Effect of Self-Care Management Protocol on Outcomes of Patients with Mythenia Gravies Undergoing Plasma Exchange

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Abstract

Background: Plasma exchange (PE) is a highly efficient therapy for Myasthenic Gravies. Nurses are playing an energetic role in prevention, early recognition of complications and deliver appropriate care and educating patient how to manage self-care management of their treatment and decrease complications of plasma exchange. **Aim of the study:** was to evaluate the effect of self-care management protocol on outcomes of patients with Mythenia gravies undergoing plasma exchange. **Study design:** A quasi-experiment study design was used to conquer this aim. **Setting**: This study was conducted at the therapeutic plasma exchange room in the Hemodialysis unit in Ain Shams university Hospital affiliated to Ain Shams University. **Sample:** A Purposive sample of 60 patients with Myasthenia Gravies undergoing plasma exchange. **Tools of data collection:** Data were collected using four tools:1-Patients' with Mythenia gravies interview questionnaire, 2- Patients' with Mythenia gravies knowledge questionnaire related to plasma exchange, 3- Myasthenia Gravis Activities of Daily Living scale (MG-ADL) and 4- Complications checklist of plasma exchange. **Results:** This study illustrates a highly statistically significant difference between study and control groups regarding incidence of complications Post Implementation of Self-management protocol P <0.001. Also, displays a significant positive correlation between total satisfactory knowledge and incidence of complications as well as Mild daily living scale pre/post and follow up post implementation of Self-management protocol among both groups at p= <0.001. **Conclusion:** study resolved that there was an enhancement in knowledge, activities and outcomes of patients with Mythenia gravies undergoing plasma exchange after implementation of self-care management protocol. **Recommendation:** Accessibility of self-care management booklet in all settings of plasma exchange.

Keywords: Myasthenia Gravies, Outcomes, Plasma exchange, Self-care management.

Introduction

Myasthenia gravis (MG) is an autoimmune neural disorder considered by flawed transmission at the neuromuscular junction. The occurrence of the disease is 4.1 to 30 cases per million person-years, and the frequency rate ranges from 150 to 200 cases per million. MG is deliberated a classic example of antibody-interceded autoimmune disease. The main clinical manifestation of MG is fatigable muscle weakness, which may disturb ocular, bulbar, respiratory and limb muscles. Clinical manifestations vary according to the type of autoantibody, and whether a thymoma is existing **(Dresser et al., 2021).**

Myasthenia gravis (MG) is an incorrigible disease that necessitates proper self-management. Self-management is definite as the day-to-day managing of chronic conditions by people over the progression of an illness. Although self-management is often used interchangeably with terms such as self-care, self-directive, patient education, and patient counseling, self-management has changed beyond the practice of merely providing information and rising

patient knowledge **(Bartlett et al., 2020).**

Outcomes of patients with MG may be improved with some combination of medications, thymectomy, plasma exchange and other therapies which enable most patients with MG to lead normal or near-normal lives. Sometimes people experience remission. However, for some people daily activities is affected significantly - either by the severity of the disease or severity of side effects from the medication. Generally, those who are quickly diagnosed and receive effective treatment have the best outcomes **(Ali et al., 2022).**

Self-management is a likeable new phenomenon within healthcare but has established increased attention as an applicable management strategy for chronic health conditions; it is the philosophy that acknowledges neurological conditions, such as MS, as a permanent experience. Self-management emphases on providing the individual with the skills and capability to achieve their symptoms, monitor check medication regimens and physical disability, involve in physical activity, preserve nutritional status, and adapt to the psychological requires of their condition **(Hevey et al., 2020).**

Therapeutic plasma exchange (TPE) is a way of blood cleansing permitting to remove inflammatory mediators and antibodies by using extracorporeal circuit. The technique is used in a diversity of conditions, including autoimmune diseases as myasthenia. TPE is an invasive procedure, but when implemented by suitably trained and qualified staff, it is comparatively harmless. Life-threatening periods as shock (anaphylactic or septic), hypotension needing vasopressor drugs or bleeding are erratic. The peak frequent, but not extremely severe complications are urticaria, pruritus, hypocalcemia and slight hypovolemia. Adversative effects are accompanying more usually with the applying of fresh-frozen plasma (FFP) consumed as a substitution solution paralleled with human albumin solutions (**Wang et al., 2022).**

The responsibility of nurse is very essential and various in dealing with patients undergoing TPE, as the nurse must support the patient to obtain information, keep safety, and gain appropriate care inside the framework of nursing process. Also, the clinical responsibilities of the nurse contain compliance to quality guarantee criteria targeting to deliver great quality healthcare facilities **(Hamza et al., 2019).**

Patient education is a crucial component of all nurses' responsibilities that should be offered to patients about the vital principles of plasma exchange procedure. Uninterrupted patient's education will aid them overwhelmed the undesirable attributes of their treatment, allocate with their disease with readiness, actively take part in a plan of care and motivate the greatest level of rehabilitation. As well as, education courses may decline the psychological stress of the plasma exchange patients, raise their responsibility and their knowledge regarding the treatment of this restorative method and secure patient safety and the deliverance of suitable care **(Thompson et al., 2021).**

Significance of the study

Plasma exchange is habitually used as a saving therapy for peoples who are in state of crisis or acute exacerbation. The National Institution of Health (NIH) approximates up to 50–125 per million populations endure from autoimmune disease and that the occurrence is expanding **(Streeter, 2020).** The annual incidence of MG is about 30 new cases per million and about 15–20% of these patients will develop myasthenia gravis

crisis (MGC). As per the consensus of American Society for Apheresis **(Strasser, 2023).**

In Egypt, at Ain Shams university Hospital, there were about 1987 patients who were treated with Plasma Exchange therapy in 2023 and about 110 cases of them is diagnosed with MG. **(Statistical Information System. Ain Shams University, 2023).**

Plasma exchange (PE) is reflected first-track therapy for controlling of acute myasthenic crisis. In patients staging with acute MG, PE can recover symptoms quickly, containing respiratory function and disability. Many MG patients involve chronic long-term preservation PLEX in combination with medical management. At today, there is a dearth of data to specify which MG patients will have resolve of symptoms with PE and which will entail chronic conservation therapy. The major impartial of this study was to evaluate the effect of self-care management protocol on outcomes of patients with Mythenia gravies undergoing plasma exchange **(Dogra et al., 2020).**

Aim of the study

This study aimed to evaluate the effect of self-care management protocol on outcomes of patients with mythenia gravies undergoing plasma exchange through the following:

- Assessing level of knowledge of patients with mythenia gravies undergoing plasma exchange
- Assessing level of self-care activities of patients with mythenia gravies undergoing plasma exchange
- Develop and implement self-care management protocol for patients with mythenia gravies undergoing plasma exchange
- Evaluating the effect of self-care management protocol on outcomes of patients with mythenia gravies undergoing plasma exchange

Operational definition:

- Self-care management protocol: is handling with the chronic condition (symptoms, treatment, physical, psychological and related lifestyle modifications) in such a manner that the condition is optimally combined into one's life.
- Patient's outcomes: improving patient's with mythenia gravis undergoing plasma exchange therapy general condition regarding increasing activity of daily living, and the incidence of complications associated with plasma exchange therapy.

Research Hypothesis

H 1: Self-care management protocol will improve knowledge of patients with mythenia gravies undergoing plasma exchange.

H 2: Self-care management protocol will improve activities of patients with mythenia gravies undergoing plasma exchange.

H3: Self-care management protocol will improve outcomes of patients with mythenia gravies undergoing plasma exchange.

Subjects and Methods

A- Research design:

A quasi-experimental design pre/posttest for study and control groups was utilized in this study. It is used to appraise the effect of an intervention in the lack of randomization. The pre-test/post-test research proposal covers assessing significant after effects both before representing the sample to a stimulant of about kind and after exposure to the stimulant. By initiating experimentation in this direction, a researcher can worth

modification is focused outcomes to be wide-open to the stimulant **(Braddock, 2019).** The post-test permits the researchers to determine the direct effects of the treatment on the outcome variable(s). Added to the pre-test and immediate post-test, a delayed post-test(s) is often incorporated to study the treatment effects over the lengthier term (**Miller et al., 2020).**

B- Setting:

This study performed at the therapeutic plasma exchange room in the Hemodialysis unit in Ain Shams university Hospital affiliated to Ain Shams University. Therapeutic plasma exchange room involves six Fresenius plasma exchange apparatuses including two (Hepatitis C Virus) HCV apparatuses and one SICHUAN Nigale apparatus, six chairs for patients, one oxygen tube, emergency apparatus trolley, and Cardiopulmonary Resuscitation (CPR) equipment, three pulse oximeters, three blood pressure measurement appliances, two water basins, one refrigerator for plasma, weight, and height measuring gauge, six isolated curtains, and cupboard for all tools of unit.

C- Subject:

Purposive sample of 60 patients from total number of patients 110 with MS undergoing plasma exchange were enlisted in the present study using purposive sampling that was distributed by half through simple randomization for both study and control groups that met the choosy criteria encompassed in the study sample according to the criteria for choice. The sample size is decided according to the power analysis formulation as following:

$$n = \left(\frac{Z_{1-\alpha/2} + Z_{1-\beta}}{ES} \right)^2$$

Standard normal deviate for $\alpha = Z\alpha = 1.870$

Standard normal deviate for $\beta = Z\beta = 1.356$.

α = Standard normal deviate for $\alpha = 1.9600$.

$Z\beta$ = Standard normal deviate for $\beta = 0.8816$.

$B = (Z\alpha + Z\beta)2 = 7.8479$.

$C = (E/S\Delta)2 = 0.1111$.

$N = B/C = 59.6398$.

$n = (\frac{1.78+0.88}{0.1111})^2 = 59.8398 \approx 60$ patients

Regarding above formula the sample size prerequisite per group is 30 patients divided according simple randomization technique by using computer.

Inclusion criteria:

-Adult Patients from both genders diagnosed with mythania gravis.

-Patients undergoing plasma exchange and number of plasma exchange periods were not fewer than five.

- Not gotten the similar intervention from other researchers and health professionals and accept to join to this research.

Exclusion criteria:

-Patient with psychological and emotional drawback.

- Patient with MG who did not get TPE during hospitalization.

-Patients experience other immunological disease.

D-Tools of data collection

I. Patients' with Mythenia Gravies interview questionnaire:

It was planned by the researchers; it implicated the following two parts:

Part 1:Patient Socio demographic Data: This part was utilized to assess socio demographic data of the studied patients involving age, gender, marital

status, educational level, occupation, residence and living status.

Part 2:Patients' Health History: This part was utilized to assess patients' clinical data as present history (Onset of diagnosis, Type of MG, Primary symptoms, No. of myasthenic crisis episodes (Recurrence) and Primary method of diagnosis), Past history (Experiencing from any chronic disease, Trigger for myasthenic crisis, Plasma exchange for myasthenic crisis periods, Time since onset of procedure/previous months and Irregularities in results of the laboratory test before procedure , past medical and surgical history of the patients that was involving diagnosis, duration of disease, other combined disease, family history, surgical history and medications used.

II. Patients' with Mythenia Gravies knowledge questionnaire related to plasma exchange:

It was planned by the researchers after appraising related literatures **(Mohamed Hamed & Ali Ibrahim, 2021 and Hamza & Hassanein, 2019),** to assess Patients' learning needs regarding plasma exchange. It entails of 4 subgroups (Concept of plasma exchange (6 items), Method of performing plasma exchange (8 items), plasma exchange arrangements & techniques (6 items) and Difficulties after plasma exchange (10 items)). It composed 30 items. The correct answer for each item was (1) and incorrect answer was (0) with total score (30) grades. Total score characterized as, ≥ 80 % had satisfactory level of knowledge, while < 80 % had unsatisfactory level of knowledge.

III- Myasthenia Gravis Activities of Daily Living scale (MG-ADL).

MG-ADL an effort less eight-questions patient-reported scale standard scale adopted from (Wolfe et al., 1999) to measure MG symptoms and their effects on daily activities .It involves 8-items, with apiece response graded as 0 (normal), 1 (mild), 2 (moderate) and 3 (severe). Two questions point ocular, three oropharyngeal, one respiratory, and two extreme functions. The test–retest reliability coefficient was 93.7%, with a less 95% confidence interval at 87.3% **(Muppidi et al., 2011).**

A person's total score can range from 0 (normal) to 24 (most severe disability).

- Score ≤ 8 representing mild disability
- Score range from 9-16 representing moderate disability
- Score range from 17-24 representing severe disability

IV: Complications checklist of plasma exchange:

It was planned by the researchers and referenced from **(Ahmed &Elderiny, 2020 and Hamza et al., 2019)**, the tool filled through the plasma exchange session to observe the patient during the therapy and record the problems that occurred and estimate the reappearance of complications before and after implementation of self-care management protocol. This tool encloses22 complications of plasma exchange, items are categorized on a 4-point Likert scale shifting from (1) for never, (2) for rarely, (3) sometimes, and (4) for always, such as Fainting, Bleeding, Hypotension, Bruising or swelling at the needle insertion sites, Convulsions, Nausea ,Vomiting, Excessive itching or rash, Anaphylactic reactions, Fatigue/ tired, Hyperthermia, Arrhythmias, Abdominal pain, Shivering, Cramps, Dyspnea, Blurred vision, Drowsiness, Colic, Numbness around mouth and peripheral limbs, Feeling cold/hypothermia, and Joint pain.

Scoring system: The lower score for the tool was 22 and the bigger one was 88. The mean and standard deviations of all responds was determined and compared among the two groups of the study. The tool fulfilled throughout the plasma exchange session to inspect the patient during the therapy and note the complications that occurred.

Mythenia gravies plasma exchange self-care management protocol booklet

Developed by the researchers and written in Arabic language directed by images, centered on the assessment of patients' knowledge regarding plasma exchange, in addition to revise the latest and associated literature **(Ahmed &Elderiny 2020 and Mohamed Hamed & Ali Ibrahim 2021).**The booklet was administered for every patient; it was covered of three parts as follow: Part (1).Introduction about Mythenia Gravies, definition, reasons, factors that exaggerate signs & symptoms, complexities and management. Part (2). Patient knowledge about plasma exchange, description, performance mechanism, staying on the machine, arrangements, possible hazards and side effects, what patient can be acted before, throughout and after procedure, sense after exchange, period of exchange session and number of sessions. Part (3). Self-care practices for patients concerning medication, methods to relieve fatigue, diet and vitamins, exercises and life style adaptation to increase activity of daily living.

Mythenia gravies plasma exchange self-care management protocol booklet was reviewed by five experts, three professors of Medical-Surgical Nursing in addition to two professors of Nephrology and Immunology, at Ain Shams University for content validity. Based on the judgment of a panel of expertise, certain adjustments were performed, and then the ultimate model was developed.

Tools validity and reliability

Validity: evaluating face and content validity of the recommended tools throughout a jury of seven experts five professors of Medical-Surgical Nursing in addition to two assistant professors from Faculty of Nursing, Ain Shams University, who revised the instrument, for clearness, significance, inclusiveness, comprehension, and easiness for application, no changes were requisite.

Reliability: Alpha Cronbach test was utilized to determine the internal consistency of the study tools. Patients' with mythenia gravis knowledge questionnaire regarding plasma exchange were reliable at (0.92), MG-ADL was reliable at (93.7). Complications checklist of plasma exchange was reliable at (0.94).

Preparatory phase:

Administrative design: The necessitated official approvals were obtained from the administrators of the Ain Shams University Hospital.

Ethical considerations

The researchers got the required approval of the Ethical Research Committee, Faculty of Nursing, Ain Shams University (Study No.2403248). An authorized letter was released from the Faculty of Nursing, Ain Shams University to the study setting to achieve their consent to assemble essential data. An authorized approval was gotten from the managers and header of the department of the nominated hospital setting after clarification of the aim of the study. So as to protect patients' claims in the ambit of the study, before the primary interview, consent was confined from each patient after being familiar about the

character, purpose, and profits of the study. Patients were also alert of that partaking is totally voluntary and might pull out at any time without free handed reasons. Privacy and anonymity of the data was assured by proving that the personal information will be retained private after being incorporated with the researchers and assured patients that the data would be utilized only for the research purpose. Furthermore, the intercession used in the existing study is risk-free and harmless to participants.

Pilot Study:

As soon as approval was permitted to continue with the proposed study, a pilot study was conducted before beginning data collection on six of directed patients (10% of sample) from the previously mentioned setting according to the inclusion criteria and excluded from the main sample to determine viability, the clearness, applicability of the tools, and estimate the time required to gather data to identify any possible hindrances that might suffer the researchers and limit with data collection.

I- Implementation phase

Field work: The study was conducted from the beginning of January 2024 to July 2024, involving the development of the tools. It was centered on revising recent and applicable literature as regard Mythenia gravis, plasma exchange and self-care management. The researchers were visiting Medicine unit (No.6) in immunology department and therapeutic plasma exchange room in the Hemodialysis unit around five days/week for six months from 9.00 am to 2.00 pm. The aim of the study was harmlessly simplified to patients who consented to participate in the study preceding data collection. Data collection was done by the researchers use up the same tools for the same patients who accomplished inclusion criteria; before and after implementation of self-care management (3-4 sessions and 6-9 sessions of plasma exchange).The baseline assessment: The first time; the participants besides working health care staff were assembled by the researchers to simplify the aim and work plan of the study to achieve their collaboration, and attain consent from the partakers. The researchers acquired approval to fulfill the study from both faculties of nursing and the settings' managers.

Tools were planned and assessed through piloting and checked for validity and reliability. Then tools were translated into Arabic and tested again for validity and reliability. Personalized interview session was presented to each participant by the researchers to assemble Patients' with mythenia gravies interview questionnaire, patients' with mythenia gravies knowledge questionnaire related to plasma exchange, and MG-ADL scale throughout pre-plasma exchange phase. Constructed on patients' level of knowledge, the researchers established a self-care management booklet in Arabic language utilizing the applicable literature **(Ahmed &Elderiny 2020 and Mohamed Hamed & Ali Ibrahim 2021).** Complications checklist of plasma exchange tool was full up for the provost phase by observing the participants to recognize the incidence of complications accompanying with plasma exchange procedure during and after the session of plasma exchange that persisted naturally from 2 to 3 hours for both groups underneath the study. Participants grabbed their time to relax after beginning of the plasma exchange therapeutic session, afterward took one-hour self-care management educational session. Instructions contained in the educational session were elucidated by the researchers to the study group and

their caregivers go along with figures and videos about technique of plasma exchange, patient preparation, complications that may rise, examples of self-care protocol regarding how to deal with severe complications and methods of prevention, next feedback was gotten by the researchers throughout the prearranged hour.

Self-care management protocol for patients with mythenia gravies undergoing plasma exchange implementation was carried out at Medicine unit (No.6) in immunology department and therapeutic plasma exchange room in the Hemodialysis unit affiliated to Ain Shams University Hospital over five days for every five to six patients, conferring to their level of education and understanding. The study subjects were categorized into small groups; each one consisted of 3 – 4 patients per each training session. The handout was distributed to all patients included in the self-care management protocol. The researchers demonstrated the components of the self-care management protocol to the patient through sessions. Each session takes 25-40 minutes; the total sessions were 2 to 3 theoretical sessions for each patient's group and 1 to 2 practical sessions for each patient's group and it was conducted through small group discussion, role play by researchers as to act how they figure the occurrence of PE complications, and demonstration for how to prevent or recover of these accompanied complications and thus improve their outcomes, supported by using posters and booklet guided by guidelines recommended by The American Society for Apheresis (ASFA) for therapeutic plasma exchange **(ConnellySmith et al., 2023).**

II- Evaluation phase:

The researchers evaluated the effect of self-care management protocol after implementation by matching the results pre implementation, post and follow-up to evaluate the mean differences in occurrence of complications among patients undergoing plasma exchange procedure, the 2nd measurement (post Self-care management) after 3-4 sessions after plasma exchange by using the same data collection tools for both groups; Patients' with mythenia gravies interview questionnaire, Patients' with mythenia gravies knowledge questionnaire related to plasma exchange, MG-ADL scale and complications checklist of plasma exchange after the first intervention then the 3rd measurement (follow-up Self-care management) after 6-9 sessions of plasma exchange, the participants were assessed for the second time to escalate the difference in the incidence of complications after implementation of self-care management protocol to give possibility for participants at the study group to implement all the clarified information for a whereas to diminish the frequency of complications.

The participants were evaluated through assessment of their outcomes before and after the plasma exchange sessions (Data collection tools), and observed during receiving plasma exchange therapy for their general condition regarding increasing activity of daily living, and the incidence of complications associated with plasma exchange therapy. After accomplishment of data collection, all participants in control group as well as have received a copy from the self-care management protocol. Sever complicated patients were observed and followed up by a specialist.

III- Statistical Design:

Statistical Package for Social Science (SPSS) version 20 was utilized. Data

were obtainable using descriptive statistics in the form of frequencies and percentages. The chi-square test was used to recognize the relationship between qualitative variables and Mean ± SD also was used. Statistical significance was considered at p-value≤ 0.05, and < 0.001 was considered highly significant. r-test was utilized as an inferential statistic was used to explore the correlation between patients' satisfactory knowledge and Mild daily living scale level with complications of plasma exchange in the study and control groups pre- and post-implementation of self-care management protocol.

Results

Table 1: Displays the mean age for study group and control group was (39.7± 12.3, 36.9± 15.6) years old respectively, females more proportion (80 %, 66.6%) in both study and control group respectively, also 66.6%, 73.3% of participants were married in both groups respectively. regarding education level, primary and secondary education were dominant in study group (33.4%), while secondary education was the highest in control group (40.0%) correspondingly, and 83.3%, 66.7% of both groups respectively are working, and their work need manual or heavy work with percentage of (80%, 75%) in the study and control group respectively. In addition, the farthermost of both groups were living in rural areas (74.3.0%, 66.7%).

Table 2: Shows the mean of MG onset of diagnosis was (6.6±4.2, 6.1±3.8) in both groups respectively and the most common type was ocular MG in both groups (73.3%, 66.7%) accordingly. The primary symptoms were distributed as the highest percentage was ocular symptoms and neck weakness (26.7%, 23.3%) in study group and (23.3%, 26.7%) in control group, and the mean of MG crisis

recurrence was (6.2±1.8, 5.8±1.4) in both groups, also the primary method of diagnosis in both groups was clinical exam. Also, it shown the highest triggers for myasthenic crisis were Immunotherapies Medication non-adherence, and Checkpoint inhibitors in the study group (100%. 93.3%), while in control group were (93.3%, 83.3%). The table shows the mean of plasmapheresis session was (10.2±2.0, 9.4±2.5) in both groups relatively. Abnormalities in laboratory tests before the procedure showed that anemia &hyponatremia is the prevalent abnormalities in the study group (80%, 80%) and in control group (90% & 90%), regarding past history 50%, 46.7% suffering of HF in both groups. Also, it's found a high significant relation at P <0.001 in MG type, triggering factors, and labs abnormalities among both groups.

Figure (1). Clarifies that 70%, 60 % of the control group have surgical history and family history respectively, while 60%, 65% of the study group have surgical history and smoking history respectively.

Table (3). Indicates significant improvement in mean and standard deviations in patients' knowledge about plasma exchange in post and follow-up implementation of self-management protocol in the study group (**13.9 ± 6.6&21.5 ± 5.8 respectively)** compared to pre – test(2.7±1.3). Also, it shows a high significant difference between pre and post/ follow up tests in the study group at P <0.001.

Table (4). Indicates significant improvement in the study group mean and standard deviation of Daily Living scale in post and follow-up implementation of self-management protocol in the study group (**10.6 ± 1.4 & 20.7 ± 2.3 respectively)** compared to pre – test**(4.7 ± 1.3).** Also it shows a high significant difference between pre and post/ follow up tests in the study group at P <0.001.

Table (5). Indicates a significant improvement in the mean and standard deviations of the study group according occurrence of complications Post Implementation of Self-management protocol. Also it shows a high significant difference between the study group and control group at P <0.001.

Table (6) Shows a significant positive correlation between total satisfactory knowledge and occurrence of complications pre/post and follow up implementation of Self-management protocol among both groups at p= <0.001.

Table (7) Presents a significant positive correlation between total satisfactory knowledge and Mild daily living scale pre/post and follow up implementation of Self-management protocol among both groups at p= <0.001.

Table 1: Frequencies and percentages distributions of patients related to socio-demographic characteristics among study and control groups (n=60) (30/each group)

Items	Studied Patients (n=60)			
	Study Group (30)		Control Group (30)	
	No	%	No	%
Age				
•20 ≤40	15	50%	12	40%
•40≤ 50	10	33.3%	10	33.3%
•+50	5	16.7%	8	26.7%
Mean ± SD	**39.7± 12.3**		**36.9± 15.6**	
Gender				
•Female	24	80%	20	66.6%
•Male	6	20%	10	33.4%
Marital status				
•Single	10	33.4%	8	26.7
•Married	20	66.6%	22	73.3
Educational level				
•Read and write	5	16.7%	6	20%
• Primary	10	33.3%	10	33.4%
•Secondary	10	33.3%	12	40%
•University	5	16.7%	2	6.6%
Occupation				
•Not work	5	16.7%	10	33.3%
•Work	25	83.3%	20	66.7%
Type of working	N=25		N=	
•Employee	5	20%	20	25%
•Manual/Heavy work	20	80%	5 15	75%
Residence				
•Urban	5	16.7%	10	33.4%
•Rural	25	74.3%	20	66.6%
Living Status				
•Alone	10	33.4%	10	33.4%
•With Family	20	66.6%	20	66.6%

Table 2: Health history frequencies and percentages among study and control groups (n=60) (30/each)

Items	Studied Patients (n=60)			
	Study Group (30)		Control Group(30)	
	No	%	No	%
Onset of diagnosis				
• 1<3 years	10	33.4%	12	40%
• 3<6 years	15	50%	15	50%
• ≥6 years	5	16.6%	3	10%
Mean ± SD	**6.6±4.2**		**6.1±3.8**	
Type of MG				
• Ocular MG	22	73.3%	20	66.7%
• Generalized MG	8	26.7%	10	33.3%
Primary symptoms*				
• Ocular (Eyelid droop, Double vision)	8	26.7%	7	23.3%
• Facial expression	5	16.7%	5	16.7%
• Upper extremity weakness	5	16.7%	6	20%
• Lower extremity weakness	5	16.7%	4	13.3%
• Neck weakness	7	23.3%	8	26.7%
No. of myasthenic crisis episodes (Recurrence)				
• < 4times/month	10	33.3%	12	40%
• >4times/month	20	66.7%	18	60%
Mean ± SD	**6.2±1.8**		**5.8±1.4**	
Primary method of diagnosis*				
• Serology	24	80%	20	66.7%
• Clinical exam	30	100%	30	100%
Triggers for myasthenic crisis*				
• Infection	20	66.7%	24	80%
• Changes in myasthenia treatment regimen	24	80%	21	70%
• Immunotherapies Checkpoint inhibitors (ipilimumab, nivolumab)	28	93.3%	25	83.3%
• Contraindicated medication	19	63.3%	16	53.3%
• Post-operative state	21	70%%	23	76.7%
• Medication non-adherence	30	100%	28	93.3%
Plasmapheresis sessions				
• ≤ 5	0	0	5	16.7%
• ≥ 6	30	100%	25	83.3%
Mean ± SD	**10.2±2.0**		**9.4±2.5**	
Abnormalities in laboratory test before procedure*				
• Anemia	24	80%	27	90%
• Leukocytopenia	19	63.3%	23	76.7%
• Hypokalemia	20	66.7%	18	60%
• Hyponatremia	24	80%	27	90%
• Hypocalcemia	16	53.3%	11	36.7%
Past history				
• COPD • HF • Others (asthma, anemia, DVT, malignancy, OSA)	5 15 10	16.7% 50% 33.3%	5 14 11	16.7% 46.7% 36.6%

***Answers are not mutually exclusive**

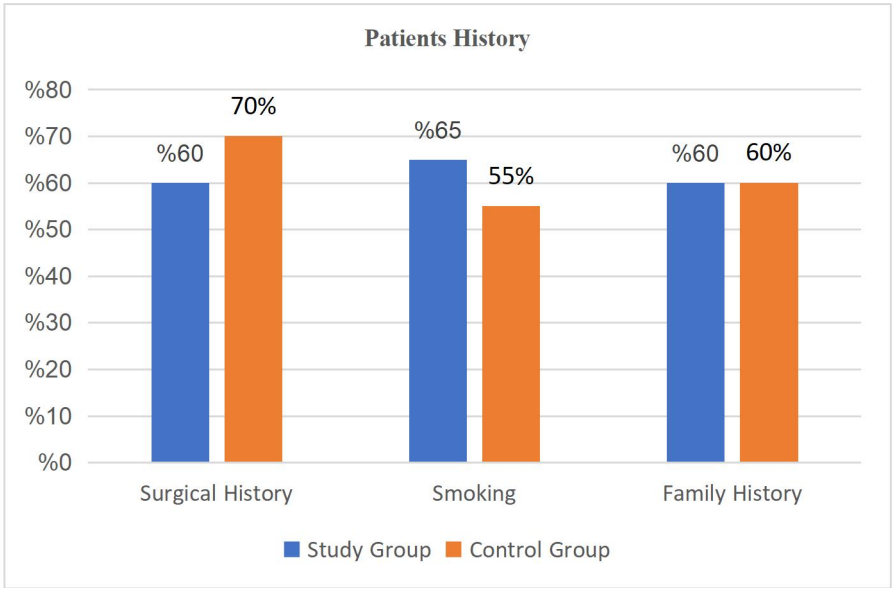

Figure 1: Percentage distributions of patients' history among study and control groups

Table 3: Comparison of Satisfactory Knowledge about plasma exchange Pre/post and Follow up Implementation of self-management protocol among both groups (n=60).

Items	Study Group (n=30)			Control group (n=30)		
	Pre	**Post**	**Follow-up**	**Pre**	**Post**	**Follow-up**
Concept of plasma exchange	4 (13.3%)	20 (66.6%)	25 (83.3%)	2 (6.6%)	4 (13.3%)	5 (16.6%)
Mechanism of performing plasma exchange	0	15 (50%)	25 (83.3%)	0	0	0
Complications after plasma exchange	2 (6.6%)	20 (66.6%)	23 (76.6%)	2 (6.6%)	4 (13.3%)	6 (20%)
Plasma exchange guidelines	0	20 (66.6%)	27 (90%)	0	0	0
$\overline{X}$ ± SD	**2.7±1.3**	**13.9 ± 6.6**	**21.5 ± 5.8**	**1.1±0.9**	**2.4 ± 1.6**	**3.3 ± 2.7**
T1-pvalue/ Study group (pre & post-tests)			6.441	<0.001**		
T2-pvalue/ Study group (post & follow- up tests)			6.582	<0.001**		
T3-pvalue/ Control group (pre & post-tests)			1.088	0.278		
T4-pvalue/ Control group (post & follow-up tests)			1.043	0.324		

* P < 0.05 (Significant)**P <0.001(Highly Significant)

Table 4: Comparison of Patients Daily Living scale Pre/post and Follow up Implementation of self-management protocol among both groups (n=60).

Items	Studied patients (n=60)					
	Study Group(30)			Control group(30)		
	Pre	Post	Follow- up	Pre	Post	Follow-up
Mild Disability	5 (16.6%)	12 (40%)	23 (76.7%)	5 (16.6%)	4 (13.3%)	0
Moderate Disability	11 (36.6%)	8 (26.7%)	2 (6.6%)	10 (33.3%)	10 (33.3%)	10 (33.3%)
Severe Disability	14 (46.7%)	10 (33.3%)	5 (16.6%)	15 (50%)	16 (53.3%)	20 (66.6%)
$\overline{X}$ ± SD	**3.7 ± 1.4**	**4.1.6 ± 10**	**3.2.7 ± 20**	**1.9 ± 2.1**	**2.4 ± 1.6**	**0.1 ± 0.1**
T1-pvalue/ Study group (pre & post-tests)			4.654	<0.001**		
T2-pvalue/ Study group (post & follow- up tests)			5.989	<0.001**		
T3-pvalue/ Control group (pre & post-tests)			2.046	0.467		
T4-pvalue/ Control group (post & follow- up tests)			4.076	0.298		

* P < 0.05 (Significant)**P <0.001(Highly Significant)

Table5: Comparison of Mean and standard deviations of both groups according occurrence of the complications Post Implementation of Self-management protocol (n=60).

Complications	Total patients n=60		T-test	P-value
	Study (n=30)	Control (n= 30)		
	X±SD	X±SD		
Fainting	9.9±2.9	21.7±6.0	7.442	<0.001**
Bleeding	11.8±2.0	18.2±2.9	6.453	<0.001**
Hypotension	15.3±4.3	26.6±3.1	4.365	<0.001**
Needle bruises/ swelling at needle insertion sites	12.1±2.3	25.9±2.8	5.321	<0.001**
Convulsions	10.4±2.1	26.9±1.1	4.311	<0.001**
Nausea	11.8±2.6	24.6±2.6	5.232	<0.001**
Vomiting	11.2±1.2	23.4±3.0	4.733	<0.001**
Excessive itching/ rash	14.8±2.2	22.1±4.4	4.273	<0.001**
Anaphylactic reactions	9.7±2.3	18.1±5.5	7.356	<0.001**
Fatigue and tired	12.1±3.4	21.7±6.0	6.516	<0.001**
Hyperthermia	11.3±2.9	18.6±2.6	6.472	<0.001**
Arrhythmias	9.8±4.2	19.0±5.3	7.553	<0.001**
Abdominal pain	10.2±3.4	24.6±2.9	6.312	<0.001**
Shivering	15.8±3.5	27.4±1.3	8.432	<0.001**
Cramps	14.2±2.1	21.5±6.4	8.743	<0.001**
Dyspnea	11.6±3.5	23.6±4.5	5.262	<0.001**
Blurring of vision	11.7±2.3	21.8±6.3	6.321	<0.001**
Drowsiness	11.1±1.6	20.3±5.6	4.536	<0.001**
Colic	9.8±2.9	22.0±1.2	8.464	<0.001**
Numbness of limbs & around mouth	11.4±2.0	24.7±2.4	4.413	<0.001**
Feeling cold/ Hypothermia	13.5±2.4	25.3±3.3	7.565	<0.001**
Joint pain	12.3±1.7	22.6±3.8	5.432	<0.001**

**P <0.001(Highly Significant)

Table 6: Correlation between patients Total satisfactory knowledge and complications Post Implementation of Self-management protocol among both groups (n=30).

Items	r p-value	Total level of satisfactory knowledge (n=60)			
		Study Group(n=30)		Control Group(n=30)	
		Pre/Post	Post/ Follow-up	Pre/Post	Post/Follow-up
Occurrence of complications	r	0.714	0.895	0.544	0.565
	p-value	<0.001**	<0.001**	0.342	0.547

**P <0.001(Highly Significant)

Table 7: Correlation between patients Total satisfactory knowledge and Mild daily living scale Post Implementation of Self-management protocol among both groups (n=30).

Items	r p-value	Total level of satisfactory knowledge (n=60)			
		Study Group(n=30)		Control Group(n=30)	
		Pre/Post	Post/ Follow-up	Pre/Post	Post/Follow-up
Mild DLS	r	0.594	0.689	0.398	0.402
	p-value	<0.001**	<0.001**	0.342	0.547

**P <0.001(Highly Significant)

Discussion

Myasthenia Gravis is a rare chronic disease caused by a person's antibodies attacking healthy tissue in the body. Plasma exchange may work by inducing immune regulation **(Chen et al., 2024).** PE can help relieve MG symptoms, such as muscle weakness, balance problems, and difficulty breathing, by filtering the antibodies that are causing the autoimmune response from the plasma. Plasma Exchange is recommended for people with moderately severe MG symptoms, as well as for people who cannot tolerate immunosuppressant's **(Ipe et al., 2021).**

The characteristics of the study samples displays that half of both groups (study & control) at 40 years old, and more than two thirds were married females in both groups. This results in the same line with **Dresseret al, (2021)** who study titled "Myasthenia Gravis: Epidemiology, Pathophysiology and Clinical Manifestations", and concluded that most participants were females and significantly more females in age categories under 65 years, but for the 65 + years category there were more males. Also it's revealed by **Howard, (2023)** who study "Clinical overview of MG" that women are more affected by MG than men, with a 3:1 sex ratio prior to 40 years of age. However, as the population ages, men are increasingly more affected after age 50, resulting in closer to a 1:1 sex ratio at advanced ages. This might be due to that, stress, viral infections, pregnancy, and childbirth trigger the development of MG, contributing to the middle-age sex disparities.

Regarding educational level, primary and secondary levels were dominant in both groups correspondingly

and only one third of both groups are working in heavy and manual careers. These results are same reported by **Sansoni et al., (2023)** who study titled "Clinical features, treatments, their impact, and quality of life for Myasthenia Gravis patients in Australia" Reflecting the sample's age nearly half of participants were retired, but only one third was still working full-time or part-time. For those working needed to take time off work due to MG; for those that were unemployed, retired or with disability indicated ceasing work. In addition, more than two thirds of both groups were living in rural areas this may explained by lack of specialized health settings which results in no follow-ups and low awareness levels.

These results congruent with **Restivo et al., (2020)** who studied "Myasthenia Gravis Associated with SARS-CoV-2 Infection" and found that gender is a deciding epidemiological risk factor for the development of autoimmune diseases, given that the immune system is subject to sexual dimorphism. Many autoimmune diseases, including myasthenia gravis, are more common in females than in males.

In the same context **Erika et al., (2020)** who stated in a study titled "Employment in Myasthenia Gravis" that, as a chronic disease, MG has a severe impact on patients' lives and their socioeconomic status. The loss of productivity, premature retirement, or job loss can cause relevant problems both on outcomes of the diseases and employment status.

The study showed the mean of MG onset of diagnosis was around 6.5yrs in both groups this result in disagreement with **Ahmed & Elderiny (2020)** who found in a study titled "Effect of Educational Package on Complications Associated with Plasmapheresis among Patients with Autoimmune Disorders" the mean number of plasmapheresis sessions was 7.1±1.3, and 7.2±1.1 in the study and control groups.

The study revealed the most common type was ocular MG in both groups, and the primary symptoms were distributed as the highest percentage was ocular symptoms and neck weakness this is accordance with **Ali et al., (2022)** who stated in as study titled "Outcomes and characteristics of myasthenia gravis" that most common initial presentation was ocular weakness, and concluded that, most patients with ocular and bulbar presentation developed generalized weakness during the follow up period.

The study revealed that more than two thirds of both groups are suffering of high episodes of MG crisis. This result is different according to **Chien et al., (2023)** in his study about "Myasthenia gravis and independent risk factors for recurrent infection" who stated that approximately 10% to 20% of patients with myasthenia gravis (MG) have experienced myasthenic crisis (MC), which contributes to morbidity and mortality.

Also, it has shown the highest triggers for myasthenic crisis were Immunotherapies Medication non-adherence, and Checkpoint inhibitors in the study group.These results disagreed with **Kassardjian et al., (2020)** who found in a study titled "Serious infections in patients with myasthenia gravis" MG crisis triggered by infection which associated with poor outcomes.

Regarding Abnormalities in laboratory tests before the procedure showed that anemia & hyponatremia is the prevalent abnormalities on the contrary the study of **Ahmed &Elderiny (2020)** showed the abnormalities in results of the laboratory test before the procedure was hyponatremia which was

the prevalent abnormality in two-thirds of the study group, followed by hypocalcemia and leukocytopenia. These results could be related to the nature of diseases that required recurrent treatments with a close time interval to get rid of the body from toxins, and also lead to a reduction of some electrolytes and blood cells result from the use of replacement fluids.

The current study found that half of the patients complain of cardiovascular disease. These findings are in agreement with **Nelke et al (2022)** who reported in a study titled "Independent Risk Factors for Myasthenic Crisis and Disease Exacerbation" that myasthenia gravis is well known to be associated with comorbidities, with hypertension and other cardiovascular diseases representing the most common category, while pulmonary diseases represent a smaller portion.

The present study indicates that there was significant improvement in mean and standard deviations in patients' knowledge about plasma exchange in post and follow-up implementation of self-management protocol in the study group this is may be due to work overload and lack of nurses' time to give health education to every patient. This is supported by study done by **Hamza, et al (2019)** about Effect of Applying Guideline for Patients Undergoing Plasmapheresis Outcomes at Mansoura University Hospital and revealed that two third of studied patients had poor knowledge about their disease, plasmapheresis procedure and its side effect, complications and guidelines.

This study revealed that there was significant improvement in the study group mean and standard deviation of Daily Living scale in post and follow-up implementation of self-management protocol in the study group compared to pre implementation of self-management protocol in the study group. This is may be due to improvement of patients, knowledge after implementation of self-management protocol leads to improvement in physical functions and daily living activities. This was congruent with **Ahmed et al., (2022)** in a study titled Needs Assessment for Patients Undergoing Plasmapheresis: Suggested Guidelines and revealed that more than one third of patients were partially physically dependent and about one third of them were minimally physically dependent and effect on performance of activity of daily living (ADLs). And in the same line with **Hamed & Ibrahim (2021)** in a study titled Effect of Self- Care Management Strategy on Self- Efficacy for Patients with Myasthenia Gravis and illustrated that there was decreased in total mean score of myasthenia gravis activity daily living with statistical significance after one month and after three months of self-care management strategy implementation. Which indicate an improvement in myasthenia gravis symptoms after implementing self –care management strategy.

The results of the present study showed that there was a significant improvement in the mean and standard deviations of the study group according occurrence of complications Post Implementation of Self-management protocol. This is may be due to improvement of patients' knowledge after implementation of self-management protocol which describe the early detections and avoidance of complications. This was in the same line with **Ahmed &Elderiny (2020)** in a study titled Effect of Educational Package on Complications Associated with Plasmapheresis among Patients with Autoimmune Disorders" and revealed that there was a statistically significant decline in report of the plasmapheresis

associated complications after implementing the educational package in the study group compared to the control group.

Conclusion

The current study resolved and concluded that there was an enhancement in knowledge, activities and outcomes of patients with Mythenia Gravies undergoing plasma exchange after implementation of self-care management protocol.

Recommendations

Based on the finding of the present study, the researchers recommended the following:

- Accessibility of self-care management booklet in all settings of plasma exchange.
- Replication of the present study on larger sample is recommended to achieve generalizability.
- Developing and implementing training program for patient with Myasthenia Gravis to improve their outcomes.

References

Ahmed H, Mohamed H, Abd-Elsalam Sh. (2022). Needs Assessment for Patients UndergoingPlasmapheresis: Suggested Guidelines.Egyptian Journal of Health Care, EJHCVol 13. No.4. PP 65-79.

Ahmed. S & Elderiny. S. (2020). Effect of Educational Package on Complications Associated with Plasmapheresis among Patients with Autoimmune Disorders. Egyptian Journal of Health Care, EJH Vol. 11 No. 3. PP 878-891.

Ali, A., Almalki, D., Kotb, M. A., &Alenazi, R. S. (2022). Outcomes and characteristics of myasthenia gravis: A 10-year retrospective cross-sectional study at King FahadMedical City. Neurosciences (Riyadh, Saudi Arabia), 27(4), 237–243. https://doi.org/10.17712/nsj.2022.4.20220038.

Bartlett, S. J., Lambert, S. D., McCusker, J., Yaffe, M., de Raad, M., Belzile, E., ...&Lyddiatt, A. (2020). Self-management across chronic diseases: targeting education and support needs. *Patient education and counseling*, *103*(2), 398-404.

Braddock, K. (2019). A brief primer on experimental and quasi-experimental methods in the study of terrorism.International Centre for Counter-Terrorism. URL: https://icct.nl/wp-content/uploads/2019/01/ICCTBraddock-Brief-Primer-on-Experimental-Methods-Studyof-Terrorism-January2019.pdf

Chen, J., Feng, L., Li, S., Wang, H., Huang, X., Shen, C., & Feng, H. (2024). Therapeutic Plasma Exchange in AChR-Ab Positive Generalized Myasthenia Gravis: A Real-World Study About Its Early Response. Journal of inflammation research, 17, 2299–2308. https://doi.org/10.2147/JIR.S455104

Chien, C. Y., Chang, C. W., Liao, M. F., Chu, C. C., Ro, L. S., Wu, Y. R., Chang, K. H., Chen, C. M., & Kuo, H. C. (2023). Myasthenia gravis and independent risk factors for recurrent infection: a retrospective cohort study. BMC neurology, 23(1), 255.https://doi.org/10.1186/s12883-023-03306-3.

Connelly-Smith, L., Alquist, C. R., Aqui, N. A., Hofmann, J. C., Klingel, R., Onwuemene, O. A., ... & Dunbar, N. M. (2023). Guidelines on the Use of therapeutic apheresis in clinical practice–Evidence-Based approach from the Writing Committee of the American Society for Apheresis: The Ninth Special Issue. *Journal of clinical apheresis*, *38*(2), 77-278.

Dogra, A., Rana, K., Rathod, C., & Prakash, S. (2020). Outcome of therapeutic plasma exchange in Myasthenia gravis patients. Journal of Family Medicine and Primary Care, 9(12), 5971-5975.

Dresser L, Wlodarski R, Rezania K, Soliven B. (2021). Myasthenia Gravis: Epidemiology, Pathophysiology and Clinical Manifestations. J Clin Med. May 21;10(11).2235. doi: 10.3390/jcm10112235. PMID: 34064035; PMCID: PMC8196750.

Erika Guastafierro; Irene Tramacere; Claudia Toppo; Matilde Leonardi; Renato Mantegazza; Silvia Bonanno; Rita Frangiamore; Alberto Raggi*Neuroepidemiology.* (2020). Employment in Myasthenia Gravis: A Systematic Literature Review and Meta-Analysis. 54 (4).304–312.https://doi.org/10.1159/000506310.

Hamed S & Ibrahim R. (2021).Effect of Self- Care Management Strategy on Self- Efficacy for Patients with Myasthenia Gravis. Egyptian Journal of Health Care, EJH Vol.12 no.1.PP 531- 553.

Hamza, G., Mohamed, H. A., & Hassanein, A. A. (2019). Effect of Applying Guideline for Patients Undergoing Plasmapheresis Outcomes at Mansoura University Hospital. *IOSR Journal of Nursing and Health Science (IOSR-JNHS)*, *8*, 80-88.

Hevey, D., Wilson O'Raghallaigh, J., O'Doherty, V., Lonergan, K., & Marese Heffernan; Victoria Lunt; SineadMulhern; Damien Lowry; Niamh Larkin; Kathy McSharry; David Evans; Jackie Morris Roe; Mike Kelly; Peter Pardoe, Harry Ward; Sean Kinsella. (2020). Pre-post effectiveness evaluation of Chronic Disease Self-Management Program (CDSMP) participation on health, well-being and health service utilization. *Chronic illness*, *16*(2), 146-158.

Howard JF Jr. (2023). Clinical overview of MG.Myasthenia Gravis Foundation of Americ.The University of North Carolina at Chapel Hill

Ipe TS, Davis AR, Raval JS. (2021). Therapeutic Plasma Exchange in Myasthenia Gravis: A Systematic Literature Review and Meta-Analysis of Comparative Evidence. Front Neurol. Aug 31; 12:662856. doi: 10.3389/fneur. 662856.PMID: 34531809; PMCID: PMC8439193.

Kassardjian CD, Widdifield J, Paterson JM, Kopp A, Nagamuthu C, Barnett C. (2020). Serious infections in patients with myasthenia gravis: population-based cohort study. Eur J Neurol; 27:702–708. doi: 10.1111/ene.14153.

Miller, H, Kerlinger, F. N., & Lee, H. B. (Eds.) (2020). Foundations of Behavioral Research (4th Ed.). Orlando, FL: Harcourt College Publishers.

Mohamed Hamed, S., & Ali Ibrahim, R. (2021).Effect of Self-Care Management Strategy on Self Efficacy for Patients with Myasthenia

Gravis. *Egyptian Journal of Health Care*, *12*(1), 531-553.

Muppidi,S., Wolfe, G. & Conaway, M. (2011). MG-ADL: still a relevant outcome measure, Muscle Nerve 44(5).727–731.

Nelke C, Stascheit F, Eckert C, Pawlitzki M, Schroeter CB, Huntemann N. (2022). Independent risk factors for myasthenic crisis and disease exacerbation in a retrospective cohort of myasthenia gravis patients. JNeuroinflammation;19: 89.doi: 10.1186/s12974-022-02448-4.

Restivo DA, Centonze D, Alesina A, Marchese-Ragona R. (2020). Myasthenia Gravis Associated With SARS-CoV-2 Infection. Ann Intern Med. 2020;2(August).2019–20.

Sansoni J, Menon N, Viali L, White S, Vucic S. (2023). Clinical features, treatments, their impact, and quality of life for Myasthenia Gravis patients in Australia,Journal of Clinical Neuroscience,Volume 118, Pages 16-22, ISSN 0967-5868.
https://doi.org/10.1016/j.jocn.2023.09.023

Statistical Information System. (2023). Ain Shams University.

Strasser, E. (2023). Principles of therapeutic apheresis in neurological disease. Transfusion Medicine and Hemotherapy, 50(2), 88-97.

Streeter Jr, O. E. (2020). Precision Medicine. *Precision Medicine: A Multidisciplinary Approach: Clinics Collections*, *8*, 29-37.

Thompson, D. L., May, E. J., Leach, M., Smith, C. P., & Fereday, J. (2021). The invisible nature of learning: Patient education in nursing. *Collegian*, *28*(3), 341-345.

Wang, Y., Huan, X., Jiao, K., Jiang, Q., Goh, L. Y., Shi, J., …& Zhao, C. (2022). Plasma exchange versus intravenous immunoglobulin in AChR subtype myasthenic crisis: a prospective cohort study. *Clinical Immunology*, *241*, 109058.

Wolfe, G. I., Herbelin, L., Nations, S. P., Foster, B., Bryan, W. W., &Barohn, R. J. (1999). Myasthenia gravis activities of daily living profile. Neurology, 52(7), 1487-1487.