Effect of Educational Package on Complications Associated with Plasmapheresis among Patients with Autoimmune Disorders

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Abstract

Autoimmune disorders represent an extreme range of clinical conditions affecting different organs, with the production of autoantibodies as a main pathogenic mechanism that strongly needs treatment with plasmapheresis. **Aim**: Evaluate the effect of educational Package on complications associated with plasmapheresis among patients with autoimmune disorders. **Method*:*** Quasi-experimental design was implemented on a purposeful sample selected by simple randomization on (100) one-hundred patients undergoing plasmapheresis; from the 1st of July, 2019 to the end of January, 2020. **Tools**: Two tools were used to conduct this study including interview questionnaire to assess demographic and clinical characteristics of the patients, and body system plasmapheresis related complications scale to assess complications associated with plasmapheresis. **Results:** The most obvious diagnosis was Myasthenia Gravis in (48.0% and 52.0%) followed with Guillain-Barre syndrome in (40.0%, 36.0%) of the study and control group correspondingly. The most commonly reported complications in both groups were vomiting, citrate induced hypocalcaemia, angioedema, hematoma, and arrhythmias with the same priority order after educational package implementation with ($P<0.05$). **Conclusion**: A statistical significant decline occurred in the report of plasmapheresis-associated complications after the application of an educational package ($P<0.05$). **Recommendations:** Further researches are needed to study the effect of different management strategies on controlling the most common plasmapheresis-associated complications.

Keywords: Autoimmune Disorders, Educational Package, Plasmapheresis, Associated Complications.

Introduction:

Plasmapheresis or therapeutic plasma exchange (TPE) is known as an extracorporeal technique, as well as one or more plasma volumes, are detached and replaced with, albumin plus crystalloids solution or fresh frozen plasma in a diseased person. The plasmapheresis machines are based upon two basic philosophies; centrifugation or filtration of blood through a dialyzer ***(Gerogianni et al., 2015).*** Treatment with Plasmapheresis aims at removing pathogens, chemicals, antibodies and immune complexes, antigens, or toxins from the patients' body ***(Hamza et al., 2019).***

Plasmapheresis is the standard treatment for Autoimmune diseases including Guillain-Barre syndrome, Good pasture's syndrome, myasthenia gravis, familial hypercholesterolemia, and thrombotic thrombocytopenic purpura. Moreover, it is the second line of treatment for various neurologic, hematologic, or nephrologic diseases such as chronic inflammatory demyelinating polyradiculoneuropathy, hyperviscosity syndrome, cryoglobulinemia, pediatric autoimmune neuropsychiatric disorders, Rh incompatibility-associated serological disorders, and renal transplant rejection (***Szczepiorkowski et al., 2010***). Hematological indications for plasmapheresis include ABO-incompatible marrow transplant, autoimmune hemolytic anemia, aplastic anemia, hyperviscosity in monoclonal gammopathies, coagulation factor inhibitor, pure red cell aplasia, post transfusion purpura, thrombotic thrombocytopenic purpura, and red cell alloimmunization in pregnancy ***(Woźniak et al., 2015).***

Plasmapheresis as well as any therapeutic procedure is associated with the incidence of several complications that are categorized into life-threatening and non-life-threatening. The life-threatening complications include hypotension requiring pressor amines, shock, hemolysis, and arrhythmias requiring treatment. Non-life-threatening complications include: hypotension not requiring pressor amines, arrhythmias need fluid supply or sinking naturally, anxiety/ or agitation need sedation, bradycardia, tachycardia, allergic reactions, sensation of cold/ or

paresthesias, fever, lower limb pain, vascular accesses bleeding or hematoma, abdominal pain, and eyelid tremor. Moreover, there are abnormalities in results of the laboratory tests such as leukocytopenia, anemia, thrombocytopenia, hyponatremia, hypokalemia, and hypocalcemia ***(Szczeklik et al., 2013).***

The role of nurse is very important and multiple in managing patients undergoing plasmapheresis, as the nurse is the responsible one to direct the patient, coordinate, advice, train and participate in clinical research. The nurse assisting the patient to get information, maintain safety, and obtain appropriate care inside the framework of nursing process. ***(Gerogianni & Panagiotou, 2014)***. Also, the clinical responsibilities of the nurse include adherence to quality assurance criteria aiming to provide high-quality healthcare services. In addition, the nurse is responsible about good hands of patients' records, amenability with the nursing guidelines and protocols, and ensuring medical secrecy (***Kritikaki, 2012).***

Patients' education is a crucial element of all nurses' roles as continuous patient education will help overwhelmed the undesirable aspects of treatment, cope with the disease, and energetically play a part in a plan of care (***Chapman, 2014***). Effective education can be achieved by continuous training packages through distributing leaflets, practicing therapeutic communication, attentive listening without criticism, and group working with others (***Hamza, et al., 2019***). The sounded research points on this topic included only assessment of complications in descriptive researches, or educational programs to improve knowledge in very few researches, so the researchers were attracted to implement educational package and evaluate its effect on the occurrence of complications associated with plasmapheresis treatment and monitor the difference in their occurrence among these group of patients.

Significance of the study

Autoimmune diseases were estimated by the National Institutes of Health as the most prevalent in the USA, affecting up to 23.5 million Americans, but the American Autoimmune Related Disease Association (AARDA) said that 50 million Americans suffer from autoimmune disease ***(AARDA, 2019).*** In Egypt, there are no estimates about autoimmune diseases, but a study by ***El-Tallawy, et al., (2010)*** using a door-to-door survey on 62,583 people from (2005–2009), stated that the prevalence rate of myasthenia gravis per million person/years was 32/1000000.

Prior researches discussed the procedure of plasmapheresis itself, assessing associated complications, in addition to very few ones discussed the role of the nurse in plasmapheresis, but less attention has been given to improve and control these complications. With an increased number of researches on plasmapheresis, there is a need to determine the potential effect of education on complications associated with plasmapheresis. Therefore, the current study was designed to fix the weight of an educational package on complications associated with plasmapheresis among patients with autoimmune disorders. Also, it will increase the awareness of nursing staff and aid them in establishing comprehensive management plan for patients with autoimmune disorders undergoing plasmapheresis.

Aim of the study

This study aimed at evaluating the effect of educational package on complications associated with plasmapheresis among patients with autoimmune disorders.

Objectives:

- Assess the clinical characteristics of patients with plasmapheresis.
- Assess complications among patients undergoing plasmapheresis.
- Evaluate complications associated with plasmapheresis after implementation of an educational package.

Research hypothesis

The educational package will reduce the frequency of complications associated with plasmapheresis among patients with autoimmune disorders.

Operational definitions:

Autoimmune diseases are diseases that attack the personnel subjective immune system including Myasthenia Gravis (MG), Guillain-Barre syndrome (GBS), Chronic inflammatory

demyelinating polyneuropathy, and Autoimmune hemolytic anemia.

Educational Package means providing knowledge, in addition to formal and instructive education.

Plasmapheresis is the plasma exchange with albumin plus crystalloids solution, or fresh frozen plasma.

Subject and Methods

Design

This study was implemented using quasi-experimental design of the research with a simple randomized control and study group.

Participants and settings

One-hundred (100) patients undergoing plasmapheresis were recruited in the present study using purposive sampling that was divided by half through simple randomization for both study and control groups, from the blood bank joined to Suez-Canal University hospitals and Emergency unit fused to Ain Shams University hospital, Egypt, from the first of July 2019 to the end of January 2020. Plasmapheresis machines at both settings work by centrifugation.

The enclosure norms were included patients aged 20 to 50 years old, one month as a minimum since the start of plasmapheresis treatments, cognitive health with good consciousness level to be able to understand simple instructions, and the number of plasmapheresis sessions were not less than five. The exclusion criteria include patients who are unstable hemodynamically and have other chronic diseases such as hypertension or renal failure as they will affect the study results.

After obtaining informed consent by the researchers; participants were allocated into two equal groups (50) for each using a simple randomization technique. Group (I) who identified as study group was submitted to an educational package to control and/or reduce complications associated with plasmapheresis, and Group (II) who identified as the control group had routine care without following the educational package.

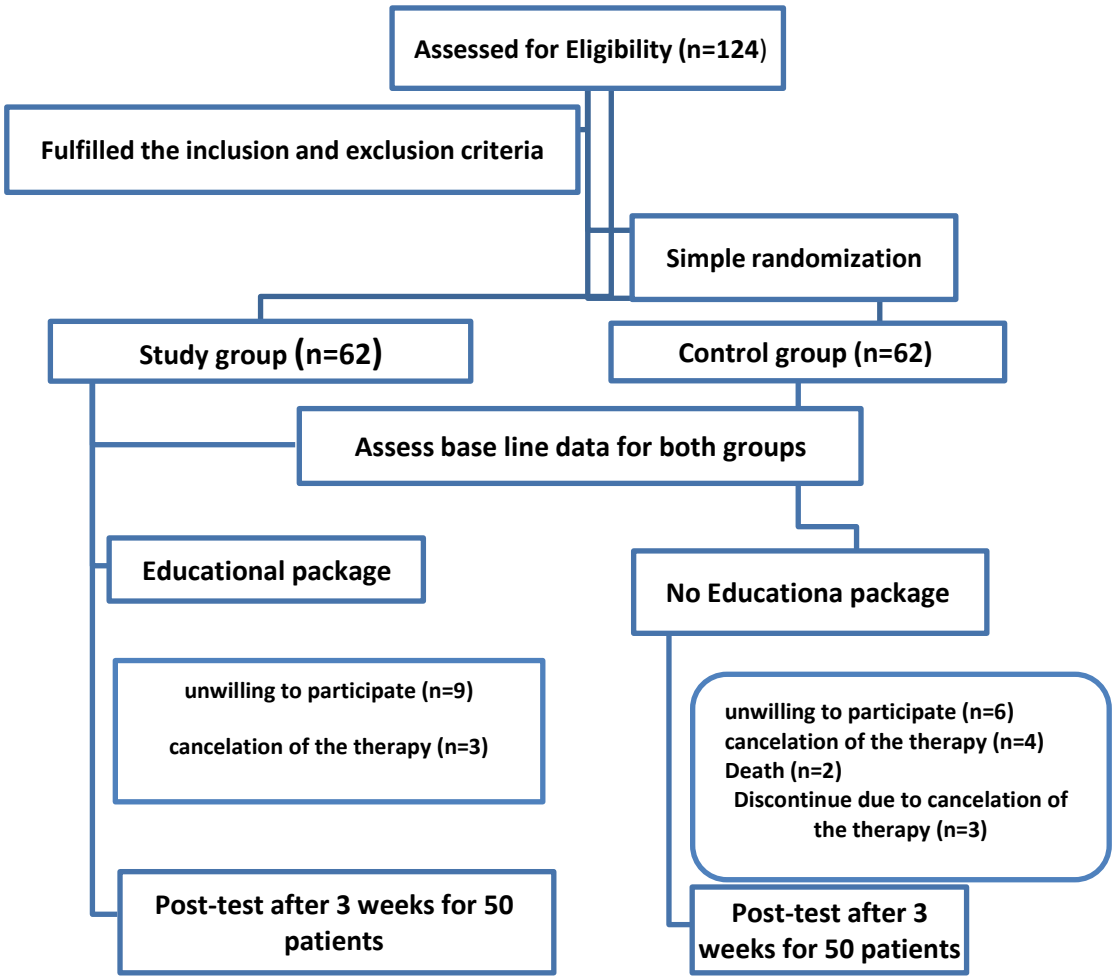
The size of the research sample was considered via the program of epidemiological information (EPI info.) version 6.02 considering the total number of patients undergoing plasmapheresis and enrolled to the both previously listed settings, with alpha error at 5%, confidence level at 95%, Beta error at 20%, and the study power at 80%. The equation used to reckon sample size for this study was:

$$= \frac{Z\ 2 * (p) * (1-p)}{C\ 2}$$

As: Z value = 1.96 for 95% confidence level

p = percentage picking a choice, 0.5 used for needed sample size, and articulated as decimal
C = confidence interval and articulated as decimal

Flow chart for sampling technique



Tools for data collection: Two tools were developed to assemble information for this study

The tool I: Interview questionnaire: that was designed by the researchers and alienated into two parts

Part (1): is containing demographic characteristics, encompassed six questions, as each participant in the study provided data on their age, sex, residence area, marital status, occupation, and education.

Part (2): Patients' clinical characteristics, that encompassed three questions as diagnosis, time since treatment with plasmapheresis onset, and abnormalities in results of the laboratory test before plasmapheresis procedure. All questions at tool I were completed from the patients' records and admission sheets.

Tool II: Body system plasmapheresis related complications scale, which was designed by the researchers and referenced from ***(Szczeklik et al., 2013)*** to assess the recurrence of complications among participants before and after applying the educational package. It contained a total of 32 items that were answered by five Likert scales ranged from never to almost always, and all items are classified into eight groups of complications.

Group one asked about vascular access-related complications that contained four items, group two asked about the procedure-related complications that contained five items, group three asked about the anticoagulation use related complications that contained three items, group

four asked about the cutaneous related complications that contained four items, group five asked about the respiratory related complications that contained five items, group six asked about the cardiovascular related complications that contained three items, group seven asked about the central nervous system related complications that a three items, and group eight asked about the gastrointestinal system-related complications that contained five items.

Scoring of the Body system plasmapheresis related complications scale:

The score of every question was ranged from one to five as (1) for never, (2) for rarely, (3) for every once in a while, (4) for sometimes, and (5) for almost always. The lesser score for the tool was 32 and the greater one was 160. Then the mean and standard deviation of all answers was calculated and compared among the two groups of the study. The tool filled throughout the plasmapheresis session to monitor the patient during the therapy and record the complications that occurred. Score for worse conditions is equal to or less than 96 and score for better conditions is equal to or more than 97.

Validity and reliability:

The scale for complications associated with the plasmapheresis showed excellent internal consistency with (alpha coefficient = 0.92 to 0.96 crosswise two administrations over 6 months); that means high reliability. With regard to validity; inter-rater (ICC 0.96, 95%, and CI 0.92 to 0.98), in addition to intra-rater (ICC 0.99, 95%, and CI 0.99 to 1.00).The two tools utilized by this study were revised and appraised by a panel of 7 experts (5 in the medical-surgical nursing specialty, and 2 in hematologic medicine) before applying them to the participants to ensure their validity, with consideration of the experts' comments.

Pilot study:

The pilot study was implemented to test the clarity and applicability of the designed tools' contents . It was ratified by ten percentage of all the study sample. The pilot was included in the total study sample, as no modifications were done on the instruments.

Work Procedure

Data was collected from the 1st of July, 2019 to the end of January, 2020 through the following phases.

Phase I: Preparation and Assessment

Assessment of the participants was done at the beginning of the study as they were assessed primarily before the presentation of the educational package to identify the occurrence of complications associated with plasmapheresis procedure as well as the patients' clinical characteristics to obtain baseline data.

At first, the participants as well as working health care staff were met by the researchers to clarify the aim and work plan of the study to obtain their cooperation, and obtain consent from the participants. The researchers got permission to implement the study from both faculties of nursing and the settings' managers.

Tools were designed and tested through piloting and checked for validity and reliability. Then tools were transformed into Arabic and tested again for validity and reliability. Moreover, the researchers designed the educational package and framing it in a colored simple booklet fortified with pictures to simplify needed instructions for patients. It was referenced from ***(UC San Diego Health system, no year; Carey & Seale, 2013)***. All knowledge included in the educational package was transformed into Arabic and revised to ensure their accuracy.

Phase II: Implementation

The researchers considered the clinical diagnosis of patients, in addition to their general health status, and wait until the patient becomes stable and calm, then start to fill the study tools.

- Tool one was completed from the participants' medical records and included lab investigations at first before participants started the plasmapheresis session.
- Tool two was filled for the principal phase by monitoring the participants during and

after the plasmapheresis session that lasted naturally from 2 to 3 hours for both groups under the study.

- The researchers visited the study settings six days/week for seven months from 9.00 am to 2.00 pm.
- Participants took their time to relax after initiation of the plasmapheresis therapeutic session, then received one-hour educational package with one theoretical session.
- Instructions included in the educational package were explained by the researchers to the study group and their caregivers accompanied by figures and videos, then feedback was obtained by the researchers through the predetermined hour.
- The study instruments were filled by the researchers, because of the clinical condition of the participants' majority.
- The instructions included in the educational package was guided by Guidelines issued in the American Society for Apheresis, 2016 (ASFA-G) by ***(Schwartz et al, 2016)***; and Guidelines for Therapeutic Plasma Exchange in Critical Care by the National Health Service ***(NHS, 2019),*** which are consistent with the subsequent contents and objectives of the study and the educational package.

Educational package contents and objectives	
Objectives	**Content**
Diminish occurrence of complications associated with plasmapheresis	• What is Plasmapheresis? • What is plasma? • Plasmapheresis Procedure • Why is it necessary? • Potential Risks and Side Effects • How long does a procedure take? • How often will patient need treatment? • What can patient do before the procedure? • What can patient do during the procedure? • What can patient do after the procedure?

Phase III: Evaluation:

The evaluation was done after implementation of the educational package; to evaluate the mean values of difference in occurrence of complications among patients undergoing plasmapheresis procedure. The two tools were used by both groups throughout the study phases. All of the participants at the two groups under the study were assessed for the second time to appreciate the difference in the occurrence of complications after three weeks from giving the educational package to give chance for participants at the study group to implement all the explained contents for a while to reduce the incidence of complications.

The patients were evaluated through assessment of their laboratory investigations before and after the plasmapheresis session, and monitored during receiving plasmapheresis therapy for their physiologic responses. After completion of data collection, all participants in group one of the study (the control) have received a copy from the educational package. Complicated cases or patients with worse complications were referred to revise a specialist in the prevalent problems, with regular follow-up by the special physician.

Ethical considerations:

Approval was obtained to implement the study after its appreciation from the nursing faculty ethical committee. The researchers announced themselves to all the studied patients of both groups prior implementation of the study; and the study aim was expounded to obtain cooperation of all participants. Written consent was obtained from the participants before filling the research instruments. Data confidentiality was guaranteed to all the participants, with the assurance that they have voluntary participation in this study in addition to be able to withdraw at any time from the study.

Data Analysis

The data were coded, entered, and analyzed using SPSS program version 25. Nominal data were analyzed using descriptive statistics such as interpreting the participants' demographic and clinical characteristics. Differences between variables across phases of the study were analyzed using One Way ANOVA. The statistical significance was assessed using, the arithmetic means, the standard deviation (*SD*), (*X2*), and (*t-test*) to explore the relationship between variables. The significance level was identified at $P < 0.05$.

Results

Table 1, shows a total of 100 patients for both groups (50) for each group with mean age (41.8 ± 9.1, 42.3 ± 7.1) years old among the study and control group respectively, males more prevalent in (68.0%, 58.0%) of the study and control group respectively, furthermost of participants were married (50.0%, 44.0%) at the study and control group respectively. Concerning the level of education, illiteracy was dominant among both groups (40.0%, 58.0%) correspondingly. The farthest of both groups were living in rural areas (62.0%, 58.0%), and their work need manual effort (46.0%, 38.0%) at the study and control group respectively.

Table 2 shows clinical characteristics of both groups, it is observed that the most apparent diagnosis was Myasthenia Gravis in (48.0% and 52.0%), followed with Guillain-Barre syndrome in (40.0%, 36.0%) of the study and control group correspondingly. Meantime since the onset of procedure was 1.6 ±1.5 months previously in the study group and 1.7±1.3 month in the control group. The mean Number of plasmapheresis sessions was 7.1±1.3, and 7.2±1.1 in the study and control groups respectively. Abnormalities in results of the laboratory tests before the procedure showed that hyponatraemia is the prevalent abnormality in the study group (66.0%) followed with hypocalcaemia and leukocytopenia in (48.0%, 44.0%) respectively; but among the control group (62.0%, 50.0%, 46.0%) showed hypocalcaemia, hyponatraemia, and leukocytopenia one-to-one.

Table 3 demonstrates the distribution of both groups according to the occurrence of complications during the plasmapheresis procedure after implementation of the educational package. Statistical significant decrease among the study group of Vascular Access associated complications with the most prevalent one was hematoma with ($p<0.001$). Procedure-related complications were significantly decreased with the most apparent complication was citrate induced hypocalcaemia with ($p< 0.02$). Concerning cutaneous complications, swelling (angioedema) was the most decreased after application of the educational package with ($p<0.00$).

Concerning cardiovascular complications associated with plasmapheresis, they were decreased significantly among the study group with the most apparent one was arrhythmia with ($p<0.00$). The most repeated gastrointestinal complication was vomiting and it was statistically decreased in the study group after application of the educational package with ($P<0.03$). Other complications concerning anticoagulation use, respiratory system, and central nervous system was decreased in the study group but without statistical significant change among both groups.

Table 4, reflects a comparison between the studied groups according to pre and post-educational package mean values of plasmapheresis-associated complications. It can be noticed that a statistically significant decline in the report of plasmapheresis associated complications post-educational package in the study group compared to the control group ($P=0.001^*$ and 0.0064^*) correspondingly. There is no statistically significant change in the report of complications among the control group at the post-educational package implementation, as they didn't receive any intervention.

Figure 1, shows that very few percentage of patients undergoing plasmapheresis have severe complications with the treatments as 4% was appeared among the study group, and 6% among the control group without significance difference among both groups as $P= 0.08$.

Figure 2, shows that the measures used to manage patients with severe complications include the referral to a physician with specific specialty proper to the type of complication, emergency care implemented by a specialist during plasmapheresis session, and stop the plasmapheresis procedure. These measures were implemented in (2%, 1%, 3%) of the control group respectively, and in 1%, 2%, 1%) of the study group respectively. These measures were implemented among both groups without significance difference as $P= 0.093$.

Table 1. Distribution of both groups according to demographic characteristics (n=100)

Demographic characteristics	Groups				Test (*P*-Value)
	(study) (n = 50)		(control) (n = 50)		
	No	%	No	%	
Age	20 – 50 Years old				T = 0.35 (0.731)
Mean ± SD	41.8 ± 9.1		42.3 ± 7.1		
Sex					X^2 = 0.16 (0.687)
Male	34	68.0%	29	58.0%	
Female	16	32.0%	21	42.0%	
Marital status					X^2 = 6.0 (0.046*^)
Single	10	20.0%	15	30.0%	
Married	25	50.0%	22	44.0%	
Widow	15	30.0%	13	26.0%	
Education					X^2 = 3.4 (0.324^)
Illiterate	20	40.0%	29	58.0%	
Primary	9	18. 0%	6	12.0%	
Secondary	7	14.0%	5	10.0%	
High education	14	28.0%	10	20.0%	
Residence					X^2 = 0.16 (0.686)
Rural	31	62.0%	29	58.0%	
Urban	19	38.0%	21	42%	
Occupation					X^2 = 6.0 (0.049*^)
Don't work	12	24.0%	14	28.0%	
Manual work	23	46.0%	19	38.0%	
Employee	15	30.0%	17	34.0%	

X^2: Chi-square test, P value based on Mont Carlo exact probability, * $P < 0.05$ (significant).

Table 2. Distribution of both groups according to clinical characteristics (n=100)

Clinical characteristics	Groups				Test (*P*-Value)
	Study (n = 50)		Control (n = 50)		
	No	%	No	%	
Diagnosis					X^2 = 0.44 (0.505)
Myasthenia Gravis (MG)	24	48.0%	26	52.0%	
Guillain-Barre syndrome (GBS).	20	40.0%	18	36.0%	
Chronic inflammatory demyelinating polyneuropathy	2	4.0%	4	8.0%	
Autoimmune hemolytic anemia	4	8.0%	2	4.0%	
Time since onset of procedure/previous months,					*T = 0.37 (0.733)*
mean (SD)	1.6 ±1.5		1.7±1.3		
Number of plasmapheresis sessions					*T = 0.49 (0.422)*
	7.1±1.3		7.2±1.1		
Abnormalities in results of the laboratory test before procedure					X^2 = 0.04 (0.839)
Anemia	16	32.0%	15	30.0%	
Leukocytopenia	22	44.0%	23	46.0%	
Thrombocytopenia	17	34.0%	19	38.0%	
Hypokalaemia	13	26.0%	15	30.0%	
Hyponatraemia	33	66.0%	25	50.0%	
Hypocalcaemia	24	48.0%	31	62.0%	

X2: Chi-square test, ^ P value based on Mont Carlo exact probability, * P < 0.05 (significant), NA: Not Applicable, t: independent samples t-test.

Table 3. Distribution of both groups according to occurrence of complications among patients undergoing plasmapheresis procedure after implementation of the educational package (n=100)

Complications	Groups		X2	(*P*-Value)
	Study (n = 50)	Control (n = 50)		
	X±SD	X±SD		
Vascular Access				
Hematoma	29.6±3.2	33.2±3.5	5.5	0.000 **
Pneumothorax (internal jugular)	19.8±5.6	18.1±5.5		
Retroperitoneal bleed (femoral)	20.7±5.8	26.6±3.8		
Infection	22.9±2.8	25.9±2.8		
Procedure				
Bleeding	25.7±4.9	29.9±5.6	2.2	0.02*
Edema	22.8±4.3	24.6±2.6		
Loss of cellular elements(platelets)	20.8±3.1	23.4 ±3.0		
Anaphylactic Reactions	26.7 ±3.2	30.3±3.6		
Hypocalcaemia (citrate induced)	44.8±8.1	48.1±4.4		
Anticoagulation				
Bleeding	21.8±5.5	21.7±6.0	0.02	0.8
Numbness and tingling of extremities	29.8±5.0	30.8 ±5.0		
Metabolic Alkalosis(with FFP)	20.5±6.4	19.0±5.3		
Cutaneous				
Swelling (angio-edema)	41.5±10.1	46.4±6.7	3.6	0.00*
Urticaria (hives)	27.9±3.7	30.4±3.3		
Redness(erythema)	19.0±5.3	21.5±6.4		
Itching(pruritus)	22.3±2.7	24.6±2.9		
Respiratory				
Wheeze	21.6±5.4	21.8±6.3	1.7	0.08
Dyspnea	18.9±5.6	20.3±5.6		
Laryngeal obstruction (causing stridor)	30.3±5.1	30.8±5.1		
Rhinitis	44.5±7.9	46.2±7.5		
Hypoxia	41.5±7.9	42.2±7.5		
Cardiovascular				
Hypotension	18.8±5.5	21.7±6.0	3.6	0.00*
Tachycardia	20.5±6.4	23.0±5.3		
Arrhythmias	28.8±5.0	34.8 ±5.0		
Central Nervous System				
Confusion	19.5±6.4	19.0±5.3	2.7	0.06
Feeling of impending doom	20.8±5.5	21.7±6.0		
Altered levels of consciousness	4.7±5.0	5.8 ±5.0		
Gastrointestinal				
Nausea	23.7±4.9	28.9±5.6	2.4	0.03*
Vomiting	42.8±8.1	49.1±4.4		
Diarrhea	21.8±4.3	25.6±2.6		
Abdominal cramps	31.7 ±3.2	37.3±3.6		
Metallic taste	22.8±3.1	23.4 ±3.0		

X2: Chi-square test, ^ P value based on Mont Carlo exact probability, * P < 0.05 (significant), NA: Not Applicable, t: independent samples t-test.

Table 4. Mean values of plasmapheresis complications at Pre and post implementation of the educational package among both groups (n=100)

Groups				
Plasmapheresis associated complications	**Pre-educational package**	**post- educational package**	**T-test**	**P-value**
	X± SD	**X ± SD**		
Study group	48.20±6.52	40.40±3.83	4.954	.0001*
Control group	44.53±4.99	43.38±7.79	2.129	.0664

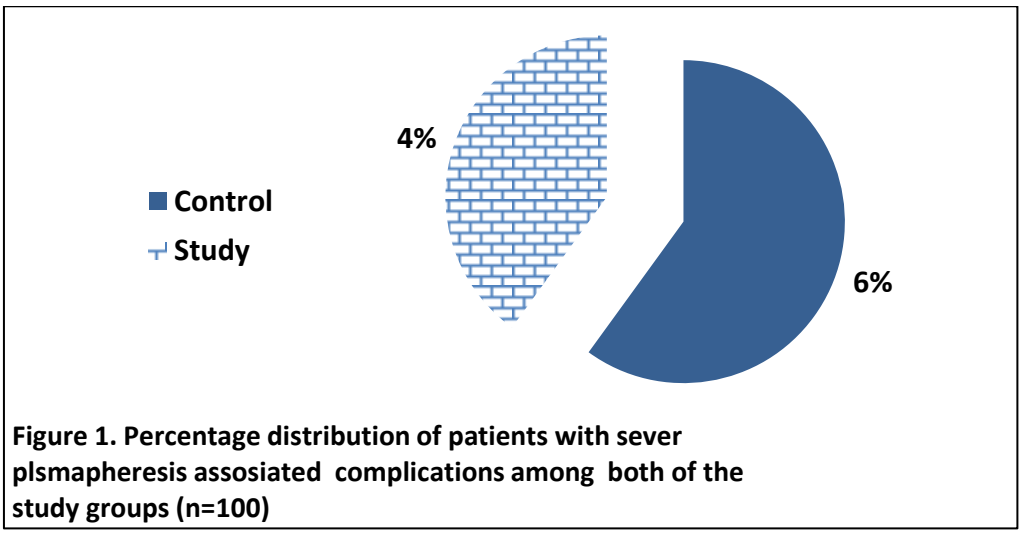


Figure 1. Percentage distribution of patients with sever plsmapheresis assosiated complications among both of the study groups (n=100)

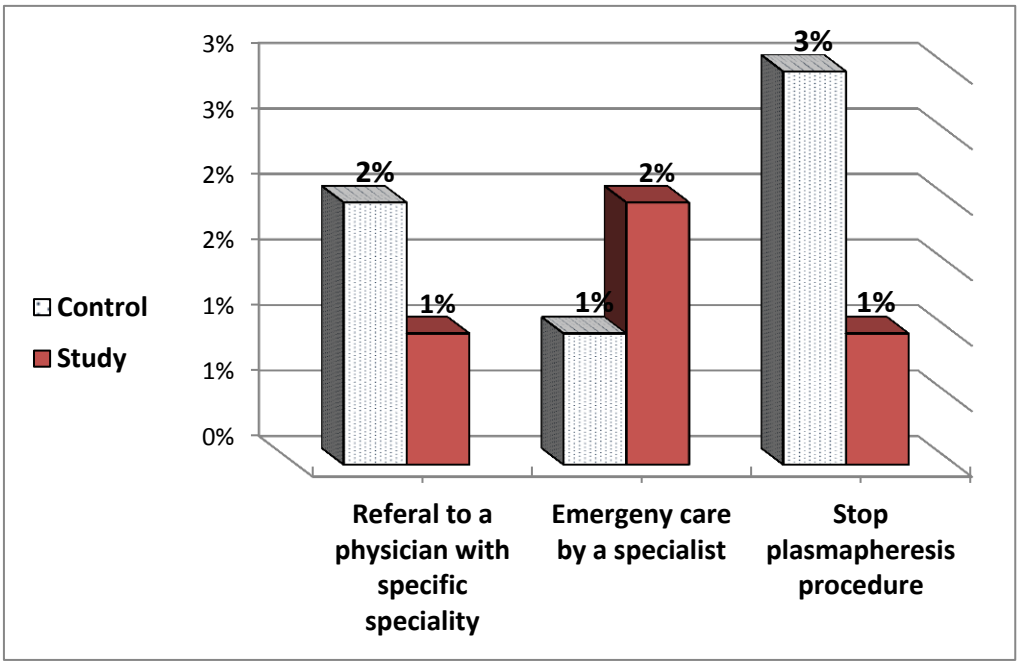


Figure 2: Measures done for patients with severe complications associated with plasmapheresis among both groups

Discussion

Before the beginning of therapeutic plasmapheresis, the nurse is in charge of the verification of the identity of patient, getting the patient's informed consent to perform the procedure, taking a full patient history, preparing the plasmapheresis machine, substiting liquids, set venipuncture, in addition to the effective use of plasmapheresis apparatus. The nephrology – hematology nurse teaches the patient to obtain a light meal before the treatment, reduces his anxiety, ensures a hot environment, and heating the replacement fluids especially in winter months ***(Gerogianni and Panagiotou, 2014).***

Patient monitoring during the plasmapheresis procedure is very critical and includes continuous observations for any symptoms or complications and documentation of the patient's physiological state. The device monitoring includes pressure monitor limits, blood leak, air detector, plasma volume removed,

fluid replacement, and the amount of anticoagulant used ***(Carey and Seale, 2011).***

To fulfill the aim of the study, the results of the current study showed that the entire participants of both groups under the study have a close mean age of (41.8 ± 9.1, 42.3 ± 7.1) years old for the study and control group respectively. Males were more prevalent in both groups at more than half of the participants, furthermost of both groups were married in around half of the participants. Concerning the level of education, illiteracy was dominant among two-fifths of the study group and more than half of the control group. The farthest of both groups were living in rural areas, and their work need manual effort by more than two-thirds of both groups.

These results could be related to the relation between autoimmune complications' incidence among adult people, especially in men as they are prone to extra psychological stress in their lives as a result of marriage and life burdens. Also, people who are illiterate and live in rural areas had low awareness levels that could cause some diseases as a result of no follow-up of preventive measures.

A study by ***Hamza et al., (2019)*** on 160 purposive sample using a quasi-experimental study design, at the plasmapheresis unit in the blood bank center at Mansoura University Hospitals, Dakahlia, Egypt to evaluate efficacy of Guideline for Patients Undergoing Plasmapheresis Outcomes at Mansoura University Hospital ; found that the age of the studied patients lies within the mean of 44.99 ± 8.90 years. equaled in sex ratio, with three-quarters of them married. Slightly less than half of the patients were secondary and university educated and more than half of the studied patients were from urban areas. With regard to occupation; one-third of the patients were manual workers, slightly less than half of the patients were employees and around one-fifth were housewives.

Concerning clinical characteristics of the participants, it is observed that the most apparent diagnosis was Myasthenia Gravis in around half of the two groups under the study, followed by Guillain-Barre syndrome in more than one-third of the two study groups. This could be related to the truth that according to the categories of indications, plasmapheresis is standard therapeutic care for Guillain-Barre syndrome. ***Carey & Seale, (2013)*** stated that plasmapheresis is a Category I Standard acceptable therapy for Guillain-Barre syndrome and Myasthenia gravis. Also, ***Schwartz et al., (2016)*** stated that Myasthenia Gravis and Guillain-Barre syndrome according to (ASFA 2016) guidelines are Categorized as the first line indications for plasmapheresis.

The current study showed that the mean number of plasmapheresis sessions was 7.1±1.3, and 7.2±1.1 in the study and control groups respectively. Abnormalities in results of the laboratory test before the procedure showed that hyponatraemia is the prevalent abnormality in two-thirds of the study group, followed by hypocalcaemia and leukocytopenia with the same order in slightly less than half of the participants; but among the control group around half of the participants showed hypocalcaemia, hyponatraemia, and leukocytopenia one-to-one in priority. 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.

An observational, retrospective study without a control group by ***Szczeklik et al., (2013)*** involved 370 plasmapheresis procedures in 54 patients treated in ICU and underwent therapeutic plasma exchange procedures by the years of 2006–2011. The results showed that one-third of the studied patients undergoing plasmapheresis to treat Myasthenia gravis, followed by one-quarter complained of Guillain-Barré syndrome. And abnormalities in lab investigations were ordered as anemia in three-quarters of patients, thrombocytopenia in less than two-thirds, hypokalaemia and hypocalcaemia in more than one-third, followed with hyponatraemia in more than one-fifth, and finally leukocytopenia in minority.

According to the occurrence of complications during the plasmapheresis procedure after implementation of the educational package, the current study showed a statistically significant decline among the study group of Vascular Access-associated complications with the most prevalent one was hematoma. Procedure-related complications were

significantly decreased with the most apparent complication was citrate induced hypocalcaemia. Concerning cutaneous complications, swelling (angioedema) was the most decreased after the application of the educational package.

This could be related to recurrent vein punctures that lead to different complications such as veins rupture causing extravasation of fluids under the skin. Also, the centrifugation's fluid could induce allergic skin reactions and reduction of calcium level in blood; but the education improves patients' awareness which in turn potentiate compliance and adherence to prescribed medications and educational instructions leading to reduction of therapy side effects and complications.

Concerning cardiovascular complications associated with plasmapheresis, the current study revealed a significant decrease among the study group with the most apparent one was arrhythmia. The most repeated gastrointestinal complication was vomiting and it was statistically decreased in the study group after application of the educational package. These results could be related to the fact that the replacement fluid used leads to the irregularity of heart rate and gastric upset as side effects.

Other complications concerning anticoagulation use, respiratory system, and central nervous system were decreased in the study group but without statistical significant change among both groups. These complications are related to the effect of replacement fluid used in the procedure and added substances and medications, the disproportion between the volume of transfused fluids and removed plasma, in addition to the anaphylactic or vasovagal reactions. The non-significant change may be related to the elective administration of these substances which have a basic role in the procedure but improvement occurs as the patients followed the educational packages.

A study by ***Szczepiorkowski et al., (2010)*** to incorporate evidence-based medicine into the well-defined and widely accepted ASFA Categories to revise Guidelines on the Use of Therapeutic Apheresis in Clinical Practice—Evidence-Based Approach; stated that the typical TPE strategy in patients with Guillain- Barre syndrome, myasthenia gravis, chronic inflammatory demyelinating polyradiculoneuropathy, and patients with autoimmune hemolytic anemia; is to exchange 200-250 mL of patient plasma/kg body weight over 10-14 days.

This will generally require 5-6 TPE procedures with 5% albumin replacement. Fresh frozen plasma is not routinely used for replacement. Since autonomic dysfunction may be present, affected patients may be more susceptible to volume shifts, blood pressure and heart rate changes during extracorporeal treatment. Relapses may occur in approximately 10% of patients 2-3 weeks following either treatment with TPE. When relapses occur, additional therapy usually TPE can be helpful.

Falck & Heitz, (2018) stated that the patient can optimize the success of plasmapheresis procedure and minimize symptoms, side effects, risks, and complications by following some steps to be prepared for the procedure which occurs through education and giving instructions for patients including having suitable prescribed diet, getting good sleep, appropriate fluid intake, up-to-date vaccination, avoidance of tobacco use, taking prescribed medications, and wearing comfortable clothes.

It is worth noting that the risks and complications associated with TPE can be greatly mitigated by highly experienced and skilled staff, in addition to the involvement of patients in their care through following the educational instructions ***(Kaplan, 2012).*** Moreover, close communication and teamwork among all intensive care specialists, clinical and apheresis staff, and patients are always conducive to successful clinical results and improved patients outcomes with the plasmapheresis therapy ***(Shelat, 2010).***

The current study revealed a statistical significant decline in report of the plasmapheresis associated complications after implementing the educational package in the study group compared to the control group, and there is no statistical significant change in report of complications among the control group at the post-educational package

implementation, as they didn't receive any interventions. This result could be related to the information that education has sound in improving patient outcomes and reduction of treatment complications with a good prognosis.

This study showed that very few percentage of patients undergoing plasmapheresis have severe or dangerous complications with the treatments among both groups, without significance difference. The measures used to manage patients with severe complications include the referral to a physician with specific specialty proper to the type of complication, emergency care implemented by a specialist during plasmapheresis session, and stop the plasmapheresis procedure among both groups without significance difference .

In the same line ***Tawalbeh, (2018)*** who evaluated the Effect of Education on Knowledge and Self-care Behaviors, stated that educational programs should be implemented in clinical health care settings to enrich knowledge and self-care activities. In addition, other studies by **(*Zanaboni et al., 2013; Lilholt et al. 2015)*** documented that after planned health educational guidelines the majority of studied patients had an excellent level of knowledge of their symptoms and health status in post-test with a significant difference.

Study limitations

The current study faced some limitations that enclosed noisy and uncomfortable environment to introduce the educational package to patients, some educational sessions were canceled and not completed because of the physiological condition of the patient or major complications faced by patients during receiving therapy. Also the sample included in the study was purposeful that can lead to some bias.

The researchers tried to overcome these limitations by waiting patients to relax after the therapy initiation to be able to complete the educational package, classify the sample randomly into both groups, and collect data from more than one place. In addition, the researchers excluded deteriorated patients from the study to avoid external issues affecting the results.

Conclusion and recommendations:

The current study concluded that there was a decrease in the report of plasmapheresis-associated complications after the application of an educational package with statistically significant dissimilarity, as education enhances awareness and increases compliance to instructions' implementation with reduced complications.

The current study recommended the availability of simplified printed educational instructions or pamphlets to patients undergoing plasmapheresis at the different settings that introduce these services. Also, structured training programs should be planned and implemented to escalate nurses' roles and increase their responsiveness. Moreover, further researches are needed to study the effect of different management strategies on control of the most common and threatening associated complications.

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