parents
	Type of family relationship (first and second degree)
Patient demographic information (lifestyle)	Alcohol consumption
	Smoking
	Opioid drug consumption
	Consumption of other stimulants
Disease information	MG type (ocular, general, congenital)
	Antibody (positive, negative)
	Antibody type (AChR, MuSK)
	Thymus status (With or without tumor)
	Thymectomy status
	Thymus tumor stage
	Patient classification according to MGFA scale
Medication information	Names of medications used for MG
	Dosage of medications taken for MG
	Date of prescribing medications for MG
	Other medications
	Drugs to avoid or caution in MG
	MG medication side effects information
	Drugs interactions

Table 1. Identified capabilities for the Myasthenia Gravis (MG) application (continue)

Axis	Information elements with a CVR of 1
Paraclinical information	Daily breathing
	Pulmonary function test
	Maximal inspiratory pressure
	Maximal expiratory pressure
	FVC
	FEV
	FEV1/FVC ratio
	Complete blood count
	Mean corpuscular volume
	White blood cell
	Red blood cell
	Platelets
	Neutrophil
	CD19
	CD20
	Alanine aminotransferase
	Aspartate transaminase
	Alkaline phosphatase
	TSH
	T3
	T4
	Muscle specific tyrosine Kinase
	Acetylcholine receptor
	Single fiber electromyography
	Repetitive nerve stimulation
	Chest CT report
	Chest MRI report
Symptoms and complaints	MG-QOL15 questionnaire
	Shortness of breath during activity
	Shortness of breath while sitting
	Shortness of breath while lying down
	Dysphagia in fluids
	Dysphagia in solids
	Food stuck in the throat
	Leaking of food or fluids from the nose
	One-sided drooping eyelid
	Two-sided drooping eyelid
	Weakness of the upper muscles during activity
	Weakness of the upper muscles at rest
	Weakness of the lower muscles during activity
	Weakness of the lower muscles at rest
	Inability to control neck (sagging neck)

MG: Myasthenia gravis; FVC: Forced Vital Capacity; FEV: Forced Expiratory Volume; CVR: Content validity ratio; MG-QOL: Myasthenia Gravis-Quality of Life; MRI: Magnetic resonance imaging; CT: Computed tomography; TSH: Thyroid-stimulating hormone

On the "Patient Profile" page, 7 sections are provided to the physician: patient demographic information, disease information, medication information, paraclinical information, questionnaires, reports, and chat.

On the "Patient Demographic Information" page, 7 important items are completed and recorded by the physician and the rest by the patient himself. Disease information is also recorded by the physician after diagnosis and examination. The "Medication Information" page has 3 sections: MG medications, other medications, and history of prescribed medications. After the patient's appointment, the physician records the name, dose, and duration of the prescribed medications in the "MG Medications" section (Figure 1). Moreover, if the patient is taking other medications for various reasons, their names are registered by the physician in the section "Other Medications".

Table 2. Identified capabilities for the Myasthenia Gravis (MG) application

Features with a CVR of 1
Ability to record and change the type, dose, or timing of MG-related medication by the physician
Ability to register other medications used by the patient by the physician
Ability to adjust the reminder of medication use by the patient
Ability to schedule the next appointment by the patient
Ability to view the list of patients under treatment for each physician
Ability to search for any patient by the physician
Ability to analyze the answers of patient questionnaires and provide the final score
Ability to fill the MG-ADL and MG-Composite questionnaire by the physician during the patient visit
Ability to warn the physician when prescribing contraindications or caution in taking MG
Ability to save and display the date and time of registration of all data
Ability to provide educational content to patients
Ability to have patient-physician communication via chat (text only)
Ability to display patient questionnaire reports based on the total score of the questionnaire in the form of diagrams for the physician
Ability to display the report of physician questionnaires based on the total score of the questionnaire in the form of diagrams for the physician
Ability to display a comprehensive report of the selected paraclinical information in the form of tables for the physician
Medication reminder
Appointment reminder
Questionnaire completion reminder for the patient
Send an alert to the physician during an emergency via SMS
Receive the last location of the patient during an emergency situation and send it to the doctor through SMS

CVR: Content validity ratio; MG: Myasthenia gravis; MG-ADL: Myasthenia Gravis-Activities of Daily Living

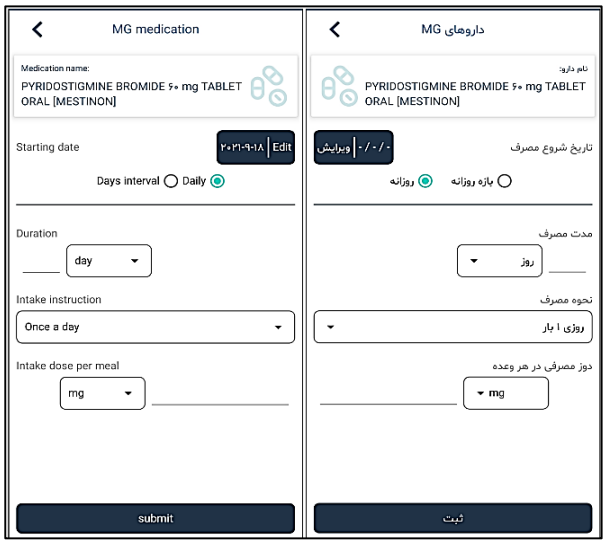

Figure 1. Myasthenia gravis (MG) medication page in the physician app

On the "Paraclinical Information" page, the physician can view the results of various tests that the patient has submitted in the form of file or photo, based on the type of report and its date. These tests include blood tests, repetitive nerve stimulation (RNS), Single-fiber electromyography (SFEMG), chest computed tomography (CT), and chest magnetic resonance imaging (MRI). The "Questionnaires" page presents two standard and valid MG disease questionnaires, Myasthenia Gravis Activities of Daily Living scale (MG-ADL) and Myasthenia Gravis Composite (MGC) scale, which are completed by the physician during the patient appointment.

The "Reports" page also consists of 3 sections: patient questionnaire reports, physician questionnaire reports, and a comprehensive report. Results are provided in the form of diagrams so that the course of the disease can be observed and examined by a physician.

The main page of the patient application contains a welcome message, date and time announcement, medication reminders, reminder for the next appointment, and the next date for questionnaire completion. There is also a hamburger menu on the left side of this page (Figure 2). This menu contains the following sections: patient demographic information, disease information, medication information, paraclinical information, the QOL-15 questionnaire, symptoms and complaints, appointment reminder setting, physician information, educational content, about us, and update.

On the "Patient Demographic Information" page, the patient can record and edit the necessary information, as well as view the information recorded by the physician. Disease information is

only visible to the patient. The medication information page has 3 sections: "Medication List", "List of Unallowed Medications" and "Medication Side Effects".

Figure 2. Burger menu in the patient app

On the "Paraclinical Information" page, there are 2 sections: "View Paraclinical Information" and "Send Reports File" (Figure 3). On the physician's information page, the patient can view all the information recorded by the physician, except their national code and medical council code.

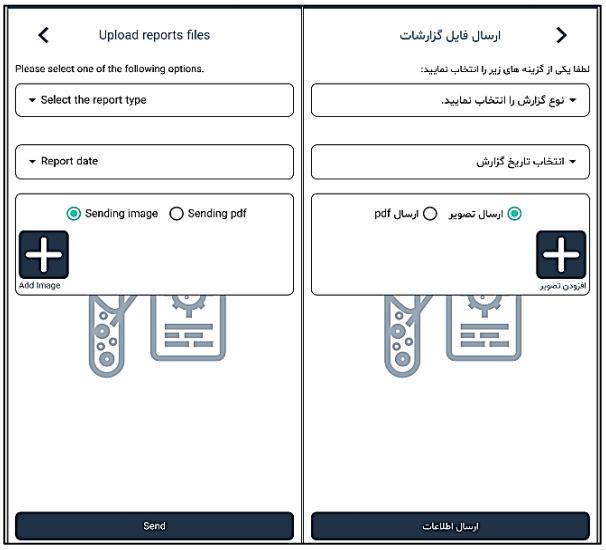

Figure 3. Upload reports file page in the patient app

In the "Visit Reminder Setting" section, the patient sets the reminder schedule by selecting the visit location, date, and time. According to the monthly reminder that the application sends to the patient, he/she completes the QOL-15 questionnaire and informs the treating physician of his/her condition. Some of the questions on the "Symptoms and Complaints" page have alerts, meaning, if the patient chooses yes, an SMS will be sent to their physician.

Ultimately, the MG application was evaluated with the participation of 5 neurologists, all of whom were men. The frequency of physicians in age groups was as follows: 4 physicians in the age group of 31-50 years and 1 physician in the age group of > 50. Furthermore, 1 physician had 1-5 years, 2 physicians had 6-10 years, and 2 physicians had > 10 years of work experience. After evaluation of the application by the neurologists, questionnaires were collected and analyzed, the results of which are presented in table 3.

Table 3. Results of physicians' usability and satisfaction assessment of the Myasthenia Gravis (MG) application

Phrase	Mean ± SD
Overall reactions to the application	8.50 ± 0.51
Screen	8.55 ± 0.25
Terminology and application information	8.00 ± 0.51
Learning	8.40 ± 0.59
Capabilities of the application	7.72 ± 0.48
Total score	8.23 ± 0.47

SD: Standard deviation

The average and standard deviation of the total scores obtained from the perspective of physicians were 8.23 and 0.47; this score is within the range of 6.1-9, which shows that the physicians evaluated the application at a good level. According to the results, the lowest average score was related to the "Capabilities of the application" section, the most important reason being the lack of suitability of the application design for different users. Moreover, the highest average score was related to the "Screen" section, which is due to the good and accurate design of the user interface and user experience, legibility of the letters, and the sequence of the screens.

Discussion

Analysis of the data obtained from the questionnaire to determine the information elements and capabilities of the program showed that, according to the point of view of the experts participating in the research, all items were considered necessary to design and create the application. The most important features of this program include alerting the physician when the patient is unwell, the possibility of sending a

message in the chat section, reminding the user of medication, and providing a variety of reports to monitor the patient's condition.

In a study, Shahin et al. examined the validity and reliability of the minimum data set for the multiple sclerosis (MS) registry.[27] This minimal data set included the 6 axes of patient demographic information, MS family history, diagnoses, disease course, disability status, and medications. The family history axis included family history and degree of family relationship. Symptoms' onset dates, date of diagnosis, type of MS, number of hospitalizations, medications used in the past 3 years, and start and end dates of medications were among the other items in this minimum data set.[27] In the present study, these information elements have been considered for MG disease.

In the study by Razazian et al., the results of the MS registry in Kermanshah, Iran, in 2019 were also reviewed.[28] In this system, factors such as age, sex, marital status, employment status, history of other diseases, family history of MS, and family history in terms of degree and type of MS could be recorded.[28] In the present study, all the above information elements have also been considered for MG disease, and thus, in this regard, it is consistent with the study by Razazian et al.[28]

Klumpp et al. designed and developed an application called "Apkinson" to monitor Parkinson's disease.[29] In the study by Klumpp et al., by analyzing the speech signal during a telephone call and using a specific speech test, efforts were made to determine the severity and progression of Parkinson's disease for the patient much more accurately than through regular examinations. The program included sections such as telephone call detection, telephone call recording, and signal analysis.[29] Although the study by Klumpp et al. differs from the present study in terms of utilization technique, it has dealt with the issue of disease monitoring.[29]

In another study, Fruhauf et al. used a 20-item usability and satisfaction questionnaire to evaluate the usability and satisfaction of the remote monitoring system for psoriasis patients.[30] The overall score obtained in this study showed that user satisfaction was higher than 83%.[30]

Conclusion

As mentioned above, MG has different clinical signs depending on the degree of muscle involvement. Symptoms gradually begin in the morning and increase at night.[31] Mobile health provides new opportunities for easy and thorough access to medical services, and can improve the current poor management of some diseases.[32] The result of this study was the designing and development of a mobile-based application for stability monitoring of MG patients, which was conducted with the aim of creating the necessary grounds for symptom control, continuous monitoring of MG patients, and effective patient-physician communication. Therefore, this application can be considered as a model for designing and creating similar programs for disease monitoring, treatment management, and patients' medication adherence control, with aim to increase QOL and reduce complications of the disease for patients.

Conflict of Interests

The authors declare no conflict of interest in this study.

Acknowledgments

This study was funded by the Iranian Center of Neurological Research (ICNR) affiliated to Tehran University of Medical Sciences under Grant number 1400-1-233-52759.

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